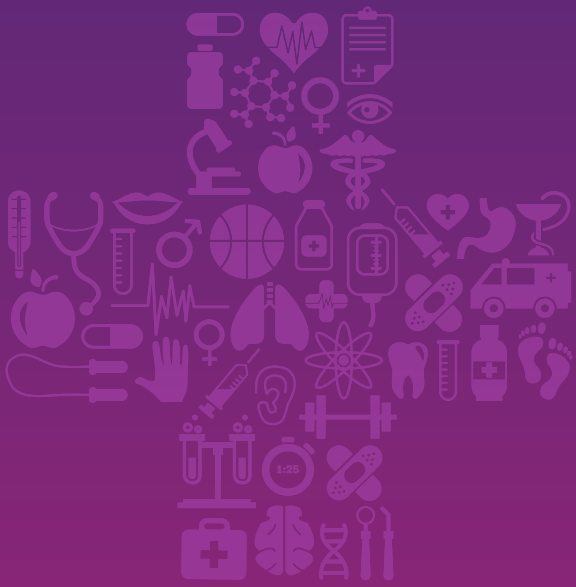
# Product Guide

9th Edition



*Since 1958*

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH

# Preface

It is our immense pleasure to present the 9th edition of "Product Guide". The focus of this book is to provide information on ***SQUARE'***s products. This compilation is enriched with abridged prescribing information of the products of ***SQUARE*** Pharmaceuticals Ltd. which includes active ingredient, indication, dosage & administration, contraindication & precaution, side effects, use in pregnancy & lactation, pediatric use and preparation.

Product Guide can be browsed in two different ways, either by product name wise index' or 'generic name wise index'.

We shall consider our labor amply rewarded if the doctors find this book useful in their daily practice.

We believe that we would be able to keep on our endeavor to bring continual improvement with the support of our valued doctors.

Sincerely
**Product Management Department**
***SQUARE Pharmaceuticals Ltd.***

# SQUARE PHARMACEUTICALS LTD.

## Milestone of excellence


1958
Debut of Square Pharmaceuticals as a Partnership Firm.
1964
Converted into a Private Limited Company.
1974
Technical collaboration with Janssen Pharmaceuticals, Belgium, a subsidiary of Johnson & Johnson Intl, USA.
1985
Achieved market-leadership in the Pharmaceutical market of Bangladesh among all national and multinational companies.
1987
Pioneer in Pharmaceutical export from Bangladesh.
1991
Converted into a Public Limited Company.
1994
Initial Public Offering of Square Pharmaceutical's shares.
1995
Chemical Division starts production of pharmaceutical bulk products (API).
1997
Won the National Export Trophy for exporting pharmaceuticals.
2001
US FDA/UK MHRA standard new Pharmaceutical factory goes into operation built under the supervision of Bovis Lend Lease, UK.
2002
Square enlisted as UNICEF's global supplier.
2005
Inception of Square Herbal & Nutraceuticals Ltd.
2007
Square Pharmaceuticals Ltd., Dhaka Unit gets the UK MHRA approval.
2009
Starts manufacturing of insulin, hormone & steroid products maintaining quality standards of US FDA, MHRA in dedicated manufacturing facility complying with the cGMP of WHO.
2013
Samson H Chowdhury "Centre of Excellence" starts its journey.
2014
Liquid Formulation Unit of Square Pharmaceuticals Ltd., Pabna Site gets PIC/S (Pharmaceutical Inspection Co-operation Scheme) approval.
2015
Square Pharmaceuticals gets USFDA's approval.
2016
Dhaka Site's solid dosage unit and Metered Dose Inhaler unit get MCC (Medicines Control Council) , South Africa and PIC/S approval.

# SQUARE PHARMACEUTICALS LTD.

## Milestone of excellence

## 2019

- Won the “President's Award for Industrial Development” as a successful Enterprise in the category of Large Scale Industry.

President's Award for Industrial Development.

Table of content by Product name

# Ace®

**Active Ingredient**
Paracetamol.

**Indication**
Fever, headache, toothache, earache, bodyache, myalgia, dysmenorrhoea, neuralgia & sprains. colic pain, back pain, chronic pain of cancer, inflammatory pain, post-vaccination pain & fever of children. Rheumatism & osteoarthritic pain & stiffness of joints in fingers, hips, knees, wrists, elbows, feet, ankles & top & bottom of the spine.

**Dosage & Administration**
*Tablet:* Adult 1-2 tablets every 4 to 6 hours up to a maximum of 4 g (8 tablets) daily. Children (6-12 years) 1/2 to 1 tablet 3 to 4 times daily. *XR Tablet:* 2 tablet every 6 to 8 hourly upto a maximum of 6 tablets daily. *Syrup & Suspension:* Children from 3 months to 1 year : 1/2 to 1 teaspoonful 3 to 4 times daily. 1-5 years: 1-2 teaspoonful 3 to 4 times daily. 6-12 years : 2-4 teaspoonful 3 to 4 times daily. Adults 4-8 teaspoonful 3 to 4 times daily. *Paediatric Drop:* Children Upto 3 months: 0.5 ml (40 mg) 4 to 11 months: 1.0 ml (80 mg). 1 to 2 years: 1.5 ml (120 mg) Dose can be repeated, every 4 hours.
*Suppository:* Suppository should be administered rectaly. Children 3 months - 1 year : 60-120 mg 4 times daily. Children below 5 years : 125-250 mg, 4 times daily. Children 6-12 years : 250-500 mg, 4 times daily. Adults & children over 12 years : 0.5 - 1 mg, 4 times daily.

**Contraindication & Precaution**
Known sensitivity to Paracetamol.

**Side Effect**
Side effects are significantly mild, though haematological reactions have been reported. Pancreatitis, skin rashes, & other allergic reactions occur occasionally.

**Use in Pregnancy & Lactation**
Paracetamol is safe in all stages of pregnancy & lactation.

**Preparation**
500 mg Tablet, XR Tablet, 60 ml & 100 ml syrup, 60 ml Suspension, 30 ml Paediatric Drops, 125, 250 & 500 mg Suppository.

# Ace® Plus

**Active Ingredient**
Paracetamol & Caffeine.

**Indication**
Fever, headache, migraine, muscle ache, backache, toothache & menstrual pain.

**Dosage & Administration**
Adults : 1-2 tablets every 4-6 hours. Maximum dose: 8 tablets daily. Not recommended for children below 12 years.

**Contraindication & Precaution**
Hypersensitivity to Paracetamol, Caffeine or any other components of it.

**Side Effect**
This combination may cause skin rashes, neutropenia & gastrointestinal disturbances etc. High dose administration may cause hepatotoxicity.

**Use in Pregnancy & Lactation**
Although there is epidemiological evidence of the safety of Paracetamol in pregnancy & lactation, medical advice should be sought before using this product.

**Drug Interaction**
It increases the Effect of chloramphenicol & coumarin anticoagulant. Risk of hepatotoxicity of Paracetamol may be increased in alcoholics or in

patients taking other anti-epileptic medications.

**Precaution**
Should be given cautiously in the following cases: In patients with hepatic or renal failure, in patients taking other hepatotoxic medication. Prolonged use of the drug without consulting a physician should be avoided.

**Preparation**
Paracetamol 500 mg & Caffeine 65 mg.

haematological reactions have been reported. Pancreatitis, skin rashes and other allergic reactions may occur occasionally.

**Overdose**
Moderate overdose : 6-10 gm/day. Excessive overdose : More than 10 gm/day.
Symptoms of overdose include pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12-48 hours after ingestion. In severe poisoning hepatic failure may progress to encephalopathy, coma and death.

**Preparation**
1000 mg tablet

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# Ace Power

**Active Ingredient**
Paracetamol BP 1000 mg

**Indication**
• Fever, common cold and influenza.
• Headache, toothache, earache, bodyache, myalgia, dysmenorrhoea, neuralgia and sprains.
• Colic pain, back pain, post-operative pain, postpartum pain, chronic pain of cancer, inflammatory pain, post-vaccination pain and fever of children.
• Rheumatism and osteoarthritic pain & stiffness of joints in fingers, hips, knees, wrists, elbows, feet, ankles and top & bottom of the spine.

**Dosage & Administration**
1 tablet every 6 hour

**Contraindication**
Known sensitivity to Paracetamol.

**Side Effect**
Side effects are significantly mild, though

# Acetram™

**Active Ingredient**
Paracetamol 325 mg & Tramadol HCl 37.5 mg.

**Indication**
Acetram tablet is indicated for the management of moderate to moderately severe pain in adults & also indicated for the short-term (five days or less) management of acute pain.

**Dosage & Administration**
Acetram tablet can be administered without regard to food. For the management of pain, the recommended dose is 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day.
In case of short-term (five days or less) management of acute pain, the recommended dose is 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day.

**Contraindication & Precaution**
This is contraindicated in any situation where opioids are contraindicated. This combination preparation should be used with caution when taking medications such as tranquilizers, hypnotics or other opiate containing analgesics.

**Side Effect**
The following adverse reactions may happen to this therapy: asthenia, fatigue, hot flushes, dizziness, headache, tremor, abdominal pain, constipation, diarrhea, dyspepsia, flatulence, dry mouth, nausea, vomiting, anorexia, anxiety, confusion, euphoria, insomnia, nervousness, somnolence pruritus, rash, increased sweating etc.

**Use in Pregnancy & Lactation**
Pregnancy Category C, should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Its safety in infants & newborns has not been studied.

**Preparation**
Paracetamol 325 mg & Tramadol HCl 37.5 mg Tablet.

# Adryl®

**Active Ingredient**
Diphenhydramine.

**Indication**
For the treatment of following: 1) Seasonal, perennial & vasomotor rhinitis, 2) urticaria, angioneurotic edema, anaphylaxis, 3) pruritus, 4) preanesthetic medication, emesis, motion sickness, 5) miscellaneous including meniere's diseases & parkinsonism, 6) cough & cold. Sometimes it may use as a night time sleep aid & for the short-term management of insomnia.

**Dosage & Administration**
Most allergic conditions are controlled with 25 to 50 mg i.e., (12.5 to 25 ml of syrup) 3 to 4 times a day.
Children 6 to 12 years of age : 10 mg i.e., (5 ml of syrup) 3 to 4 times a day.
Children 1 to 6 years of age: 5 mg i.e., (2.5 ml of syrup) 3 to 4 times a day.
In motion sickness: Adults : 25 to 50 mg 3 to 4 times a day. Children (above 9.1 kg): 12.5 to 25 mg 3 to 4 times a day (5mg/ kg/ 24 hours).
*In parkinsonism:* Adults: 25 to 50 mg 3 to 4 times a day. Children (above 9.1 kg) : 12.5 to 25 mg 3 to 4 times a day (5mg/ kg/ 24 hours).
*In insomnia:* Adults & children over 12 years of old : A dose of 20 to 50 mg is used as hypnotic in insomnia.
*In cough & cold:* Adults: 25 mg every 4 hrs. Not to exceed 150 mg in 24 hours. Children (6 to 12 years) **:** 12.5 mg every 4 hours. Not to exceed 75 mg in 24 hours. Children (2 to 6 years): 6.25 mg every 4 hours.

**Contraindication & Precaution**
Contraindicated for the premature or newborn infants. Any patients in whom drowsiness is undesirable e.g. drivers, machine operators. Patients with known hypersensitivity to Diphenhydramine or any components of the product. Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined.

**Drug Interaction**
Antituberculous agent, para-aminosalicylic acid (PAS), alcohol, other CNS depressants (hypnotics, sedatives, tranquilizers, etc), MAO inhibitors.

**Side Effect**
Side effects include drowsiness, dizziness, dryness of mouth, blurred vision, nausea & vomiting.

**Uses in Pregnancy & Lactation**
Should be used in pregnancy only if clearly

needed. Use in lactating mother is not recommended.

**Preparation**
10 mg/5 ml Syrup.

# Afun®

**Active Ingredient**
Clotrimazole.

**Indication**
Dermatomycoses due to *Candida, Trichophyton,* Moulds & other fungi, skin diseases showing Superinfections with these fungi e.g. inter digital mycoses, paronychia, Candida vulvitis, balanitis, pityriasis versicolor & erythrasma.

**Dosage & Administration**
2-3 times daily.

**Contraindication & Precaution**
Hypersensitivity to clotrimazole.

**Side Effect**
Local irritation or burning may occur in very few cases.

**Use in Pregnancy**
It is recommended that Clotrimazole should be used in pregnancy only when considered necessary by the physician.

**Preparation**
10 gm Cream.

# Afun® VT

**Active Ingredient**
Clotrimazole.

**Indication**
Vaginitis, vaginal itching, burning & discharge associated with recurrent vaginal yeast infections (vaginal candidiasis) due to Candida or Trichomonas, Super-infections with Clotrimazole-sensitive bacteria.

**Dosage & Administration**
Afun® VT: 3 consecutive nights, 1 Afun® vaginal tablets are inserted as deeply as possible into the vagina.

**Contraindication & Precaution**
Hypersensitivity to Clotrimazole. This is best achieved when lying on the one's back with the knees slightly bent. It is recommended that the treatment should be timed as so to avoid the menstrual period. For prevention of re-infection the partner should be treated locally with Clotrimazole cream at the same time. Afun VT is colorless & do not stain the underwear.

**Side Effect**
Local irritation or burning sensation.

**Use in Pregnancy**
It is recommended that Clotrimazole should be used in pregnancy only when considered necessary by the physician.

**Preparation**
200 mg Vaginal Tablet with an applicator.

# Alacot® Eye Drops

**Active Ingredient**
Olopatadine 0.1% .

**Indication**
Indicated for the treatment of the signs & symptoms of allergic conjunctivitis.

**Dosage & Administration**
One drop in each affected eye two times per day at an interval of 6 to 8 hours.

**Contraindication & Precaution**
Olopatadine Hydrochloride ophthalmic solution is contraindicated in persons with a known hypersensitivity to Olopatadine Hydrochloride. Olopatadine Hydrochloride ophthalmic solution should not be used to treat contact lens related irritation. Patients who wear soft contact lenses should be instructed to wait at least ten minutes after instilling Olopatadine Hydrochloride ophthalmic solution before they insert their contact lenses.

**Use in Pregnancy & Lactation**
Should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the fetus. Caution should be exercised when Olopatadine Hydrochloride ophthalmic solution is administered to a nursing mother.

**Side Effect**
Headaches have been reported at an incidence of 7%. The following adverse experiences have been reported in less than 5% of patients: Asthenia, blurred vision, burning or stinging, cold syndrome, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, nausea, pharyngitis, pruritus, rhinitis, sinusitis, & taste perversion.

**Preparation**
0.1% Eye Drops.

# Alacot® Max Eye Drops

**Active Ingredient**
Olopatadine 0.7%

**Indication**
Indicated for the treatment of the signs and symptoms of allergic conjunctivitis
Dosage & Administration
The recommended dose is one drop in the affected eye(s) once-daily

**Contraindication & Precaution**
It is contraindicated in patients with known hypersensitivity to any ingredient of this formulation. Patients who wear soft contact lenses should remove their lenses prior to instilling Olopatadine 0.7% ophthalmic solution and should wait at least 10 minutes after instillation of the eye drops.

**Side Effect**
Most common side-effects are blurred vision, dry eye, superficial punctate keratitis, dysgeusia and abnormal sensation in the eye.

**Use in Pregnancy & Lactation**
There are no adequate and well-controlled studies in pregnant women. Olopatadine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when Alacot® Max is administered to a nursing mother.

**Use in Children**
It is not recommended for use in children below 2 years

**Preparation**
5 ml solution in plastic dropper bottle

# Alacot® DS Eye Drops

**Active Ingredient**
Olopatadine 0.2%.

**Indication**
Alacot DS Eye Drops is indicated for the treatment of the signs & symptoms of allergic conjunctivitis.

**Dosage & Administration**
One drop in the affected eye once a day.

**Contraindication & Precaution**
Olopatadine Hydrochloride ophthalmic solution is contraindicated in persons with a known hypersensitivity to Olopatadine Hydrochloride. Olopatadine HCl ophthalmic solution should not be used to treat contact lens related irritation. Patients who wear soft contact lenses should be instructed to wait at least ten minutes after instilling Olopatadine Hydrochloride ophthalmic solution before they insert their contact lenses.

**Side Effect**
Headaches have been reported at an incidence of 7%. The following adverse experiences have been reported in less than 5% of patients: Asthenia, blurred vision, burning or stinging, cold syndrome, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, nausea, pharyngitis, pruritus, rhinitis, sinusitis & taste perversion.

**Use in Pregnancy & Lactation**
There are no adequate & well controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the fetus. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when Olopatadine Hydrochloride ophthalmic solution is administered to a nursing mother.

**Use in Children**
It is not recommended for use in children below 2 years.

**Preparation**
Each plastic dropper bottle contains 5 ml of Olopatadine HCl USP 0.2% sterile solution.



# Alarid®

**Active Ingredient**
Ketotifen.

**Indication**
Symptomatic treatment of allergic conditions including rhinitis & conjunctivitis. Prophylactic treatment of bronchial asthma.

**Dosage & Administration**
Adults : 1 mg twice daily with food. If necessary the dose may be increased to 2 mg twice daily in severe cases. Children above 3 years : 1 mg twice daily with food. Patients known to be easily sedated should begin treatment with 0.5 to 1 mg at night for the first few days or as directed by the physician. Use in elderly : Same as adult dose or as advised by the physician.

**Contraindication & Precaution**
A reversible fall in the platelet count has been observed in a few patients receiving Ketotifen concomitantly with oral antidiabetic agent & it has been suggested that this combination should therefore be avoided. Although there is no evidence of any teratogenic effect,

recommendations for Ketotifen in pregnancy or when breast feeding can not be given. It is important to continue the previous treatment for a minimum of two weeks after starting Ketotifen to avoid the possibility of exacerbation of asthma. This applies specially to systemic corticosteroids & ACTH because of the possible existence of adrenocortical insufficiency in steroid dependent patient.

**Side Effect**
Drowsiness & in isolated cases, dry mouth & slight dizziness may occur at the beginning of treatment but usually disappear spontaneously after a few days.

**Preparation**
1 mg Tablet, 1 mg/ 5 ml Syrup.

components. Alarid 0.025% eye drops should not be instilled while the patient is wearing lenses.

**Side Effect**
1-2%: Burning/stinging, punctate corneal epithelial erosion. <1%: Blurring of vision upon drug instillation, dry eyes, eyelid disorder, conjunctivitis, eye pain, photophobia, subconjunctival haemorrhage.

**Use in Pregnancy & Lactation**
Systemic levels after ocular administration are much lower than after oral use. Caution should be exercised when prescribing to pregnant women.

**Use in Children**
Children under 3 years of age: Consult with a doctor.

**Preparation**
0.025% Eye Drops.

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# Alarid® Eye Drops

**Active Ingredient**
Ketotifen Fumarate.

**Indication**
For the treatment of signs & symptoms (itchy, watery, red & swollen eyes & eyelids) of allergic conjunctivitis including vernal kerato-conjunctivitis, vernal-keratitis, blepharitis, blepharo-conjunctivitis, & giant papillary conjunctivitis.

**Dosage & Administration**
Adults & children 3 years & older: 1 drop in the affected eye(s) twice daily, every 8-12 hours, not more than twice per day.

**Contraindication & Precaution**
Hypersensitivity to Ketotifen or any of the

# Alatrol®

**Active Ingredient**
Cetirizine.

**Indication**
Seasonal Allergic Rhinitis, Perennial Allergic Rhinitis, Chronic Idiopathic Urticaria, & Pruritus. It is also used in allergen induced asthma.

**Dosage & Administration**
Administered with or without food. Adults & Children 6 years & older :
Tablet: 1 tablet daily. Syrup: 2 teaspoonfuls once daily or 1 teaspoonful twice daily.

In patients with decreased renal function (Creatinine clearance 11-31 ml/min), patients on hemodialysis (Creatinine clearance less than 7 ml/min) & in hepatically impaired patients , a dose of 1/2 tablet or 1 teaspoonful once daily is recommended. Children 2-6 years : Syrup: 1 teaspoonful once daily or 1/2 teaspoonful twice daily. Children 6 months - <2 years : Syrup: 1/2 teaspoonful once daily. The dose in children 12-23 months of age can be increased to a maximum dose as 1/2 teaspoonful every 12 hours. Paediatric Drops: 1 ml, once daily. The dose in children 12-23 months of age can be increased to a maximum dose as 1 ml, every 12 hours.

**Contraindication & Precaution**
Hypersensitivity or idiosyncrasy to cetirizine or to its parent compound ,hydroxyzine.
Caution should be exercised when driving a car or operating a heavy machinery. Concurrent use with alcohol or other CNS depressants should be avoided because additional reduction in alertness & additional impairment of CNS performance may occur.

**Drug Interaction**
No clinically significant drug interactions have been found.

**Use in Pregnancy & Lactation**
Cetirizine should be used in pregnancy only if clearly needed. Use in lactating mother is not recommended.

**Preparation**
10 mg Tablet, 5 mg/5 ml Syrup, 2.5 mg/ml Paediatric Drops.

# Alenvir™

**Active Ingredient**
Tenofovir Alafenamide

**Indication**
Tenofovir Alafenamide is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease.

**Dosage & Administration**
The recommended dosage of Tenofovir Alafenamide is 25 mg (one tablet) taken orally once daily with food. No dosage adjustment is required in patients with mild, moderate, or severe renal impairment. Tenofovir Alafenamide is not recommended in patients with end stage renal disease (estimated creatinine clearance below 15 mL/min). No dosage adjustment is required in patients with mild hepatic impairment (Child-Pugh A). Tenofovir Alafenamide is not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.

**Side Effects**
Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate in combination with other antiretrovirals. A majority of these cases have been in women.

**Precaution**
Tenofovir Alafenamide alone should not be used in patients with HIV infection. Lactic acidosis and severe hepatomegaly with steatosis have been reported with the use of nucleoside analogs. Discontinuation of anti-hepatitis B therapy, including Tenofovir Alafenamide, may result in severe acute exacerbations of hepatitis B. Patients who discontinue Tenofovir Alafenamide should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment.

**Use in Pregnancy & Lactation**
It is not known whether Tenofovir Alafenamide and its metabolites are present in human breast milk, affect human milk production, or have effects on the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Tenofovir Alafenamide and any potential adverse effects on the breastfed infant

**Overdose**
If overdose occurs, monitor patient for evidence of toxicity. Treatment of overdosage with Tenofovir Alafenamide consists of general supportive measures including monitoring of vital signs as well as observation of the clinical status of the patient.

**Preparation**
25 mg Tablet

# Alice™

**Active Ingredient**
Ivermectin.

**Indication**
It is indicated for the topical treatment of head lice infestations in patients 6 months of age and older.

**Dosage & Administration**
Only for topical use in scalp & scalp hair. It is not for oral, ophthalmic, or intravaginal use.
Alice™ Lotion should be applied to dry hair in an amount su¬cient to thoroughly coat the hair and scalp. Keep lotion on the hair and scalp for 10 minutes, and then rinse o with water.
The tube is intended for single use; any unused portion should be discarded. Contact with eyes should be avoided.

**Contraindications & Precautions**
In order to prevent ingestion, it should only be administered to pediatric patients under the direct supervision of an
adult. In case of accidental poisoning, supportive therapy, if indicated, should include parenteral uids and electrolytes,
respiratory support (oxygen and mechanical ventilation if necessary) and pressor agents if clinically signicant hypotension is present. Induction of emesis and/or gastric lavage as soon as possible, followed by purgatives and other routine anti-poison measures, may be indicated if needed to prevent absorption of ingested material.

**Side Effects**
Conjunctivitis, ocular hyperemia, eye irritation, dandru , dry skin, skin burning sensation, etc.

**Use in Pregnancy & Lactation**
Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the
potential benefit justifies the potential risk to the fetus. Caution should be exercised when this lotion is administered to a nursing woman.

**Preparation**
60 gm lotion.



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# Almex®

**Active Ingredient**
Albendazole.

**Indication**
Single or mixed intestinal infections caused by various helminths.

**Dosage & Administration**
12 to 24 months: 200 mg as a single dose (Half of Almex 400 tablet or 5 ml Almex suspension). Adults & children (over 2 years): Ascariasis, enterobiasis, trichuriasis & hookworm infestation - 400 mg (One Almex 400 tablet or 10 ml Almex suspension) single dose. Strogyloidiasis or taeniasis - 400 mg once daily for three consecutive days. Giardiasis - 400 mg once daily for five days. Hydatid disease (Echinococcosis) - 400 mg twice daily for 28 days. For cystic echinococcosis the 28-days course may be repeated after 14 days without treatment to a total of three treatment cycles. For alveolar echinococcosis, 400 mg twice daily for 28 days followed by 14 days without treatment may need to continue for months or years.

**Contraindication & Precaution**
Should only be used in the treatment of echinococcosis if there is constant medical supervision with regular monitoring of serum transaminase concentrations & of leucocyte & platelet counts.

**Side Effect**
Epigastric pain, diarrhoea, headache, nausea, vomiting, dizziness, constipation, pruritis & dry mouth.

**Use in Pregnancy & Lactation**
Should not be administered during pregnancy & in women planning to be pregnant.

**Use in Children**
For children of 12 months & above.

**Preparation**
400 mg Tablet & 200 mg / 5 ml Suspension.

# Ambrox®

**Active Ingredient**
Ambroxol.

**Indication**
Productive cough, Acute & chronic inflammatory disorders of upper & lower respiratory tracts associated with viscid mucus including acute & chronic bronchitis, laryngitis, Pharyngitis, sinusitis & rhinitis associated with viscid mucus, Asthmatic bronchitis, bronchial asthma with thick expectoration, Bronchiectasis, Chronic pneumonia

**Dosage & Administration**
*Paediatric Drops:* 0 - 6 months old - 0.5 ml, 2 times a day, 6 - 12 months old - 1 ml, 2 times a day, 1 - 2 years old -1.25 ml, 2 times a day. *Syrup :* 2 -5 years old - 2.5 ml (1/2 teaspoonful), 2-3 times a day, 5 - 10 years old - 5 ml (1 teaspoonful), 2-3 times a day, 10 years old & adults - 10 ml (2 teaspoonful), 3 times a day. *Ambrox 75 SR Capsule:* Adults & children over 12 years old - 1 capsule, once daily

**Side Effect**
Epigastric pain, stomach overfill feeling may occur occasionally. Rarely eruption, urticaria or angioneurotic edema has been reported.

**Contraindication & Precaution**
Known hypersensitivity to Ambroxol or Bromhexine. Should be given cautiously to patients with gastric & duodenal ulceration or convulsive disorders. Patients with hepatic & renal insufficiency should take it with caution.

**Drug Interaction**
Ambroxol should not be taken simultaneously with antitussives (e.g. Codeine).

**Use in Pregnancy & Lactation**
It is advised not to use in pregnancy, especially during the1st trimester. Safety during lactation has not been established yet.

**Preparation**
6 mg/ml Paediatric Drops, 15 mg/5 ml Syrup, 75 mg SR Capsule.

# Ambrisan™

**Active Ingredient**
Ambrisentan

**Indication**
Pulmonary Arterial Hypertension

**Dosage & Administration**
Initial treatment is 5 mg once daily, & can be increased to 10 mg once daily if 5 mg is tolerated. Tablets may be administered with or without food.

**Contraindication & Precaution**
Ambrisentan may cause fetal harm when administered to a pregnant woman. Ambrisentan is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. Pregnancy must be excluded before the initiation of treatment with Ambrisentan & prevented during treatment & for one month after stopping treatment. Ambrisentan is contraindicated in patients with Idiopathic Pulmonary Fibrosis (IPF) including IPF patients with pulmonary hypertension (WHO Group 3).

**Side Effect**
Decreases in hemoglobin concentration & hematocrit have followed administration of other endothelin receptor antagonists & were observed in clinical studies with Ambrisentan.

**Drug interaction**
Multiple dose co-administration of Ambrisentan & Cyclosporine resulted in an approximately 2-fold increase in Ambrisentan exposure in healthy volunteers; therefore, limit the dose of Ambrisentan to 5 mg once daily when co-administered with Cyclosporine.

**Use in Pregnancy & Lactation**
Pregnancy Category X. It is not known whether Ambrisentan is excreted in human milk. Breastfeeding while receiving Ambrisentan is not recommended.

**Use in Children**
Safety & effectiveness of Ambrisentan in pediatric patients have not been established.

**Preparation**
5 mg Tablet.

# Amodis®

**Active Ingredient**
Metronidazole.

**Indication**
• All forms of amoebiasis (intestinal & extra-intestinal disease including liver abscess & that of symptomless cyst passers) • Trichomoniasis • Giardiasis • Bacterial vaginosis • Acute ulcerative gingivitis • Anaerobic infections including septicaemia, bacteremia, peritonitis, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis etc. • Anaerobically-infected leg ulcers & pressure sores • Acute dental infections (e.g. acute pericoronitis & acute apical infections) • Surgical prophylaxis (prevention of postoperative infections due to anaerobic bacteria, particularly species of bacteroides & anaerobic streptococci • Chronic symptomatic peptic ulcer disease (as an agent of triple therapy to eradicate *H. pylori*-the most important aetiological factor of peptic ulcer)

**Dosage & Administration**

| Indication | Duration of dosage in days | Adults & children over 10 years | Children | | |
|---|---|---|---|---|---|
| | | | 7-10 years | 3-7 years | 1-3 years |
| Trichomoniasis** | 7 | 200 mg t.i.d. or 400 mg b.i.d. | 100 mg t.i.d. | 100 mg b.i.d. | 50 mg t.i.d. |
| | 2 | 800 mg in the morning & 1.2 gm at night | | | |
| | 1 | 2.0 gm as a single dose | | | |
| Invasive intestinal amoebiasis | 5 | 800 mg t.i.d. | 400 mg t.i.d. | 200 mg q.i.d. | 200 mg t.i.d. |
| Extra intestinal amoebiasis (including liver abscess) & symptomless amoebic cyst passers | 5-10 | 400 -800 mg t.i.d. | 200 -400 mg t.i.d | 100-200 mg q.i.d | 100 -200 mg t.i.d |
| Giardiasis | 3 | 2.0 gm once daily 1.0 gm once daily 600-800 mg 500 mg | 1.0 gm once daily | 600-800 mg once daily | 500 mg once daily |
| Acute ulcerative gingivitis | 3 | 200 mg t.i.d. mg t.i.d. | 100 mg | 100 mg b.i.d. | 50 mg t.i.d. |
| Acute dental infections | 3 -7 | 200 mg t.i.d. | | | |
| Bacterial vaginosis | 5-7 | 400–500 mg twice daily | | | |
| | 1 | 2.0 gm as a single dose | | | |
| Leg ulcers & pressure sores | 7 | 400 mg t.i.d. | | | |
| Anaerobic infections | 7 | Either 400 mg every 8 hours or 500 mg every 8 hours | 7.5 mg/kg t.i.d. | 7.5 mg/kg t.i.d | 7.5 mg/kg t.i.d |

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|---|---|---|---|---|---|
| Surgical prophylaxis | | 400–500 mg 2 hours before surgery; up to 3 further doses of 400–500 mg may be given every 8 hours for high-risk procedures | 7.5 mg/kg t.i.d. | 7.5 mg/kg t.i.d. | 7.5 mg/kg t.i.d. |

**Side Effect**
Metalic taste, furred tongue, nausea, vomiting, diarrhoea, drowsiness, rashes & mild reversible leucopenia may be observed during treatment.

**Drug Interaction**
Metronidazole interacts with Warfarin, Nicoumalone, Phenytoin, Phenobarbitone, Fluorouracil, Disulfiram, Lithium, Cimetidine etc.

**Use in Pregnancy & Lactation**
Not recommended during first & later trimesters. Breast feeding should be delayed until 48 hours after discontinuing metronidazole in the mother.

**Presentation**
400 mg Tablet & 200 mg/5ml Suspension.

# Amodis® 500 IV

**Active Ingredient**
Metronidazole.

**Indication**
**Amodis®** 500 IV is indicated in the prophylaxis & treatment of infections in which anaerobic bacteria have been identified. It is indicated in:
1.The prevention of postoperative infections due to anaerobic bacteria
2.The treatment of septicaemia, bacteraemia, peritonitis, brain abscess, necrotizing pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulites, & post operative wound infections from which pathogenic anaerobes have ben isolated.

**Dosage & Administration**
**Amodis®** 500 IV should be infused intravenously at an approximate rate of 5 ml/ min. Oral medication should be substituted as soon as feasible. Treatment for 7 days should be satisfactory for most patients, but the physician might decide to prolong treatment.
*For bacterial infections:*
Adults: 500 mg (100 ml) 8 hourly.
Children: 7.5 mg/kg (1.5 ml/kg) 8 hourly.
*For treatment before & during surgery:*
Adults: 500 mg (100 ml) shortly before operation, repeated 8 hourly
Children: 7.5 mg/kg (1.5 ml/kg) 8 hourly.

**Side Effect**
Pain, tenderness, redness or swelling over vein in which the medicine is given. Other side effects are unsteadiness, fever or chills, sore throat, headache, numbness, tingling pain or weakness in the hands or feet, pain, seizures, skin itching, unusual tiredness or weakness, vaginal irritation or discharge.

**Drug Interaction**
Metronidazole shows drug interaction with the following: alcohol or alcohol-containing beverages, Barbiturates, Carbamazepin, Cimetidine, Disulfiram, Fluorouracil, Lithium, Methadone, Phenytoin, Warfarin etc.

**Use in pregnancy & lactation**
Studies have not been done in humans. Metronidazole has not been shown to cause birth defects in animal studies; however, use is not recommended during the first trimester of pregnancy. Use is not recommended in nursing mothers since metronidazole passes into the breast milk.

**Precaution**
Metronidazole should be given with caution in the following conditions- anaemia or other blood disorders, liver disease, disease of nervous system, seizures etc.

**Preparation**
500mg/100 ml intravenous infusion.

# Anadol®

**Active Ingredient**
Tramadol.

**Indication**
Post-operative pain, colic & spastic pain, cancer pain, joint pain, neck & back pain, pain associated with osteoporosis.

**Dosage & Administration**
Usual doses are 50-100 mg every four to six hours. For acute pain an initial dose of 100 mg is required.

**Contraindication & Precaution**
Hypersensitivity, acute intoxication with alcohol, hypnotics, centrally acting analgesics,

opioids or psychotropic drugs. Tramadol should be used with caution in patients with increased intracranial pressure or head injury & patients with acute abdominal conditions.

**Side Effect**
Dizziness/vertigo, nausea, constipation, headache, somnolence, vomiting, pruritus, CNS stimulation, asthenia.

**Drug Interaction**
Monoamine oxidase (MAO) inhibitors, Carbamazepine.

**Use in Pregnancy & Lactation**
Tramadol should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

**Preparation**
50 mg Capsule, 100 mg SR Capsule, 100 mg/2 ml Injection, 100 mg Suppository.

# Anclog®

**Active Ingredient**
Clopidogrel.

**Indication**
Atherosclerotic disease (ischemic stroke, myocardial infarction or established peripheral arterial disease), prophylactically in patients at the risk of thrombo-embolic disorders such as myocardial infarction & stroke.

**Dosage & Administration**
One tablet once daily.

**Contraindication & Precaution**
Hypersensitivity, Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

**Side Effect**
Hemorrhage, abdominal discomfort, nausea, vomiting, diarrhoea, headache, dizziness, vertigo, paraesthesia, rash, pruritus, hepatic & biliary disorder, neutropenia may occur.

**Drug Interaction**
Aspirin, NSAIDs should be used with cautions to patients taking Clopidogrel.

**Use in Pregnancy & Lactation**
Clopidogrel should be used in pregnant women & nursing mothers only if clearly needed.

**Preparation**
75 mg Tablet.



# Anclog® Plus

**Active Ingredient**
Clopidogrel + Aspirin

**Indication**
Prevention of atherosclerotic events in patients with history of symptomatic atherosclerotic diseases (ischemic stroke, myocardial infarction or acute coronary syndrome).

**Dosage & Administration**
Once daily.

**Contraindication & Precaution**
Hypersensitivity to any of the components or NSAIDs. Active pathological bleeding such as peptic ulcer or intracranial hemorrhage or bleeding disorders like hemophilia. Recent history of gastrointestinal bleeding.

**Side Effect**
Abdominal pain, nausea, vomiting, neuralgia, paraesthesia, rash, pruritis.

**Drug Interaction**
This combination may enhance the effect of anticoagulants.

**Use in Pregnancy & Lactation**
The combination drug should be avoided during the last three months of pregnancy. It is not recommended for use during breast feeding because of the possible risk of developing Reye's syndrome.

**Use in Children**
Safety & efficacy in the pediatric population have not been established.

**Preparation**
(Clopidogrel 75 mg + Aspirin 75 mg)/Tablet



# Anema™

**Active Ingredient**
Monobasic Sodium Phosphate and Dibasic Sodium Phosphate

**Indication**
For the relief of occasional constipation. For use where bowel cleansing is required, such as before and after lower bowel surgery, delivery and post-partum, before proctoscopy, sigmoidoscopy or colonoscopy and before radiological examinations of the lower bowel.

**Dosage & Administration**
Adults, Elderly and Children over 12 years old: 1 Anema™ (118 ml delivered dose) not more than once daily or as directed by a physician. Children aged 2 years to less than 12 years: As directed by a physician.

**Contraindication**
Do not use in patients with, Congestive heart failure, impairment of renal function, gastrointestinal obstruction, Megacolon, Paralytic ileus, Perforation, Active inflammatory bowel disease, Imperforate anus, Dehydration, Children under 2 years of age, Hypersensitivity to active ingredients or to any of the excipients of the product.

**Precaution**
Use with caution in patients, with impaired renal function, with pre-existing electrolyte disturbances or who are taking diuretics which may affect electrolyte levels, Who are taking medications known to prolong the QT interval, Ascites, Colostomy.

**Side Effect**
Phosphate Enema is well tolerated when used as indicated. However, adverse events possibly associated with the use of phosphate enema have been infrequently reported. In some cases, adverse events may occur, especially if the enema is misused.

**Use in Pregnancy and Lactation**
As there is no relevant data available to evaluate the potential for fetal malformation or other feto-toxic effects when administered during pregnancy it should only be used as directed by a physician at the time of delivery or postpartum. As sodium phosphate may pass into the breast milk, it is advised that breast milk is expressed and discarded for at least 24 hours after receiving Anema™.

**Drug Interaction**
Use with caution in patients taking calcium channel blockers, diuretics, lithium treatment or other medications that might affect electrolyte levels as hyperphosphataemia, hypocalcaemia, hypokalaemia, hypernatraemic dehydration

and acidosis may occur. No other sodium phosphate preparations including sodium phosphate oral solution or tablets should be given concomitantly. As hypernatraemia is associated with lower lithium levels, concomitant use of Anema™ and lithium therapy could lead to a fall in serum lithium levels with a lessening of effectiveness.

**Overdose**
Using more than one Anema™ in 24 hours can be harmful. In case of excessive dose, recovery from the toxic effects can normally be achieved by rehydration. Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement therapy.

**Preparation**
133 ml solution.

# Angilock®

**Active Ingredient**
Losartan Potassium.

**Indication**
Hypertension: Angilock® is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents, including diuretics.
Hypertensive patients with Left Ventricular Hypertrophy: Angilock® is indicated to reduce the risk of stroke in patients with hypertension & left ventricular hypertrophy.
Nephropathy in Type 2 Diabetic Patients: Angilock® is indicated for the treatment of diabetic nephropathy with an elevated serum creatinine & proteinuria (urinary albumin to creatinine ratio ≥300 mg/g) in patients with type 2 diabetes & a history of hypertension.

**Dosage & Administration**
Adult hypertensive patients: The usual starting dose of Angilock® is 50 mg once daily. 25 mg used in patients with possible depletion of intravascular volume (e.g., patients treated with diuretics) & patients with a history of hepatic Impairment. Angilock® can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg. The effect of Losartan is substantially present within one week but in some studies the maximal effect occurred in 3-6 weeks. No initial dosage adjustment is necessary for elderly patients or for patients with renal impairment, including patients on dialysis. A lower dose should be considered for patients with a history of hepatic impairment. There is no therapeutic experience in patients with severe hepatic impairment. Therefore, Losartan is contraindicated in patients with severe hepatic impairment.
Pediatric hypertensive patients ≥ 6 years of age: The usual recommended starting dose is 0.7 mg/kg once daily (up to 50 mg total) administered as a tablet or a suspension. Dosage should be adjusted according to blood pressure response. Doses above 1.4 mg/kg (or in excess of 100 mg) daily have not been studied in pediatric patients. Angilock® is not recommended in pediatric patients less than 6 years of age or in pediatric patients with glomerular filtration rate less than 30 mL/min/1.73 $m^2$.
Hypertensive patients with Left Ventricular Hypertrophy: The usual starting dose is 50 mg of Angilock® once daily. Hydrochlorothiazide 12.5 mg daily should be added and/or the dose of Angilock® should be increased to 100 mg once daily followed by an increase in Hydrochlorothiazide to 25 mg once daily based on blood pressure response.
Nephropathy in Type 2 Diabetic Patients: The usual starting dose is 50 mg once daily. The dose should be increased to 100 mg once daily based on blood pressure response. Angilock® may be administered with insulin & other commonly used hypoglycemic agents (e.g., sulfonylureas, glitazones & glucosidase inhibitors). Angilock® may be administered

with other antihypertensive agents & with or without food.

**Contraindication & Precaution**
Losartan is contraindicated in patients who are hypersensitive to any component of this product. Do not co-administer aliskiren with Losartan in patients with diabetes. It is also contraindicated in severe hepatic impairment. In patients who are intravenously volume depleted (e.g. those treated with high-dose diuretics), symptomatic hypotension may occur. These conditions should be corrected prior to the administration of Losartan or a lower starting dose should be used. A lower dose should be considered for patients with a history of hepatic impairment. Losartan should not be used with Potassium-sparing diuretics.

**Side Effect**
Dizziness, rash, angioedema involving swelling of the face, lips and/or tongue & serious hypotension (particularly on initiating treatment in salt-depleted patients) or renal failure (mainly in patients with renal artery stenosis) may be encountered during Losartan potassium treatment.



**Use in Pregnancy & Lactation**
Pregnancy Catagory D. Losartan Potassium should not be used in pregnancy & if pregnancy is detected Losartan potassium should be discontinued as soon as possible. Losartan Potassium should not be used in lactating mother.

**Drug Interaction**
No drug interaction of clinical significance has been identified.

**Preparation**
25 mg, 50 mg & 100 mg Tablet.

# Angilock® Plus

**Active Ingredient**
Losartan Potassium & Hydrochlorothiazide.

**Indication**
Hypertension: Angilock® Plus is indicated for the treatment of hypertension. This fixed dose combination is not indicated for initial therapy of hypertension, except when the hypertension is severe enough that the value of achieving prompt blood pressure control exceeds the risk of initiating combination therapy in these patients.
Hypertensive patients with Left Ventricular Hypertrophy: Angilock® Plus is indicated to reduce the risk of stroke in patients with hypertension & left ventricular hypertrophy.

**Dosage & Administration**
Hypertension: The usual starting dose is Angilock® Plus 50/12.5 one tablet once daily. More than two tablets of Angilock® Plus 50/12.5 or one tablet of Angilock® Plus 100/25 once daily is not recommended. Maximum antihypertensive effect is attained about three weeks after initiation of therapy. Patients whose blood pressure is not adequately controlled with Losartan or Hydrochlorothiazide monotherapy, may be switched to Angilock® Plus 50/12.5 once daily. If blood pressure remains uncontrolled after about three weeks of therapy, the dose may be increased to one tablet of Angilock® Plus 100/12.5 or two tablets of Angilock® Plus 50/12.5 or one Angilock® Plus 100/25 once daily. Patients whose blood pressure is not adequately controlled with Losartan 100 mg monotherapy, may be switched to Angilock® Plus 100/12.5 once daily. If blood pressure remains uncontrolled after about three weeks of therapy, the dose may be increased to 2 tablets of Angilock® Plus 50/12.5 or one Angilock® Plus 100/25 once daily.

**Patients with renal impairment**
The usual regimens of therapy with Angilock®

Plus may be followed as long as the patient's creatinine clearance is greater than 30 mL/min. In patients with more severe renal impairment, loop diuretics are preferred to thiazides, so Angilock® Plus is not recommended.

Patients with Hepatic Impairment: Angilock® Plus is not recommended for titration in patients with hepatic impairment because the appropriate 25 mg starting dose of Losartan cannot be given.

Severe hypertension: The starting dose of Angilock® Plus for initial treatment of severe hypertension is one tablet of Angilock® Plus 50/12.5 once daily. For patients who do not respond adequately to Angilock® Plus 50/12.5 after 2 to 4 weeks of therapy, the dosage may be increased to one tablet of Angilock® Plus 100/25 once daily. The maximum dose is one tablet of Angilock® Plus 100/25 once daily. It is not recommended for use as initial therapy in patients with intravascular volume depletion (e.g., patients treated with diuretics).

Hypertensive Patients with Left Ventricular Hypertrophy: Treatment should be initiated with Angilock® 50 mg once daily. Angilock® Plus 50/12.5 substituted if the blood pressure reduction is inadequate. If additional blood pressure reduction is needed, Angilock® Plus 100/12.5 may be substituted, followed by Angilock® Plus 100/25. For further blood pressure reduction other antihypertensives should be added.

Angilock® Plus may be administered with other antihypertensive agents. Angilock® Plus may be administered with or without food.

**Contraindication & Precaution**

This combination is contraindicated in patients who are hypersensitive to any component of this product. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs. Do not co-administer Aliskiren with this combination in patients with diabetes. Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance. Serum & urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy. Because Losartan decreases uric acid, Losartan in combination with Hydrochlorothiazide attenuates the diuretic-induced hyperuricemia. In diabetic patients, dosage adjustments of Insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

**Side Effect**

Abdominal pain, edema/swelling, palpitation, back pain, dizziness, cough, sinusitis, upper respiratory infection, rash.

**Use in Pregnancy & Lactation**

Pregnancy Catagory D . Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

**Drug Interaction**

Losartan Potassium: Concomitant use of Potassium-Sparing diuretics (e. g., Spironolactone, Triamterene, Amiloride), Potassium supplements, or salt substitutes containing Potassium may lead to increases in serum Potassium. Hydrochlorothiazide : Alcohol, barbiturates or narcotics: potentiation of orthostatic hypotension may occur. Other antihypertensive drugs additive Effect or potentiation. Cholestyramine & Colestipol resins: Absorption of Hydrochlorothiazide is impaired in the presence of anionic exchange resins.

**Preparation**
Tablet: Losartan potassium 50 mg & Hydrochlorothiazide 12.5 mg, Losartan potassium 100 mg & Hydrochlorothiazide 25 mg & Losartan potassium 100 mg & Hydrochlorothiazide 12.5 mg.

# Angivent® MR

**Active Ingredient**
Trimetazidine Hydrochloride.



**Indication**
Long-term treatment of angina pectoris.

**Dosage & Administration**
1 tablet at mealtimes in the morning & evening.

**Contraindication & Precaution**
Severe depression, severe renal failure (creatinine clearance <15 ml/min), as a precaution in the absence of currently available studies.

**Side Effect**
Rare cases of gastrointestinal disorders.

**Use in Pregnancy & Lactation**
Pregnancy: Studies in animals have not demonstrated a teratogenic Effect. However, in the absence of clinical data & for safety reasons, prescription should be avoided during pregnancy.
Breastfeeding: In the absence of data, breastfeeding is not recommended during treatment.

**Preparation**
35 mg modified release Tablet.

# Anleptic®

**Active Ingredient**
Carbamazepine.

**Indication**
Anleptic is indicated for
- Partial & secondary generalized tonic-clonic seizures
- Primary generalized tonic-clonic seizures
- Trigeminal neuralgia
- Prophylaxis of bipolar disorder

**Dosage & Administration**
*Epilepsy:*
Adults & children over 12 years of age - Initial: Either 200 mg b.i.d. for tablets & XR tablets, or 1 teaspoon q.i.d. for suspension (400 mg/day). Maintenance: usually 800-1200 mg daily.
Children 6-12 years of age - Initial: Either 100 mg b.i.d. for tablets or XR tablets, or 1/2 teaspoon q.i.d. for suspension (200 mg/day). Maintenance: usually 400-800 mg daily.
Children under 6 years of age - Initial: 10-20 mg/kg/day b.i.d. or t.i.d. as tablets, or q.i.d. as suspension.Maintenance: Ordinarily, optimal clinical response is achieved at daily doses below 35 mg/kg. If satisfactory clinical response has not been achieved, plasma levels should be measured to determine whether or not they are in the therapeutic range. No recommendation regarding the safety of Carbamazepine for use at doses above 35 mg/kg/24 hours can be made.

*Combination therapy:* Carbamazepine may be used alone or with other anticonvulsants. When added to existing anticonvulsant therapy, the drug should be added gradually while the other anticonvulsants are maintained or gradually decreased, except phenytoin, which may have to be increased.

*Trigeminal Neuralgia:* Initial: On the first day, either 100 mg b.i.d. for tablets or XR tablets, or 1/2 teaspoon q.i.d. for suspension, for a

total daily dose of 200 mg. This daily dose may be increased by up to 200 mg/day using increments of 100 mg every 12 hours for tablets or XR tablets, or 50 mg (1/2 teaspoon) q.i.d. for suspension, only as needed to achieve freedom from pain. A total dose of 1200 mg daily shouldn't be exceeded. Maintenance: Control of pain can be maintained in most patients with 400-800 mg daily. However, some patients may be maintained on as little as 200 mg daily, while others may require as much as 1200 mg daily. At least once every 3 months throughout the treatment period, attempts should be made to reduce the dose to the minimum Effective level or even to discontinue the drug.
The tablets or syrup can be taken without regards to meal.

**Contraindication & Precaution**
This medicine should not be used if anybody is allergic to one or any of its ingredients. It can not be used also in the following conditions:

- Problems with the electrical message pathways in the heart (atrioventricular block).
- History of decreased blood cell production by the bone marrow (bone marrow depression).
- Hereditary blood disorders called porphyrias.
- Allergy to tricyclic antidepressants, eg amitriptyline.
- People who have taken a monoamine-oxidase inhibitor antidepressant (MAOI) in the last 14 days.

**Side Effect**
Dizziness, drowsiness, ataxia, dry mouth, abdominal pain, nausea, vomiting, anorexia, leucopenia, proteinuria, bradycardia, heart failure & hypotension. Erythematous skin rash, aplastic anemia may also be observed.

**Use in Pregnancy & Lactation**
Pregnancy category D.

**Preparation**
200 mg CR Tablet, 100 mg/5 ml (100 ml) Suspension.

# Anril®

**Active Ingredient**
Nitroglycerin.

**Indication**
Indicated for the acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease.

**Dosage & Administration**
*400 mcg spray:* At the onset of an attack, 1 or 2 metered sprays should be administered under the tongue. No more than 3 metered sprays are recommended within a 15-minute period. If the chest pain persists, prompt medical attention is recommended. Anril Spray may be used prophylactically 5 to 10 minutes prior to engaging in activities which might precipitate an acute attack.
*Injection:* The usual dose range is 10 - 200 mcg/min. Dose up to 400 mcg/min may be required during some surgical procedures.
*2.6 mg SR (Sustained Release) Tablet:* Adults & Elderly Patients: Dosage should be adjusted to the requirements of
the individual patient but will usually be 1 or 2 tablets taken three times daily.
The lowest effective dose should be used.

**Contraindication & Precaution**
Contraindicated in patients with early myocardial infarction, severe anemia, increased intracranial pressure & those with a known hypersensitivity to Nitroglycerin.
Also contraindicated in patients who are using sildenafil citrate since sildenafil citrate has been shown to potentiate the hypotensive effects of organic nitrates.
Only the smallest dose required for Effective control of the acute anginal attack should be used. Excessive use may lead to the development of tolerance. This drug should be used with caution in patients who may be volume-depleted or are already hypotensive.

**Drug Interaction**
Antihypertensive drugs, beta-adrenergic blockers, phenothiazines, calcium channel blockers, alcohol, aspirin, ergotamine & related drugs.

**Side Effect**
Headache, facial flushing, dizziness, nausea, vomiting, feelings of weakness, postural hypotension, reflex tachycardia etc.

**Use in Pregnancy & Lactation**
Pregnancy : Pregnancy Category C. Nitroglycerin should be given to pregnant women only if clearly needed.
Nursing Mothers: Caution should be exercised when Nitroglycerin Spray is administered to a nursing woman.



**Use in Children**
Safety & Effectiveness of nitroglycerin in pediatric patients have not been established.

**Preparation**
400 mcg spray, 5 mg/ ml IV Injection, 2.6 mg SR (Sustained Release) Tablet.

# Ansulin®

**Active Ingredient**
Insulin Human (rDNA)

**Indication**
Type 1 & Type 2 Diabetes Mellitus.

**Dosage & Administration**
The average range of total daily insulin requirement for maintenance therapy in type 1 diabetic patients lies between 0.5 & 1.0 IU/kg. In pre-pubertal children it usually varies from 0.7 to 1.0 IU/kg, whereas in insulin resistant cases, e.g. during puberty or due to obesity, the daily insulin requirement may be substantially higher. Initial dosages for type 2 diabetic patients are often lower, e.g. 0.2 to 0.6 IU/kg/day.

**Contraindication & Precaution**
Hypoglycemia or the patients who have allergic reaction to insulin or any of the excipients. Inadequate dosing or discontinuation especially in type 1 diabetes, may lead to hyperglycemia. Hypoglycemia may occur if the insulin dose is too high in relation to the insulin requirement. Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycemia.

**Side Effect**
Hypoglycemia is the most common adverse effect during insulin treatment & symptoms of hypoglycemia may occur suddenly. Few cases of the allergic reaction such as red & swollen or itching are reported. It usually disappears in a few days.

**Use in Pregnancy & Lactation**
Ansulin can be used during pregnancy & lactation if required.

**Preparation**
Vials (10 ml):
Ansulin R Injection 40 IU/ml & 100 IU/ml, Ansulin N Injection 100 IU/ml, Ansulin 30/70 Injection 40 IU/ml and 100 IU/ ml, Ansulin 50/50 Injection 100 IU/ml.
Cartridges (3 ml):
Ansulin R Pen Cartridge 100 IU/ml, Ansulin 30/70 Pen Cartridge 100 IU/ml, Ansulin 50/50 Pen Cartridge 100 IU/ml.

# Antazol®

**Active Ingredient**
Xylometazoline.

**Indication**
Nasal congestion, Seasonal & perennial allergic rhinitis , Sinusitis.

**Dosage & Administration**
Adults: 2 or 3 drops adult formula (0.1%) 2-3 times daily. Children under 12 yrs : 1 or 2 drops children's formula (0.05%) in each nostril 1-2 times daily. Not to be used in infants less than 3 months.

**Contraindication & Precaution**
Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater, hypersensitive to Xylometazoline.

**Side Effect**
Burning sensation, local irritation, nausea, headache, & dryness of the nasal mucosa. Systemic cardiovascular effects have occurred, & this should be kept in mind when giving Antazol to people with cardiovascular disease.

**Preparation**
0.05% & 0.1% Nasal Drops.

# Antazol® Plus

**Active Ingredient**
Sodium Cromoglycate & Xylometazoline.

**Indication**
Prophylaxis & treatment of allergic rhinitis accompanied by nasal congestion.

**Dosage & Administration**
Adults (including the elderly) & children: One spray to each nostril four times daily.

**Contraindication & Precaution**
Known hypersensitivity to any ingredients of the preparation.

**Side Effect**
No serious side effects have been reported. Occasional irritation of the nasal mucosa, wheezing & tightness of the chest has been reported. Xylometazoline causes mild side effects such as nasal irritation, dryness of the nose, sneezing, headache, insomnia, drowsiness & palpitations.

**Preparation**
(2.6 mg + 0.0325 mg)/spray, Metered Dose Nasal Spray.



# Antista®

**Active Ingredient**
Chlorpheniramine.

**Indication**
Allergic conditions including urticaria, sensitivity reactions, angioneurotic oedema, hay fever, vasomotor rhinitis, cough, common cold, motion sickness.

**Dosage & Administration**
Adults : 4 mg 3-4 times daily. Children: Up to 1 (one) year: 1 mg twice daily. 1-5 yers: 1mg 3-4 times daily. 6-12 years: 2 mg 3-4 times daily or as directed by the physician.

**Side Effect**
Drowsiness, dizziness, headache, psychomotor impairment, urinary retention, dry mouth,

blurred vision & gastro-intestinal disturbances.

**Contraindication & Precaution**
It should be used with caution in epilepsy, prostatic hypertrophy, glaucoma & hepatic disease. The ability to drive or operate machinery may be impaired.

**Preparation**
2 mg/5 ml Syrup.

**Drug Interaction**
Cyclosporin, fibric acid derivatives, erythromycin, azole antifungals, or niacin (nicotinic acid).

**Use in Pregnancy & Lactation**
Atorvastatin is contraindicated in pregnancy & while breast-feeding.

**Preparation**
10 mg, 20 mg & 40 mg Tablet.

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# Anzitor®

**Active Ingredient**
Atorvastatin.

**Indication**
For reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B & triglycerides in patients with primary hypercholesterolemia.

**Dosage & Administration**
Usual dose is 10 mg once daily. Dosage range is Anzitor® 10 to 80 mg once daily.

**Side Effect**
Side effects are mild & transient. Reversible myositis, headache, altered liver-function tests & gastro-intestinal effects including abdominal pain, flatulence, diarrhoea, nausea & vomiting. Thrombocytopenia, rash & hypersensitivity reactions, insomnia, angioedema, anorexia, asthenia, paraesthesia, peripheral neuropathy, alopecia, pruritus, rash, impotence, chest pain, hypoglycemia & hyperglycemia.

**Contraindication**
Liver disease, myalgia, myopathy & hypersensitivity to the drug.

# Apsol®

**Active Ingredient**
Amlexanox.

**Indication**
For the treatment of Aphthous ulcers.

**Dosage & Administration**
1. Apply the paste as soon as possible after noticing the symptoms of an aphthous ulcer. Continue to use the paste four times daily, preferably following oral hygiene after breakfast, lunch, dinner, & at bedtime.
2. Dry the ulcer(s) by gently patting it with a soft, clean cloth.
3. Wash hands before applying.
4. Moisten the tip of the index finger.
5. Squeeze a dab of paste approximately 1/4 inch (0.5 cm) onto a finger tip.
6. Gently dab the paste on to the ulcer. Repeat the process if more than one ulcer.
7. Wash hands when done applying.
8. Wash eyes promptly if they come in contact with the paste.
9. Use the paste until the ulcer heals. If significant healing or pain relief has not occurred in 10 days, consultation with the physician is required.

**Contraindication & Precaution**
Amlexanox oral paste is contraindicated in patients with known hypersensitivity to Amlexanox or other ingredients in the

formulation. Wash hands immediately after applying Amlexanox oral paste, directly to ulcers with the finger tips. In the event that a rash or contact mucositis occurs, discontinue use.

**Side Effect**
Adverse reactions reported by 1-2% of patients were transient pain, stinging and/or burning at the site of application. Infrequent (< 1%) adverse reactions in the clinical studies were contact mucositis, nausea, & diarrhea.

**Use in Pregnancy & Lactation**
Pregnancy: US FDA pregnancy Category B. This drug should be used during pregnancy only if clearly needed.
Nursing Mothers: Amlexanox was found in the milk of lactating rats; therefore, caution should be exercised when administering Amlexanox oral paste to a nursing woman.

**Use in Children**
Safety & effectiveness of Amlexanox oral paste in pediatric patients have not been established.

**Preparation**
Tube containing 5 gm oral paste.



# Ariprex™

**Active Ingredient**
Aripiprazole.

**Indication**
Schizophrenia, bipolar disorder, adjunctive treatment of major depressive disorder, irritability associated with autistic disorder, agitation associated with schizophrenia or bipolar mania.

**Dosage & Administration**

| | Initial Dose | Recommended Dose | Maximum Dose |
|---|---|---|---|
| Schizophrenia – adults | 10-15 mg/day | 10-15 mg/day | 30 mg/day |
| Schizophrenia – adolescents (ages 13-17 years) | 2 mg/day | 10 mg/day | 30 mg/day |
| Bipolar mania – adults: monotherapy | 15 mg/day | 15 mg/day | 30 mg/day |
| Bipolar mania – adults: adjunct to lithium or valproate | 10-15 mg/day | 15 mg/day | 30 mg/day |

| | | | |
|---|---|---|---|
| Bipolar mania – pediatric patients (10-17 years): monotherapy or as an adjunct to lithium or valproate | 2 mg/day | 10 mg/day | 30 mg/day |
| As an adjunct to antidepressants for the treatment of major depressive disorder–adults | 2-5 mg/day | 5-10 mg/day | 15 mg/day |
| Irritability associated with autistic disorder-pediatric patients (ages 10-17 years) | 2 mg/day | 5-10 mg/day | 15 mg/day |
| | | | |

• Oral formulations: Administer once daily without regard to meals.

**Side Effect**

Vomiting, nausea, akathisia, extrapyramidal disorder, somnolence, sedation, dizziness, insomnia, tremor, restlessness, fatigue, blurred vision, salivary hypersecretion, constipation, pyrexia, drooling, decreased appetite.

Special warnings & precautions for use

Elderly Patients with Dementia-Related Psychosis: Increased incidence of cerebrovascular adverse events (eg, stroke, transient ischemic attack, including fatalities).

Suicidality & antidepressants: Increased risk of suicidality in children, adolescents, young & adults with major depressive disorder.

Tardive dyskinesia: Discontinue if clinically appropriate.

Metabolic changes: Atypical antipsychotic drugs have been associated with metabolic changes that include hyperglycemia/diabetes mellitus, dyslipidemia, & body weight gain.

Orthostatic hypotension: Use with caution in patients with known cardiovascular or cerebrovascular disease.

Seizures/Convulsions: Use cautiously in patients with a history of seizures.

**Contraindication & Precaution**

Known hypersensitivity to Aripiprazole. Use caution when operating machinery.

**Drug Interaction**

Caution should be exercised when Aripiprazole is taken in combination with other centrally acting drugs & alcohol. Carbamazepine could cause an increase in Aripiprazole clearance & lower blood levels. Ketoconazole, quinidine, fluoxetine or paroxetine can inhibit Aripiprazole elimination & cause increased blood levels.

**Use in Pregnancy & Lactation**

Pregnancy: Pregnancy category C. It should be avoided during pregnancy.

Lactation: It is recommended that women receiving Aripiprazole should not breast-feed.

**Preparation**

2 mg ,10 mg Tablet. 50 ml Oral solution

# Asynta™

**Active Ingredient**
*Suspension:* Each 5 ml suspension contains Sodium Alginate USP 500 mg & Potassium Bicarbonate USP 100 mg.
*Chewable Tablet:* Each chewable tablet contains Sodium Alginate USP 500 mg & Potassium Bicarbonate USP 100 mg.

**Indication**
Treatment of symptoms of gastroesophageal reflux such as acid regurgitation, heartburn & indigestion (related to reflux), for example, following meals, or during pregnancy, or in patients with symptoms related to reflux oesophagitis.

**Dosage & Administration**
*Suspension:* Daily 4 times, after meals & at bedtime; Adult & children over 12 years: 1-2 teaspoonful (5-10 ml) Suspension; Children 2 - 12 years: 1/2-1 teaspoonful (2.5-5 ml) Suspension.
*Chewable Tablet:* Daily 4 times, after meals & at bedtime; Adult & children over 06 years: 1-2 tablets; children 6-12 years: 1 tablet.

**Contraindication & Precaution**
This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients.

**Side Effect**
Very rarely (<1/10,000) patients may develop allergic manifestations, such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions.

**Drug Interaction**
Interaction with other medicinal products & other forms of Interaction are unknown.

**Use in Pregnancy & Lactation**
**Asynta**™ can be given in pregnant & lactating mother.

**Use in Children**
**Asynta**™ suspension can be given in children over 2 years of age. **Asynta**™ tablet can be given in children over 6 years of age.

**Preparation**
Chewable Tablet & Suspension.

# Avaspray™

**Active Ingredient**
Fluticasone Furoate

**Indication**
Fluticasone Furoate nasal spray is indicated for the treatment of the symptoms of seasonal and perennial allergic rhinitis in patients 2 years of age and older.

**Dosage & Administration**
Adults & Children over 12 years: 2 sprays in each nostril once daily.
2-12 years : 1 sprays in each nostril once daily.

**Contraindication & Precaution**
Fluticasone Furoate undergoes extensive first-pass metabolism by the liver enzyme. CYP3A4, therefore the pharmacokinetics of Fluticasone Furoate in patients with severe liver disease may be altered. Based on data with another glucocorticoid metabolized by CYP3A4, coadministration with ritonavir is not recommended because of the risk of systemic effects secondary to increased exposure to Fluticasone Furoate.

**Side-Effect**
The most common adverse reactions (>1%

incidence) included headache, epistaxis, pharyngolaryngeal pain, nasal ulceration, back pain, Nasopharyngitis, Upper Respiratory Tract Infection, nausea, and cough.

**Pregnancy & Lactation**
Pregnancy Category: C.
There are no adequate and well controlled studies in pregnant women. Fluticasone Furoate Nasal Spray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Preparation**
120 metered sprays.



# B-50® Forte

**Active Ingredient**
Vitamin B-complex.

**Indication**
Glossitis, stomatitis, cheilosis, beriberi polyneuritis.

**Dosage & Administration**
Capsule : 1-2, 3 times daily or as directed by the physician. Syrup : 2-3 teaspoonful daily. Injection **:** 2 ml daily IV or IM.

**Contraindication & Precaution**
Hypersensitivity to the components.

**Side Effect**
Rarely allergic reactions.

**Drug Interaction**
Can decrease the efficacy of levodopa.

**Use in Pregnancy & Lactation**
It is safe to use B-50® Forte in pregnancy & lactation.

**Preparation**
Capsule, 200 ml Syrup & Injection.

# Bactrocin®

**Active Ingredient**
Mupirocin.

**Indication**
Topical treatment of impetigo due to *Staphylococcus aureus* & *Streptococcus pyogenes*.

**Dosage & Administration**
A small amount of ointment should be applied to the affected area three times daily. The area treated may be covered with gauze dressing if desired.

**Contraindication & Precaution**
In individuals with a history of hypersensitivity to any of its components. If a reaction suggesting sensitivity or chemical irritation should occur with the use of Mupirocin Ointment, treatment should be discontinued & appropriate alternative therapy for the infection should be instituted. As with other antibacterial products, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. When used on the face care should be taken to avoid the eyes.

**Drug Interaction**
The effect of the concurrent application of Mupirocin & other drug products has not been studied.

**Use in Pregnancy & Lactation**
The drug is classified as Pregnancy Category B. Thus, this drug should be used during

pregnancy only if clearly needed. Caution should be exercised when it is administered to a nursing woman.

**Use in Children**
The safety & effectiveness of Mupirocin have been established in the age range of 2 months to 16 years.

**Side Effect**
Burning, stinging, pain, itching , rash, nausea, erythema, dry skin, tenderness, swelling, contact dermatitis, & increased exudate.

**Preparation**
2 % Ointment.

# Barif™

**Active Ingredient**
Febuxostat.

**Indication**
Barif is indicated for the chronic management of hyperuricemia in patients with gout.

**Dosage & Administration**
Recommended at 40 mg or 80 mg once daily. The recommended starting dose is 40 mg once daily. For patients who do not achieve a serum uric acid less than 6 mg /dL after 2 weeks with 40 mg, 80 mg is recommended.

**Contraindication & Precaution**
Febuxostat is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline.
Gout Flare: An increase in gout flares is frequently observed during initiation of anti-hyperuricemic agents, including Febuxostat. If a gout flare occurs during treatment, Febuxostat need not be discontinued. Prophylactic therapy may be beneficial for up to six months.
Cardiovascular Events: A higher rate of cardiovascular thromboembolic events was observed in patients treated with febuxostat than allopurinol in clinical trials.
Liver Enzyme Elevation: Transaminase elevations have been observed in febuxostat -treated patients.

**Side Effect**
The most common adverse events associated with the use of Febuxostat may include liver function abnormalities, nausea, arthralgia, & rash.

**Drug Interaction**
Concomitant administration of Febuxostat with azathioprine, mercaptopurine or theophylline could increase plasma concentrations of these drugs resulting in severe toxicity.

**Use in Pregnancy & Lactation**
Pregnancy Category C: Febuxostat should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
It is not known whether this drug is excreted in human milk. Caution should be exercised when Febuxostat is administered to a nursing woman.

**Use in Children**
The safety & efficacy of Febuxostat in children (under 18 years of age) has not been established.

**Preparation**
40 mg Tablet.

# Baritor™ 2

**Active Ingredient**
Baricitinib INN 2 mg.

**Indication**
Baricitinib is indicated for the treatment of adult patients with moderately to severely active Rheumatoid Arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. DOSAGE & ADMINISTRATION The recommended dose of Baricitinib is 2 mg once daily. It may be used as monotherapy or in combination with Methotrexate or other DMARDs. Baricitinib can be given orally with or without food.



**Side Effect**
The most commonly reported adverse drug reactions (ADRs) occurring in ≥ 2 % of patients treated with Baricitinib monotherapy or in combination with conventional synthetic DMARDs were increased LDL cholesterol (33.6 %), upper respiratory tract infections (14.7 %) and nausea (2.8 %).

**Precaution**
Serious Infections: Avoid use of Baricitinib in patients with an active, serious infection, including localized infections. Tuberculosis: Baricitinib should not be given to patients with active TB. Malignancy and Lymphoproliferative Disorders: Consider the risks and benefits of Baricitinib treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing Baricitinib in patients who develop a malignancy. Thrombosis: Baricitinib should be used with caution in patients who may be at increased risk of thrombosis. Gastrointestinal Perforations: Baricitinib should be used with caution in patients who may be at increased risk for gastrointestinal perforation. Vaccinations: Avoid use of live vaccines with Baricitinib.

**Contraindication**
None

**Use In Special Population**
Pregnancy:
Baricitinib is contraindicated during pregnancy Lactation: No information is available on the presence of Baricitinib in human milk. Pediatric Use: The safety and effectiveness of Baricitinib in pediatric patients has not been established. Geriatric Use: Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection. Hepatic Impairment: No dose adjustment is necessary in patients with mild or moderate hepatic impairment. Renal Impairment: Baricitinib is not recommended for use in patients with estimated GFR of less than 60 mL/min/1.73 m2.

**Drug Interaction**
Strong OAT3 Inhibitors: Baricitinib exposure is increased when it is co-administered with strong OAT3 inhibitors (such as probenecid). Other JAK Inhibitors or Biologic DMARDs: Baricitinib has not been studied in combination with other JAK inhibitors or with biologic DMARDs.

**Preparation**
2 mg Tablet

# Beclomin™ HFA Inhaler

**Active Ingredient**
Beclometasone.

**Indication**
Preventive treatment for asthma.

**Dosage & Administration**
Adults (including the elderly): The usual starting dose is 200 micrograms twice a day. In more severe cases the starting dose may need to increase to 600 to 800 micrograms per day.
Children: 50 to 100 micrograms should be given two, three or four times daily in accordance to the response. Alternatively, 100 micrograms or 200 micrograms twice daily should be given. The usual starting dose is 100 micrograms twice daily Beclometasone.

**Use in Pregnancy & Lactation**
There is inadequate evidence of safety in human pregnancy. The use of Beclometasone dipropionate in mothers breast feeding their babies requires that the therapeutic benefits of the drug be weighed against the potential hazards to the mother & baby.

**Contraindication & Precaution**
Contraindicated in patients with known sensitivity. Care is necessary in patients with active or quiescent pulmonary tuberculosis.

**Side Effect**
Candidiasis of the mouth & throat (thrush) occurs in some patients.

**Preparation**
HFA Inhaler : 100 or 250 mcg/puff , 200 puffs.

# Becospray®

**Active Ingredient**
Beclomethasone.

**Indication**
Seasonal & perennial allergic rhinitis including hay fever & non-allergic (vasomotor) rhinitis.

**Dosage & Administration**
Adults : 02 sprays in each nostril twice daily. Children (6 to 12 years of age) : 01 spray in each nostril twice daily. Children under 6 years of age : Not recommended.

**Contraindication & Precaution**
History of hypersensitivity.

**Side Effect**
Rare. Nasal septum perforation, dryness & irritation of the nose & throat, unpleasant taste & smell & epistaxis, wheezing, cataract reported.

**Drug Interaction**
None is known.

**Preparation**
50 mcg/spray, Nasal Spray.



# Benostar™

**Active Ingredient**
Benzydamine Hydrochloride

**Indication**
Benostar™ mouthwash (Benzydamine Hydrochloride) is used to treat many painful conditions affecting the throat or mouth including:
• Sore throat
• Sore tongue or gums
• Mouth ulcers
• Discomfort caused by dentures
• Pain after dental surgery etc.

**Dosage & Administration**

15 ml of Benostar mouthwash should be rinsed or gargled every 1.5–3 hours or as required, for 20-30 seconds. If stinging occurs, it can be diluted with an equal volume of water.

**Contraindication**
Patients allergic (hypersensitive) to Benostar™ (Benzydamine Hydrochloride) or other component of mouthwash should not use the preparation. Contact with eye should be avoided. If accidentally get into eyes, they should be immediately washed with cold water.

**Side effects**
Benostar™ (Benzydamine Hydrochloride) mouthwash can cause side effects, although not everybody gets them. Side effects are generally minor.

- Severe allergic reaction which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. If the swelling affects throat and makes breathing difficult and swallowing difficult, patients should be hospitalized
- Itchy rash, sometimes with pale, raised areas of skin with red edges (urticaria).
- A feeling of numbness in mouth.
- A stinging feeling in mouth – the mouthwash may be diluted with water if you experience stinging. This should help to reduce the stinging effect.

**Use in Pregnancy & Lactation**
The safety of Benostar™ (Benzydamine Hydrochloride) has not been established in pregnant patients. Risk to benefit ratio should be established if this drug is to be used in these patients.

**Pediatric Use**
It is not indicated below 12 years of age.

**Storage condition**
Keep away from light, store in cool and dry place under 30°C. Keep out of reach of children.

**Preparation**
250 ml mouthwash with a measuring cup

# Betameson™

**Active Ingredient**
Betamethasone Dipropionate.

**Indication**
Betamesol (Betamethasone Dipropionate) Cream & Ointment are indicated for the relief of the inflammatory & pruritic manifestations of resistant or severe corticosteroid responsive dermatitis. These include- atopic eczema, nummular eczema, contact dermatitis, neurodermatitis, anogenital & senile pruritus, lichen planus & psoriasis.

**Dosage & Administration**
Apply a thin film once or twice daily to cover completely the affected area. Patients with chronic psoriasis who have achieved at least a marked improvement in their psoriatic lesion (i.e., approximately 80% improvement) with Betamethasone Dipropionate may be maintained in remission with a pulse dosing regimen consisting of three consecutive applications of up to 3.5 g each of Betamethasone Dipropionate Cream & Ointment, twelve hours apart (e.g., morning, evening, following morning) to the previously affected areas once each week. For this purpose, Betamethasone Dipropionate cream & ointment should be applied to the lesion sites previously affected & treated. Patients on this pulse dose regimen who relapse should be reverted back to the conventional dosing regimen.

**Contraindication & Precaution**
Hypersensitivity to Betamethasone Dipropionate, other corticosteroids. Like other topical corticosteroids, Betamethasone Dipropionate is contraindicated in viral infections of the skin, such as vaccinia, varicella & *Herpes simplex,* also tuberculosis, acne rosacea, fungal skin infections, perioral dermatitis & ulcerative conditions.

**Side Effect**
The most frequent side effects reported with Betamethasone Dipropionate are mild to moderate transient burning/stinging, dry skin, pruritus, irritation & folliculitis. Rarely reported adverse effects include tingling, prickly skin/

tightening or cracking of skin, warm feeling, laminar scaling & perilesional scaling, follicular rash, skin atrophy, erythema, urticaria, vesiculation, telangiectasia, acneiform papules & hyperaesthesia.

**Use in Pregnancy & Lactation**
This medicine should not be used during pregnancy & during lactation unless considered essential by your doctor.

**Use in Children**
Not recommended under one year of age, or under the nappy, or airtight dressing of an infant older than one year.

**Preparation**
20 gm Cream & Ointment.

term continuous topical therapy should be avoided where possible, particularly in infants & children. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might occur.

**Side Effect**
Local atrophic changes in the skin such as thinning, striae, & dilatation of the superficial blood vessels, sufficient systemic absorption to produce the features of hypercorticism & suppression of the HPA axis.

**Use in Pregnancy & Lactation**
Topical administration of corticosteroids to pregnant animal can cause abnormalities of fetal development including cleft palate & intrauterine growth retardation & fetal ototoxicity.

**Preparation**
15 gm Cream.



# Betameson-N®

**Active Ingredient**
Betamethasone Dipropionate & Neomycin Sulphate.

**Indication**
Eczema, prurigo nodularis, psoriasis, neurodermatoses, seborrhoeic dermatitis, contact sensitivity reactions, systemic steroid therapy in generalized erythroderma, secondarily infected insect bites & anal & genital intertrigo (specially when scondary bacterial infection is present).

**Dosage & Administration**
Apply sparingly 2-3 times daily, reducing frequency as condition responds.

**Contraindication & Precaution**
Untreated bacterial, fungal or viral skin lesions, acne & perioral dermatitits. Long-

# Bicozin®

**Active Ingredient**
Thiamine, Riboflavin, Pyridoxine, Nicotinamide & Zinc

**Indication**
Treatment & prevention of B-vitamins & Zinc deficiencies.

**Dosage & Administration**
Bicozin Syrup : Adults : 10 ml (2 teaspoonfuls) 2 to 3 times daily, Children : 10 ml (2 teaspoonfuls) 1 to 3 times daily, Infants: 5 ml (1 teaspoonful) 1 to 2 times daily. Bicozin Tablet : Adults & Children over 30 kg : 1 to 2 tablets 2 to 3 times daily

**Contraindication**
In patients with a known hypersensitivity to any of the ingredients of this product.

**Side Effect**
Generally well tolerated.

**Drug Interaction**
Generally no interactions have been observed.

**Use in Pregnancy & Lactation**
Recommended.

**Preparation**
100 ml & 200 ml Syrup; Tablet.

B

# Bicozin-I®

**Active Ingredient**
Iron (III) Hydroxide Polymaltose Complex INN , Thiamine Hydrochloride BP , Riboflavin-5-Phosphate Sodium BP , Pyridoxine Hydrochloride BP , Nicotinamide BP & Zinc Sulphate Heptahydrate BP.

**Indication**
Bicozin-I syrup is indicated for the treatment & prevention of Iron, B-vitamins & Zinc deficiencies.

**Dosage & Administration**
Adults: 5 ml-10 ml (1-2 teaspoonful) 3 times daily or as recommended by the physician.
Children: 5 ml (1 teaspoonful) 3 times daily or as recommended by the physician.
Infants: 0.33 ml/kg body weight daily or as recommended by the physician.

**Contraindication & Precaution**
Bicozin-I syrup is contraindicated in patients with a known hypersensitivity to any of the ingredients of this product.

**Side Effect**
Bicozin-I syrup is generally well tolerated. However, a few side-effects of oral Iron preparations, including nausea, vomiting, constipation or diarrhoea may occur.

**Use in Pregnancy & Lactation**
Recommended.

**Drug Interaction**
No interactions have been observed. Since, the Iron is complex bound, ionic interaction with foodstuff components (phytates, oxalates, tannin, etc.) & concomitant administrations of medicaments (tetracyclines, antacids) are unlikely to occur.

**Preparation**
100 ml Syrup.

# Bimator™ Eye Drops

**Active Ingredient**
Bimatoprost & Timolol

**Indication**
Bimator Eye Drops is indicated for the reduction of intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to mono-therapy.

**Dosage & Administration**
The recommended dose is one drop in the affected eye(s) once-daily.

**Contraindication & Precaution**
It is contraindicated in patients with known

hypersensitivity to any ingredient of this formulation. Like other topically applied ophthalmic medicinal products, the active substances Timolol/ Bimatoprost may be absorbed systemically. Due to the beta-adrenergic component, Timolol, the same types of cardiovascular, pulmonary and other adverse reactions as seen with systemic beta-blockers may occur. Caution should be exercised in treating patients with severe or unstable and uncontrolled cardiovascular disease.

**Drug Interaction**
There is a potential for bradycardia when ophthalmic beta-blockers solution is administered concomitantly with oral calcium channel blockers, guanethidine, beta-adrenergic blocking agents, parasympathomimetics, anti-arrhythmics and digitalis glycosides. Concomitant ocular medications should be administered at least 5 min apart from the instillations of Bimator Eye Drops.

**Side Effect**
In clinical trials, Ocular hyperemia was reported in approximately 26% of patients. 5 to 10 % in these clinical studies included decreased visual acuity, eye discomfort, foreign body sensation, pain and pruritis.

**Use in Pregnancy & Lactation**
Use in Pregnancy: There are no adequate data from the use of the Bimatoprost / Timolol fixed combination in pregnant women. It should not be used during pregnancy unless clearly necessary.
Use in Lactation: Animal studies showed Bimatoprost is excreted in rat's milk. & Timolol is excreted in human milk. Therefore, Bimatoprost / Timolol should not be used during breastfeeding.

**Preparation**
3 ml of Bimator Eye Drops is supplied in LDPE bottle.

# Bisocam 2.5/5

**Active Ingredient**
Bisoprolol & Amlodipine combination.

**Indications**
Bisoprolol & Amlodipine combination is indicated for the treatment of hypertension as substitution therapy in patients adequately controlled with the individual products given concurrently at the same doses level as in the combination, but as separate tablets.

**Dosage & Administration**
Once daily dose with or without food.

**Contraindication & Precautions**
Bisoprolol & Amlodipine combination is contraindicated in patients with Acute heart failure, high grade aortic stenosis, cardiogenic shock, second or third degree AV block, Sick sinus syndrome, slowed heart rate, symptomatic bradycardia, symptomatic hypotension, severe bronchial asthma and hypersensitivity to Bisoprolol, Amlodipine or any of the excipients.

**Use in Pregnancy & Lactation**
Pregnancy: Bisoprolol & Amlodipine combination is not recommended during pregnancy unless clearly necessary. Nursing mothers: It is not known whether Bisoprolol or Amlodipine is excreted in human milk.

**Side Effects**
Headache, drowsiness, dizziness, bradycardia.

**Preparation**
Bisocam 2.5/5 Tablet

# Bisocor®

**Active Ingredient**
Bisoprolol Fumarate.

**Indication**
Bisocor (Bisoprolol) is indicated in the management of hypertension & in the treatment of angina. It may be used alone or in combination with other antihypertensive agents.

**Dosage & Administration**
The dose of Bisocor must be individualized to the needs of the patient. The usual starting dose is Bisocor 5 mg once daily. In some patients, Bisocor 2.5 mg may be an appropriate starting dose. If the antihypertensive Effect of Bisocor 5 mg is inadequate, the dose may be increased to Bisocor 10 mg & then, if necessary, to 20 mg once daily.



**Contraindication & Precaution**
Bisoprolol is contraindicated in patients with cardiogenic shock, overt cardiac failure, second or third degree AV block, & marked sinus bradycardia. Impaired renal or hepatic function: Use caution in adjusting the dose of Bisoprolol in patients with renal or hepatic impairment. Risk of anaphylactic reaction: While taking beta-blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive torepeated challenge, accidental, diagnostic or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.

**Use in Pregnancy & Lactation**
Pregnancy: Bisoprolol should not be used during pregnancy unless clearly necessary. If treatment with Bisoprolol is considered necessary, the uteroplacental blood flow & the foetal growth should be monitored.
Lactation: It is not known whether this drug is excreted in human milk. Therefore, breast-feeding is not recommended during administration of Bisoprolol.

**Side Effect**
Fatigue, dizziness, headache, disturbances of the gut such as nausea, vomiting, diarrhoea, constipation or abdominal pain, cold or numb extremities, e.g. hands & feet, muscle weakness or cramps, slower than normal heart beat (bradycardia), worsening of heart failure, sleep disturbance, depression, breathing difficulties due to a narrowing of the airways (bronchospasm) in people with asthma or COPD.

**Preparation**
2.5 mg & 5 mg tablet.

# Bisocor® Plus

**Active Ingredient**
Bisocor Plus 2.5/6.25 tablet: Each film coated tablet contains Bisoprolol Fumarate USP 2.5 mg & Hydrochlorothiazide BP 6.25 mg.
Bisocor Plus 5/6.25 tablet: Each film coated tablet contains Bisoprolol Fumarate USP 5 mg & Hydrochlorothiazide BP 6.25 mg.

**Indication**
Management of hypertension.

**Dosage & Administration**
Bisoprolol is an Effective treatment of hypertension in once-daily doses of 2.5 to 40 mg, while Hydrochlorothiazide is effective in doses of 12.5 to 50 mg. In clinical trials of Bisoprolol/Hydrochlorothiazide combination therapy using Bisoprolol doses of 2.5 to 20 mg & Hydrochlorothiazide doses of 6.25 to 25 mg, the antihypertensive effects increased with increasing doses of either component.

**Contraindication**
It is contraindicated in patients in cardiogenic shock, overt cardiac failure, second or third

degree AV block, marked sinus bradycardia, anuria & hypersensitivity to either component of this product or to other sulfonamide-derived drugs.

**Precaution**
Hyperuricemia or acute gout may be precipitated in certain patients receiving thiazide diuretics. Warning signs or symptoms of fluid & electrolyte imbalance include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia & gastrointestinal disturbances such as nausea & vomiting. Hypokalemia may develop.
If withdrawal of this combination therapy is planned, it should be achieved gradually over a period of about 2 weeks. Patients should be carefully observed.

**Side Effect**
Generally well tolerated. Most side effects have been mild & transient. Side effects which may occur: fatigue, dizziness, headache, bradycardia, arrhythmia, peripheral ischemia, chest pain, palpitations, rhythm disturbances, cold extremities, claudication, orthostatic hypotension, diarrhoea, constipation, nausea, dyspepsia, rhinitis, pharyngitis etc.

**Drug Interaction**
This combination drug may potentiate the action of other antihypertensive agents used concomitantly. This combination drug should not be combined with other beta-blocking agents. Patients receiving catecholamine-depleting drugs, such as reserpine or guanethidine, should be closely monitored because the added beta-adrenergic blocking action of Bisoprolol Fumarate may produce excessive reduction of sympathetic activity. In patients receiving concurrent therapy with clonidine, if therapy is to be discontinued, it is suggested that this combination drug be discontinued for several days before the withdrawal of clonidine. This combination drug should be used with caution when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine [verapamil] & benzothiazepine [diltiazem] classes) or antiarrhythmic agents, such as disopyramide, are used concurrently.
Both digitalis glycosides & beta-blockers slow atrioventricular conduction & decrease heart rate. Concomitant use can increase the risk of bradycardia.

**Use in Pregnancy & Lactation**
Pregnancy Category C. There are no adequate & well-controlled studies in pregnant women. Bisoprolol Fumarate & Hydrochlorothiazide should be used during pregnancy only if the potential benefit justifies the risk to the fetus. *Use in Nursing Mothers:* Bisoprolol Fumarate alone or in combination with Hydrochlorothiazide has not been studied in nursing mothers.

**Preparation**
Bisocor Plus 2.5/6.25 tablet, Bisocor Plus 5/6.25 tablet.



# Bonizol™

**Active Ingredient**
Zoledronic Acid

**Indication**
• Treatment of osteoporosis in postmenopausal women to reduce the incidence of hip, vertebral and non-vertebral fractures.
• Treatment of osteoporosis in men.
• Treatment of Paget's disease of bone.
•Treatment and prevention of glucocorticoidinduced osteoporosis.
• Prevention of clinical fractures in patients after hip fracture.
• Prevention of clinical fractures after a hip fracture.

**Dosage & Administration**
Treatment of postmenopausal osteoporosis:

Recommended dose is a single intravenous infusion of 5 mg Zoledronic Acid administered once a year. Adequate supplemental Calcium and Vitamin-D intake is important in women with osteoporosis if dietary intake is inadequate. Prevention of clinical fractures after a hip fracture: Recommended dose is a single intravenous infusion of 5 mg Zoledronic Acid administered once a year. In patients with a recent low-trauma hip fracture. It is recommended to give the first Zoledronic Acid infusion two or more weeks after hip fracture repairs. It is also recommended to have a loading dose of 50,000 to 1, 25,000 IU of Vitamin D given orally or via intramuscular route prior to the first administration of Zoledronic Acid solution for infusion. Supplemental Calcium and Vitamin-D intake is important in men with osteoporosis if dietary intake is inadequate.

**Treatment of osteoporosis in men**

For the treatment of osteoporosis in men, the recommended dose is a single intravenous infusion of 5 mg Bonizol™ administered once a year. Adequate supplemental Calcium and Vitamin D intake is important in men with osteoporosis if dietary intake is inadequate.

Treatment and prevention of glucocorticoid-induced osteoporosis:

Recommended dose is a single intravenous infusion of 5 mg Zoledronic Acid administered once a year. Adequate supplement of Calcium and Vitamin-D intake is important in patients with osteoporosis if dietary intake is inadequate.

Treatment of paget's disease of bone:

Recommended dose is a single intravenous infusion of 5 mg Zoledronic Acid. Re-treatment with Zoledronic Acid may be considered in patients who have relapsed, based on increases in serum alkaline phosphatase, in patients who failed to achieve normalization of serum alkaline phosphatase, or in patients with symptoms, as dictated by medical practice 12 months after the initial dose. In patients with paget's disease, adequate Vitamin-D intake is recommended in association with Zoledronic Acid administration. In addition, it is strongly advised that adequate supplemental calcium corresponding to at least 500 mg elemental calcium twice daily is ensured in patients with paget's disease for at least 10 days following Zoledronic Acid administration. Treatment should be restricted to three annual doses.

**Special dosage instruction**

Patients with renal impairment:The use of Zoledronic Acid in patients with creatinine clearance 35 mL\min.

Patients with hepatic impairment: No dose adjustment is required for patients with hepatic impairment. Elderly patients: No dose adjustment is required. However because decreased renal function occurs more common in the elderly, special care should be taken to monitor renal function.

**Contraindication & Precaution**

The drug is contraindicated in patients have hypersensitivity to the active substance or to any of the excipients or to any bisphosphonates, hypocalcaemia, renal impairment (creatinine clearance<35mL/min) current of recent uveitis, or a history of bisphosphonate-associated uveitis, pregnancy and lactation.

Patients must be appropriately hydrated prior to administration of Zoledronic Acid. This is especially important in the elderly and for patients receiving diuretic therapy. Adequate hydration can be achieved by the patient drinking two glasses of fluid (such as water) before and after the infusion. Preexisting hypocalcaemia must be treated by adequate intake of Calcium and Vitamin-D before initiating therapy with Zoledronic Acid.

**Drug Interaction**

Specific drug-drug interaction studies have not been conducted with zoledronic acid. Zoledronic acid is eliminated by renal excretion. Caution is indicated when Zoledronic Acid is administered in conjunction with drugs that can significantly impact renal function (e.g. aminoglycosides or diuretics that may cause dehydration).

**Side Effect**

The post-dose side-effects are fever, myalgia, u-like symptoms, arthralgia and headache, the majority of which occur within the first 3 days following Zoledronic Acid administration. The majority of these symptoms was mild to moderate in nature and resolved within 3 days

of the event onset. The incidence of these symptoms occurring within the first 3 days after administration of ZoledronicAcid, can be reduced with the administration of Paracetamol or Ibuprofen shortly following Zoledronic Acid administration. Severe and occasionally incapacitating bone, joint, and/or muscle pain have been infrequently reported in patients taking Zoledronic Acid.

**Breast feeding and Lactation**
Breast feeding and lactating woman should not take this medicine. It is also not recommended for using children & adolescents below 18 years of age.

**Preparation**
5 mg/ 100 ml solution for infusion.

**Side Effect**
Rare, but nausea & dizziness sometimes occur. Excitation, confusion & respiratory depression may occur after overdosage.

**Drug Interaction**
Two fatal interactions have been reported in patients taking therapeutic doses of phenelzine & dextromethorphan.

**Use in Pregnancy & Lactation**
No information is available on secretion of dextromethorphan into breast milk, so nursing mothers should be advised not to take the drug.

**Preparation**
10 mg/5 ml Syrup.



# Brofex®

**Active Ingredient**
Dextromethorphan.

**Indication**
Chronic dry cough / unproductive cough, Acute dry cough which is interfering with normal function or sleep.

**Dosage & Administration**
Adults & Children over 12 years: 15 to 30 mg 3-4 times per day. Children between 6-12 years : 5-15 mg up to 4 times per day. Children between 2 - 6 years : 2.5-5 mg up to 4 times per day.

**Contraindication & Precaution**
Concomitant use of MAO inhibitors is contraindicated with Dextromethorphan.

# Bromolac™

**Active Ingredient**
Bromocriptine.

**Indication**
Dysfunctions associated with hyperprolactinemia including amenorrhea with or without galactorrhea, infertility or hypogonadism. Prolactin-secreting adenomas, Acromegaly, Parkinson's Disease.

**Dosage & Administration**
*General:* It is recommended that Bromocriptine mesilate be taken with food. Patients should be evaluated frequently during dose escalation to determine the lowest dosage that produces a therapeutic response. *Hyperprolactinemic Indications:* The initial dosage is 1.25 mg to 2.5 mg tablet daily. An additional 2.5 mg tablet

may be added to the treatment regimen as tolerated every 2-7 days until an optimal therapeutic response is achieved. *Acromegaly:* The initial recommended dosage is 1.25 to 2.5 mg on retiring (with food) for 3 days. An additional 1.25 to 2.5 mg should be added to the treatment regimen as tolerated every 3-7 days until patient obtains optimal therapeutic benefit. *Parkinson's Disease:* The initial dose of Bromocriptine mesilate is 1.25 mg of a 2.5 mg tablet twice daily with meals.
*Prolactinomas:* 2.5 mg to 3.75 mg daily
*Inhibition of lactation*: 5 mg (1 tablet twice) daily with morning & evening meals for 14 days

**Contraindication & Precaution**
Safety & efficacy of bromocriptine mesilate have not been established in patients with renal or hepatic disease. Care should be exercised when administering Bromocriptine therapy concomitantly with other medications known to lower blood pressure.



**Side Effect**
The incidence of adverse effects are: nausea , headache, dizziness, fatigue, lightheadedness, vomiting, abdominal cramps, nasal congestion, constipation, diarrhea & drowsiness. A slight hypotensive effect may accompany treatment.

**Drug Interaction**
Bromocriptine may interact with dopamine antagonists, butyrophenones, & certain other agents. Compounds in these categories result in a decreased efficacy of Bromocriptine: phenothiazines, haloperidol, metoclopramide, pimozide. Concomitant use of Bromocriptine with other ergot alkaloids is not recommended.

**Use in Pregnancy & Lactation**
Pregnancy Category B.
*Nursing Mothers:* Bromocriptine should not be used during lactation in postpartum women.

**Use in Children**
No data are available for bromocriptine use in pediatric patients under the age of 8 years.

**Preparation**
2.5 mg Tablet.

# Bufocort™ Cozycap

**Active Ingredient**
Budesonide & Formoterol Fumarate Dihydrate.

**Indication**
Bufocort Cozycaps are indicated in the regular treatment of asthma. They are also indicated in the symptomatic treatment of severe chronic obstructive pulmonary disease (COPD), with a history of repeated exacerbations despite regular therapy with long-acting bronchodilators.

**Dosage & Administration**
Asthma : Dosage is individual & should be adjusted according to disease severity. When control has been achieved, the dose should be titrated to the lowest Effective dose. For Bufocort there are two treatment approaches

(A) Maintenance Therapy: Patients should be advised to have their separate rapid acting bronchodilator available for rescue use at all times.

*Adults (18 Years & Older)*
Bufocort - 200 Cozycaps:
1-2 Cozycaps, twice daily, maximum dose is 4 Cozycaps, twice daily.
Bufocort - 400 Cozycaps:
1 Cozycaps, twice daily, maximum dose is 2 Cozycaps, twice daily.
*Adolescents (12-17 Years)*
Bufocort - 200 Cozycaps:
1-2 Cozycaps, twice daily.
Bufocort - 400 Cozycaps:
1 Cozycap, twice daily.
*Children (6-11 Years)*
Bufocort - 200 Cozycaps:
1 Cozycap, twice daily.

(B) Single Maintenance & Reliever Therapy (For Bufocort -200 only) Patients take a daily maintenance dose of Bufocort & in combination take Bufocort as needed in response to symptoms. Patients should be advised to always have Bufocort available for use.

Patients should take 1 additional Cozycap as

needed in response to symptoms. If symptoms persist after a few minutes, an additional Cozycap should be taken. Not more than 6 Cozycaps should be taken on any single occasion.

*COPD (Chronic Obstructive Pulmonary Disease)*

Bufocort 200 Cozycaps:
2 Cozycaps , twice daily.

**Contraindication & Precaution**
Bufocort Cozycaps are contraindicated in patients with a history of hypersensitivity to any of the components of the drug product. It should be administered with caution in patient with severe cardiovascular disorders, including heart rhythm abnormalities, diabetes mellitus, untreated hypokalaemia, or thyrotoxicosis.

**Side Effect**
Hoarseness & candidiasis (thrush) of the mouth & throat, cardiac arrhythmias, muscle cramps & hypersensitivity reactions, including rash, oedema & angio-oedema can occur in some patients. Cutaneous hypersensitivity reactions, tremor, palpitations, & headache have been reported.

**Use in Pregnancy & Lactation**
Administration of Bufocort Cozycaps in pregnant women & lactating mother should only be considered if the expected benefit is greater than any possible risk to the foetus.

**Use in Children**
Safety in pediatric patients below 6 years of age is not established.

**Preparation**
200 & 400 Cozycap.

# Burna®

**Active Ingredient**
Silver Sulfadiazine.

**Indication**
The topical prophylaxis against bacterial colonization & infection in burn wounds.

**Dosage & Administration**
Once to twice daily to a thickness of approximately 1/16 inches or 1.5 mm.

**Contraindication**
It is contraindicated in patients who are hypersensitive to it or any of the other ingredients in the preparation.

**Side Effect**
Several cases of transient leukopenia have been reported in-patients receiving Silver Sulfadiazine therapy. Other infrequently occurring events include skin necrosis, erythema multiform, skin discoloration, burning sensation, rashes & interstitial nephritis.

**Use in Pregnancy & Lactation**
Pregnancy Category : B
Nursing Mother: It is not known whether Silver Sulfadiazine is excreted in human milk.

**Preparation**
1% Cream.

# Caberol™

**Active Ingredient**
Cabergoline.

**Indication**
It is indicated for the treatment of hyperprolactinemic disorders, either idiopathic or due to pituitary adenomas. It is used to stop breast milk production (lactation) soon after childbirth, stillbirth, abortion or miscarriage. It can also be used to treat other conditions caused by hormonal disturbance which can result in high levels of prolactin being produced. This includes high levels of prolactin caused by tumours of the pituitary gland in both men and women.

**Dosage & Administration**
The recommended dose of Cabergoline tablet for initiation of therapy is 0.25 mg (1/2 of Caberol 0.5 mg tablet) twice a week. Dosage may be increased by 0.25 mg twice weekly up to a dosage of 1 mg twice a week. (Dosage increases should not occur more rapidly than every 4 weeks). After a normal serum prolactin level has been maintained for 6 months, Cabergoline may be discontinued.
To prevent milk production (lactation): 1 mg (two 0.5 mg tablets) on the first day after delivery. - To stop lactation once have started to breastfeed: 0.25 mg (1/2 of Caberol 0.5 mg tablet) every 12 hours for two days.
In other conditions: initially one 0.5 mg tablet (to be taken in two doses) up to maximum dose of 4.5 mg or until have respond fully to treatment.

**Contraindication**
Cabergoline tablet is contraindicated in patients with-
• Uncontrolled hypertension or known hypersensitivity
• History of cardiac valvular disorders demonstration of valve leaflet thickening
• High blood pressure in pregnancy associated with swelling and protein in urine
• History of pulmonary, pericardial, or retroperitoneal fibrotic disorders & serious mental disease.

**Precaution**
Initial doses higher than 1.0 mg may produce orthostatic hypotension. Care should be exercised when administering Cabergoline with other medications known to lower blood pressure, hypersensitivity, severe liver disease & mental illness.

**Side Effect**
Pathological gambling, increased libido, and hypersexuality have been reported in patients treated with dopamine agonists including cabergoline. This has been generally reversible upon reduction of the dose or treatment discontinuation.

**Use in Pregnancy & Lactation**
Pregnancy category B. It is not known whether this drug is excreted in human milk.
Pediatric Use: Safety and effectiveness of Cabergoline in pediatric patients have not been established.
Geriatric Use: In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
Use in patients with hepatic impairment: Since cabergoline is extensively metabolized by the liver, caution should be used, and careful monitoring exercised, when administering Cabergoline to patients with hepatic impairment.

**Drug Interaction**
Cabergoline should not be administered concurrently with D2-antagonists, such as Phenothiazines, Butyrophenones, Thioxanthenes, or Metoclopramide, Chlorpromazine, Domperidone, and medicines to lower blood pressure.

**Preparation**
Cabergoline 0.5 mg tablet

# Calbo® 500

**Active Ingredient**
Calcium Carbonate.

**Indication**
The treatment or prevention of calcium depletion.

**Dosage & Administration**
Daily 500-1500 mg calcium is recommended.

**Side Effect**
Constipation, Hypercalcaemia.

**Contraindication & Precaution**
Hypercalcaemia & hyperparathyroidism, Hypercalciuria & nephrolithiasis, Zollinger-Ellison syndrome, Concomitant digoxin therapy (requires careful monitoring of serum calcium level).

**Drug Interaction**
Digoxin & other cardiac glycosides, tetracycline, Vitamin D primary phosphate binder.

**Use in Pregnancy & Lactation**
Calcium containing drugs have been widely used in pregnancy by way of oral calcium supplementation or antacid therapy. Calcium Carbonate can be used in lactating women too.

**Use in Children**
Calcium Carbonate has been extensively studied in children & infants with chronic renal failure & is both safe & effective.

**Use in Elderly**
Monitoring of serum calcium & phosphate is of course indicated for elderly patients.

**Preparation**
Calcium 500 mg Tablet.

# Calbo-C®

**Active Ingredient**
Calcium Lactate Gluconate, Calcium Carbonate & Ascorbic Acid (Vitamin-C).

**Indication**
Indicated in increased demand for Calcium & Vitamin-C, e.g. pregnancy, lactation, periods of rapid growth (childhood, adolescence), in old age; During infectious disease & convalescence; Treatment of calcium & vitamin C deficiency; Osteoporosis; Premenstrual syndrome; Postmenopausal problems; Adjuvant in colds & influenza.

**Dosage & Administration**
Adults & children of school age : 1 effervescent tablet daily, Children 3 to 7 years : 1/2 effervescent tablet daily, Infants : As prescribed by the physician. Dissolve one tablet in half glass (100 ml) of water.

**Contraindication & Precaution**
Hypercalcemia, Severe hypercalciuria, Severe renal failure, Patients with hyperoxalauria, Glucose - 6 - phosphate dehydrogenase deficiency, Iron overload, Larger doses may lead to gastrointestinal tract upset. For patients with mild hypercalciuria (exceeding 300 mg = 7.5 mmol/24 hours), with mild or moderate impairment of renal function or with a history of urinary concrements, monitoring of calcium excretion in the urine is required. If necessary, the dosage should be reduced or therapy should be discontinued. High doses of Vitamin-D & derivatives should be avoided during treatment with this preparation unless especially indicated.

**Side Effect**
In rare case bloating & diarrhea can occur. In predisposed patients prolonged treatment with high doses may promote the formation of calculi in the urinary tract.

**Drug Interaction**
Potentially hazardous interactions: Digoxin, Tetracycline, Frusemide, Pentagastrin, Aminophylline, Erythromycin, Nitrofurantoin,

Conjugated estrogens, Chloramphenicol. Potentially useful interactions: Vitamin-D, Oxytocin & Prostaglandins. Vitamin-C enhances iron absorption.

**Use in Pregnancy & Lactation**
Calcium containing drugs have been widely used in pregnancy by way of oral calcium supplementation or antacid therapy. Calcium Carbonate can be safely used in lactating women. Vitamin-C may be taken safely during pregnancy & lactation.

**Preparation**
Effervescent Tablet.

**Drug Interaction**
It has possible interaction with digoxin, antacids containing calcium, aluminum or magnesium, other calcium supplements, calcitriol or other Vitamin-D supplements; tetracycline, Doxycycline, aminocycline or oxytetracycline etc. So before taking any of these drugs consultations of the physicians are needed.

**Side Effect**
Allergic reactions, irregular heartbeats, nausea, vomiting, decreased appetite dry mouth & drowsiness.

**Use in Pregnancy & Lactation**
It should be used as directed by the physician during pregnancy & lactation.

**Preparation**
(Calcium 500 mg + Vitamin-D 200 I.U.)/Tablet.

C

# Calbo-D®

**Active Ingredient**
Calcium + Vitamin-D.

**Indication**
Calcium & Vitamin-D is used for the treatment of osteoporosis, osteomalacia, rickets, tetany, & parathyroid disease. It is also used as routine supplement & phosphate binder in chronic renal failure.

**Dosage & Administration**
Adults, elderly & children: 1 tablet in the morning & 1 tablet at night.

**Contraindication & Precaution**
- Hypercalcemia & hyperparathyroidism
- Hypercalciuria & nephrolithiasis
- Hypersensitivity to the component of this preparation
- Severe renal insufficiency.

# Calbo-D® Vita

**Active Ingredient**
Calcium + Vitamin-D.

**Indication**
Prevention & treatment of calcium & vitamin D deficiency, Calcium & vitamin D supplement as an adjunct to specific therapy in the prevention & treatment of Osteoporosis for patients who are at risk of calcium & vitamin D deficiency.

**Dosage & Administration**
Adult & adolescents: 1-2 tablets daily
Children: 1 tablet daily

**Contraindication & Precaution**
- Hypercalcemia & hyperparathyroidism

•Hypercalciuria & nephrolithiasis
•Hypersensitivity to the component of this preparation
•Severe renal insufficiencies

**Drug Interaction**
It has possible interaction with Digoxin, Antacids containing Calcium, Aluminum or Magnesium, other Calcium supplements, Calcitriol, Tetracycline, Doxycycline, Aminocycline or Oxytetracycline etc. So while taking Calbo-D® Vita with any of these drugs consultations of the physicians is needed.

**Side Effect**
Orally administered Calcium Carbonate may be irritating to the GI tract. It may also cause constipation. Hypercalcemia is rarely produced by administration of Calcium alone, but may occur when large doses are given to patients with chronic renal failure. Also there may be allergic reactions, irregular heartbeats, nausea, vomiting, decreased appetite dry mouth & drowsiness, skin rash.

**Use in Pregnancy & Lactation**
Calbo-D® Vita effervescent tablets can be used during pregnancy, in case of a calcium & vitamin D deficiency. However, for supplementation starting during the third trimester of pregnancy, the daily intake should not exceed 1500 mg calcium & 1000 IU vitamin D. Calbo-D® Vita effervescent tablets can be used during breast-feeding.

**Preparation**
(Calcium 600 mg + Vitamin-D 400 I.U.)/Tablet.



# Calbo® Forte

**Active Ingredient**
Each effervescent tablet contains Calcium Lactate Gluconate, Calcium Carbonate, Ascorbic Acid (Vitamin-C) & Vitamin-D.

**Indication**
Indicated as an adjunct to specific therapy for osteoporosis; Increased demand for Calcium, Vitamin-C & Vitamin-D, e.g. pregnancy, lactation, periods of rapid growth (childhood, adolescence), in old age; During infectious disease & convalescence; Treatment of calcium, vitamin-C & vitamin-D deficiency; Osteoporosis; Premenstrual syndrome; Postmenopausal problems; Adjuvant in colds & influenza.

**Dosage & Administration**
*Adults & children of school age:*
1 effervescent tablet daily
*Children 3 to 7 years:*
½ effervescent tablet daily
Infants: As prescribed by the physician
Dissolve one tablet in half glass (100 ml) of water.

**Contraindication & Precaution**
Hypercalcemia, severe hypercalciuria, severe renal failure, patients with hyperoxalauria, glucose - 6 - phosphate dehydrogenase deficiency, iron overload,
Larger doses may lead to gastrointestinal tract upset, bone metastasis or other malignant bone disease, sarcoidosis, primary hyperparathyroidism, vitamin-D overdosage.
For patients with mild hypercalciuria (exceeding 300 mg = 7.5 mmol/24 hours), with mild or moderate impairment of renal function or with a history of urinary concrements, monitoring of calcium excretion in the urine is required. If necessary, the dosage should be reduced or therapy should be discontinued. Since citrate salts have been reported to increase aluminium absorption, this preparation which contains citric acid as a constituent, should be used with caution in patients with severely impaired renal function, especially those receiving aluminium-containing preparations.

**Side Effect**
In rare case, mild gastrointestinal disturbances (bloating, diarrhea) can occur. In predisposed patients prolonged treatment with high doses may promote the formation of calculi in the urinary tract. Following administration of vitamin-D supplements occasional skin rash has been reported. Hypercalciuria & in rare cases hypocalcaemia have been seen in long term treatment with vitamin-D at high doses.

**Use in Pregnancy & Lactation**
During pregnancy & lactation treatment with Calbo Forte should always be under the direction of a physician. During pregnancy & lactation, requirements for calcium & vitamin-D are increased but in deciding on the required supplementation allowances should be made for availability of these agents from other sources.



**Preparation**
Each effervescent tablet contains Calcium Lactate Gluconate 1000 mg, Calcium Carbonate BP 327 mg, Ascorbic Acid (Vitamin-C) BP 500 mg & Vitamin-D BP 400 I.U.

# Calbo® Jr

**Active Ingredient**
Calcium Carbonate.

**Indication**
Raised calcium requirement for children & adolescents at times of rapid growth, inadequate intake of calcium in the diet due to malnutrition, prevention & treatment of osteoporosis, disorders of osteogenesis & tooth formation (in addition to specific treatment), latent tetany & during pregnancy & lactation.

**Dosage & Administration**
Children : 1 tablet daily, Adolescents: 1-2 tablets daily,
Adults : 2 tablets daily or as directed by the physician

**Contraindication & Precaution**
Hypercalcemia & hyperpara-thyroidism, Hypercalciuria & nephrolithiasis, Hypersensitivity to any component of this product, Severe renal insufficiency, Concomitant digoxin therapy (requires careful monitoring of serum calcium level). Calcium salts should be used cautiously in patients with sarcoidosis, renal or cardiac disease, & in patients receiving cardiac glycosides. Patients with a history of stone formation should also be recommended to increase their fluid intake. High doses of Vitamin D should be avoided during calcium therapy unless specifically indicated.

**Side Effect**
Constipation, Hypercalcemia.

**Drug Interaction**
Tetracycline, fluoride preparations, Vitamin D & Verapamil. The intestinal uptake of calcium maybe reduced by concomitant ingestion of certain foods (e.g. spinach, bran, & other cereal products, milk & milk products).

**Use in Pregnancy & Lactation**
Calcium containing drugs have been widely used in pregnancy. Calcium Carbonate can be safely used in lactating women.

**Preparation**
Calcium 250 mg Chewable Tablet.

# Calboral-D™

**Active Ingredient**
Calcium Carbonate USP (from coral source) + Vitamin-D USP.

**Indication**
Calcium & Vitamin-D is used for the treatment of: Osteoporosis, Osteomalacia, Rickets, Tetany , Parathyroid disease

**Dosage & Administration**
One tablet in the morning & one tablet at night.

**Contraindication**
Hypercalcemia & hyperparathyroidism, Hypercalciuria & nephrolithiasis, Hypersensitivity to the component of this preparation, Severe renal insufficiencies, Concomitant digoxin therapy (requires careful monitoring of serum Calcium level).

**Side Effect**
Orally administered Calcium Carbonate may be irritating to the GI tract. It may also cause constipation. Hypercalcemia is rarely produced by administration of Calcium alone, but may occur when large doses are given to patients with chronic renal failure. Also there may be allergic reactions, irregular heartbeats, nausea, vomiting, decreased appetite dry mouth & drowsiness. Following administration of vitamin-D Supplements occasion skin rash has been reported.

**Precaution & Warning**
When hypercalcemia occurs, discontinuation of the drug is usually sufficient to return serum Calcium concentrations to normal. Calcium salts should be used cautiously in patients with sarcoidosis, renal or Cardiac disease, & in patients receiving cardiac glycosides. Patients with a history of stone formation should also be recommended to increase their fluid intake.

**Drug Interaction**
It has possible interaction with digoxin, antacids containing Calcium, Aluminum or Magnesium, other Calcium supplements, Calcitriol, Tetracycline, Doxycycline, Aminocycline or Oxytetracycline etc. So while taking Calboral™-D with any of these drugs consultations of the physicians is needed.

**Use in Pregnancy & Lactation**
It should be used as directed by the physician during Pregnancy & Lactation.

**Preparation**
500 mg(from coral source ) & 200 IU Tablet.

# Calboral™-DX

**Active Ingredient**
Calcium Carbonate USP 1500 mg (from Coral source) equivalent to 600 mg of elemental Calcium and Vitamin D USP 400 IU.

**Indication**
Calcium and Vitamin D is used for the treatment of:
- Osteoporosis
- Osteomalacia
- Rickets
- Tetany
- Parathyroid disease etc

**Dosage & Administration**
One tablet in the morning and one tablet at night or as directed by the Physician.

**Contraindication**
- Hypercalcemia and hyperparathyroidism
- Hypercalciuria and nephrolithiasis
- Hypersensitivity to the component of this preparation
- Severe renal insufficiencies
- Concomitant digoxin therapy (requires careful monitoring of serum Calcium level)

**Side Effect**
Orally administered Calcium Carbonate may

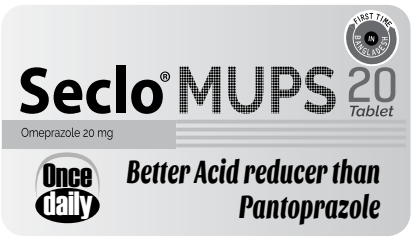
be irritating to the GI tract. It may also cause constipa-tion. Hypercalcemia is rarely produced by administration of Calcium alone, but may occur when large doses are given to patients with chronic renal failure. Also there may be allergic reactions, irregular heartbeats, nausea, vomiting, decreased appetite dry mouth and drowsiness. Following administration of Vitamin D Supplements occasion skin rash has been reported.

**Precaution And Warning**
When hypercalcemia occurs, discontinuation of the drug is usually sufficient to return serum Calcium concentrations to normal. Patients with a history of stone formation should also be recommended to increase their fluid intake.

**Drug Interaction**
It has possible interaction with digoxin, antacids containing Calcium, Aluminum or Magnesium, other Calcium supplements, Calcitriol, Tetracycline, Doxycycline, Aminocycline or Oxytetracycline
etc. So while taking Calboral-DX™ with any of these drugs consultations of the physicians is needed.

**Overdose**
Symptoms of over dose may include nausea and vomiting, severe drowsiness, dry mouth, loss of appetite, metallic taste, stomach cramps, unconsciousness, diarrhea, weakness, headache, constipa-tion, dizziness or irritability.

**Preparation**
600 mg of elemental Calcium and Vitamin D USP 400 IU.




# Calboplex®

**Active Ingredient**
Calcium, Vitamin-D & Multiminerals.

**Indication**
The well balanced formula helps to maintain strong bones & teeth as well as the health of the heart, muscles & nerves. It is also indicated for bone development & constant regeneration of bone, for the prevention & treatment of osteoporosis.

**Dosage & Administration**
1 tablet twice daily, preferably 1 tablet in the morning & 1 tablet in the evening or as directed by the physician. It is best taken with or just after main meals with a full glass of water.

**Contraindication & Precaution**
Hypercalcemia & hyperparathyroidism, Hypercalciuria & nephrolithiasis, Hypersensitivity to the component of this preparation, Severe renal insufficiency.

**Drug Interaction**
It has possible interaction with digoxin, antacids containing calcium, aluminum or magnesium, other calcium supplements, calcitriol or other Vitamin-D supplements; tetracycline, Doxycycline, aminocycline or oxytetracycline etc.

**Side Effect**
Orally administered Calcium Carbonate may be irritating to the GI tract. It may also cause constipation. Hypercalcemia is rarely produced by administration of calcium alone, but may occur when large doses are given to patients with chronic renal failure.

**Use in Pregnancy & Lactation**
It should be used as directed by the physician during pregnancy & lactation.

**Preparation**
Calcium 600 mg, Vitamin-D 200 IU & Multimineral Tablet.

# Calcitrol®

**Active Ingredient**
Calcitriol.

**Indication**

- For the treatment of established osteoporosis
- Increases spine density & total body calcium
- Significantly increases BMD
- Reduces the rate of new vertebral fracture in women with post-menopausal osteoporosis
- Restores bone metabolism in patients with predialysis chronic renal failure
- For the treatment of hypoparathyroidism & rickets

**Dosage & Administration**
*Postmenopausal osteoporosis*
The recommended dosage for calcitrol is 0.25 mcg twice daily. Serum calcium & creatinine levels should be determined at 4 weeks, 3 & 6 months & at 6 monthly intervals thereafter.
*Renal osteodystrophy (dialysis patients)*
The initial daily dose is 0.25 mcg in patients with normal or only slightly reduced serum calcium levels, doses of 0.25 mcg every other day are sufficient.
*Hypoparathyroidism & rickets*
The recommended initial dose of Calcitrol is 0.25 mcg per day given in the morning. In patients with renal osteodystrophy or hypoparathyroidism & rickets if within 2-4 weeks no satisfactory response is not observed by usual dose then dose may be increased at two to four week intervals.

**Contraindication & Precaution**
Calcitrol is contraindicated in patients with known hypersensitivity to any of its ingredients. Calcitrol is also contraindicated in all diseases associated with hypercalcemia. During Calcitrol therapy as soon as the serum calcium level rise to 1 mg/100 ml above normal or serum creatinine rises above 120 micromole/L the dosage of Calcitrol should be substantially reduced or treatment stopped altogether until normocalcemia ensues.

**Side Effect**
The incidence of adverse effects reported from clinical use of Calcitriol over a period of 15 years in all indication is very low. Occasional acute symptoms include anorexia, headache, vomiting & constipation. Chronic effects may include dystrophy, fever with thirst etc.

**Drug Interaction**
Uncontrolled intake of additional calcium containing preparations should be avoided. Concomitant treatment with a thazide diuretc increases the risk of hypercalcemia. Calcitriol dosage must be determined with care in patients undergoing treatment with digitalis, as hypercalcemia in such patients may precipitate cardiac arrhythmias. Magnesium containing drugs (eg. antacids) may cause hypermagnesemia. The dosage of phosphate binding agents must be adjusted in accordance with the serum phosphate concentration.

**Use in Pregnancy & Lactation**
There is no evidence to suggest that vitamin D is teratogenic in humans even at very high doses Calcitrol should be used during pregnancy only if the benefits outweigh the potential risk to the fetus. Mothers may breast feed while taking Calcitrol but serum calcium levels of the mother & infant should be monitored.

**Preparation**
0.25 mcg Licap.

# Caloprid™

**Active Ingredient**
Prucalopride Succinate INN equivalent to Prucalopride 1 mg.

**Indication**
CalopridTM is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

**Dosage & Administration**
Chronic Constipation Adults 2 mg once daily with or without food, at any time of the day. Due to the specific mode of action of prucalopride (stimulation of propulsive motility), exceeding the daily dose of 2 mg is not expected to increase efficacy. Older people Start with 1 mg once daily; if needed the dose can be increased to 2 mg once daily. Children Prucalopride should not be used in children and adolescents younger than 18 years Renal Impairment The dose for patients with severe renal impairment (GFR < 30 ml/min/1.73 m2) is 1 mg once daily. No dose adjustment is required for patients with mild to moderate renal impairment. Hepatic Impairment Patients with severe hepatic impairment (Child-Pugh class C) start with 1 mg once daily which may be increased to 2 mg if required to improve efficacy and if the 1 mg dose is well tolerated. No dose adjustment is required for patients with mild to moderate hepatic impairment.

**Contraindications**
Prucalopride is contraindicated in those people who are hypersensitive to the active substance or to any of the excipients and people with renal impairment requiring dialysis.

**Warnings**
Renal excretion is the main route of elimination of prucalopride. A dose of 1 mg is recommended in subjects with severe renal impairment. Caution should be exercised when prescribing Prucalopride (CalopridTM) to patients with severe hepatic impairment (Child-Pugh class C) due to limited data in patients with severe hepatic impairment. In case of severe diarrhoea, the efficacy of oral contraceptives may be reduced and the use of an additional contraceptive method is recommended to prevent possible failure of oral contraception. The tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product

**Adverse Reactions**
The most frequently reported adverse reactions associated with CalopridTM therapy are headache (17.8%) and gastrointestinal symptoms (abdominal pain), nausea and diarrhoea. The adverse reactions occur predominantly at the start of therapy and usually disappear within a few days with continued treatment. Other adverse reactions have been reported occasionally. The majority of adverse events were mild to moderate in intensity

**Drug Interactions**
In-vitro data indicate that, Prucalopride has a low interaction potential and therapeutic concentrations of Prucalopride are not expected to affect the CYP-mediated metabolism of co-medicated medicinal products. Although Prucalopride may be a weak substrate for P-glycoprotein (P-gp), it is not an inhibitor of P-gp at clinically relevant concentrations. Ketoconazole (200 mg b.i.d.), a potent inhibitor of CYP3A4 and of P-gp, increased the systemic exposure to prucalopride by approximately 40%. This effect is too small to be clinically relevant. Interactions of similar magnitude may be expected with other potent inhibitors of P-gp such as verapamil, cyclosporine A and quinidine. Studies in healthy subjects showed that, there were no clinically relevant effects of Prucalopride on the pharmacokinetics of warfarin, digoxin, alcohol, paroxetine or oral contraceptives.

**Use in Pregnancy & Lactation**
Prucalopride is not recommended during pregnancy and women of childbearing potential should use effective contraception during treatment. Animal studies do not

indicate direct or indirect harmful effects with respect to pregnancy, embryonal/ foetal development, parturition or postnatal development.
In the absence of human data, it is not recommended to use Prucalopride during breast feeding

**Overdosage**
An overdose may result in symptoms resulting from an exaggeration of prucalopride's known pharmacodynamic effects and include headache, nausea and diarrhoea. Specific treatment is not available for Prucalopride overdose. Should an overdose occur, the patient should be treated symptomatically and supportive measures instituted, as required. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

**Preparation**
1 mg and 2 mg Tablet

# Camlodin®

**Active Ingredient**
Amlodipine.

**Indication**
Hypertension, stable angina, vasospastic angina.

**Dosage & Administration**
5-10 mg once daily.

**Contraindication & Precaution**
Known hypersensitivity.

**Side Effect**
Headache, oedema, fatigue, nausea, flushing, dizziness, gum hyperplasia, erythema multiforme.

**Drug Interaction**
Digoxin, Warfarin, Cimetidine.

**Use in Pregnancy & Lactation**
Not recommended.

**Preparation**
5 mg Tablet.

# Camlodin® Plus

**Active Ingredient**
Amlodipine + Atenolol.

**Indication**
Hypertension not controlled by monotherapy, patients with angina pectoris & hypertension as co-existing diseases, Post MI, Refractory angina pectoris where nitrate therapy has failed.

**Dosage & Administration**
Initiated with a single dose of Amlodipine 5 mg + Atenolol 50 mg. Depending upon the therapeutic response, titration of the dosage is recommended. In elderly patients, it is advisable to initiate the therapy with Amlodipine 5 mg + Atenolol 25 mg tablet.

**Contraindication & Precaution**
Hypersensitivity to any of the components. Bronchospasm: The combination should be used with caution in patients with airway obstruction. Renal Impairment: Caution may be necessary if the creatinine clearance is less than 30ml/min. Hepatic impairment: Caution may be necessary in the use of the combination in patients with severe liver damage. Drug withdrawal: Any discontinuation should be gradual & under observation.

**Drug Interaction**
Disopyramide, Ampicillin, Oral antidiabetics & insulin.

**Side Effect**
Well tolerated. Overall side effects include fatigue, headache, edema, nausea, drowsiness, anxiety & depression.

**Use in Pregnancy & Lactation**
Pregnancy: The combination should be used during pregnancy only if the expected benefit outweighs the potential foetal risk. Lactation: Nursing mothers should not use the combination. If its use is considered necessary, breast feeding should be stopped.

**Preparation**
(Amlodipine 5 mg+Atenolol 50 mg) Tablet, (Amlodipine 5 mg + Atenolol 25 mg) Tablet.



# Camlosart™

**Active Ingredient**
Amlodipine + Olmesartan.

**Indication**
Hypertension, alone or with other antihypertensive agents. It can be used as initial therapy.

**Dosage & Administration**
One tablet (5/20 mg) once daily. Maximum dose two tablets (10/40 mg) once daily. May be taken with or without food.

**Contraindication & Precaution**
Hypersensitivity to any of the components of this combination product. When pregnancy is detected, this combination drug should be discontinued as soon as possible. Symptomatic hypotension may occur after initiation of therapy. Exercise caution: when administering this combination, particularly in patients with severe aortic stenosis. Patients may develop increased frequency, duration or severity of angina or acute MI on starting calcium channel blocker therapy or at the time of dosage increase. Patients with Congestive Heart Failure: Calcium channel blocker should be used with caution in patients with Impaired Renal Function / Hepatic Impairment/congestive heart failure.

**Side Effect**
Edema, dizziness, flushing, palpitation, vomiting, diarrhoea, rhabdomyolysis, alopecia, pruritus, urticaria etc.

**Drug Interaction**
No significant drug interactions have been observed when used individually or in combination.

**Use in Pregnancy & Lactation**
Not recommended.

**Use in Children**
Safety & effectiveness have not been established.

**Preparation**
(Amlodipine 5 mg + Olmesartan 20 mg) Tablet.
(Amlodipine 5 mg + Olmesartan 40 mg) Tablet.

# Canaglif™

**Active Ingredient**
Canagliflozin

**Indication**
Canaglif is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.

**Dosage and administration**
The recommended starting dose of CanaglifTM is 100 mg once daily, taken before the first meal

of the day. Dose can be increased to 300 mg once daily in patients tolerating CanaglifTM 100 mg once daily who have an eGFR of 60 mL/min/1.73 m2 or greater and require additional glycemic control.
If the eGFR of Patients is 45 to 60 mL/min/1.73 m2, the dose of CanaglifTM should be 100 mg once daily.

**Side effects**
Side effects include: Dehydration, Vaginal yeast infection, Yeast infection of the penis (balanitis or balanoposthitis)

**Adverse reactions**
- Hypotension
- Impairment in Renal Function
- Hyperkalemia
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues
- Genital Mycotic Infections
- Hypersensitivity Reactions
- Increases in Low-Density Lipoprotein (LDL-C)

**Precaution**
Hypotension: Before initiating Canagliflozin, assess volume status and correct hypovolemia in patients with renal impairment, the elderly, in patients with low systolic blood pressure, or if on diuretics, ACEi, or ARB. Monitor for signs and symptoms during therapy.
Impairment in Renal Function: Monitor renal function during therapy. More frequent monitoring is recommended in patients with eGFR below 60 mL/min/1.73 m2. Do not initiate Canagliflozin if eGFR is below 45 mL/min/1.73 m2.
Hyperkalemia: Monitor potassium levels in patients with impaired renal function and in patients predisposed to hyperkalemia.
Hypoglycemia: Consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia when used in combination with Canagliflozin.

**Contraindication**
History of a serious hypersensitivity reaction to Canagliflozin, Severe renal impairment (eGFR less than 30 mL/min/1.73 m2), end stage renal disease or patients on dialysis.

**Use in pregnancy and lactation**
Pregnancy: Pregnancy Category C.
Nursing Mothers: It is not known if Canagliflozin passes into breast milk. Discontinue drug or nursing

**Preparation**
100 mg Tablet

# Candex®

**Active Ingredient**
Nystatin.

**Indication**
Oropharyngeal & Esophageal Candidiasis.

**Dosage & Administration**
Children: In intestinal & oral candidiasis (thrush) 1,00,000 units (1 ml) should be dropped into the mouth four times daily. The longer the suspension is kept in contact with the affected area in the mouth, before swallowing, the greater will be its effect. For prophylaxis in the newborn the suggested dose is 1,00,000 units (1 ml) once daily or as prescribed by the physician. Adult: For the treatment of intestinal or esophageal candidiasis 5,00,000 units (5 ml) by mouth 3 or 4 times daily. The dose may be doubled, if required. For prophylaxis of intestinal candidiasis in adults 10,00,000 units (10 ml) daily. For prophylaxis to suppress the over growth of Candida albicans in patients receiving broad spectrum antibiotic therapy 10,00,000 units (10 ml) daily. For the treatment of dental sores & oral infection 1,00,000 units (1 ml) suspension should be dropped into the mouth four times daily. Older people with intestinal candidiasis who are unable to swallow tablets should be given 5,00,000 units (5 ml) suspension four times daily.

**Contraindication & Precaution**
Hypersensitivity.

**Side Effect**
Oral irritation or sensitization, nausea, diarrhoea, gastrointestinal distress, nausea & vomiting. Rash, including urticaria has been reported rarely.

**Drug Interaction**
Not known.

**Use in Pregnancy & Lactation**
Nystatin should be prescribed during pregnancy only if the potential benefits to be derived outweigh the possible risks involved; caution should be exercised when Nystatin is prescribed for nursing woman.

**Preparation**
1 lac unit/1 ml Suspension.



# Carbizol®

**Active Ingredient**
Carbimazole.

**Indication**
Management of hyperthyroidism, thyrotoxicosis (including thyroid storm), & also for the preparation of patients for thyroidectomy. It can also be used in combination with radio-active ablative therapy.

**Dosage & Administration**
Adults: The initial dose: 20 - 60 mg, in 2-3 divided doses until the patient is euthyroid. Daily dosage should be divided.

*Maintenance regimen:* Dose is gradually reduced to maintain a euthyroid state. Final dosage is usually in the range of 5 - 15 mg/day which may be taken as a single daily dose.

Neonates & Children below 12 years:
The usual initial dose is 250 mcg /Kg/day in divided doses.

*Duration of treatment:* 18 to 24 months

**Contraindication & Precaution**
Patients with known hypersensitivity to Carbimazole or other thiourea antithyroid agents.

**Pregnancy & Lactation**
Recommended but the smallest effective dose should be used least overdosage adversely affects the foetus.

**Use in Children**
Recommended

**Drug Interaction**
Iodine or iodine excess may decrease the response to Carbimazole.

**Side Effect**
Rarely seen; rash, pruritis, skin pigmentation, paraesthesias, urticaria, headache, arthralgia, & gastro-intestinal disturbances.

**Preparation**
5 mg Tablet.

# Carva®

**Active Ingredient**
Aspirin.

**Indication**
Antithrombotic action, mediated through inhibition of platelet activation, secondary prophylaxis following myocardial infarction & unstable angina or cerebral transient ischemic attacks.

**Dosage & Administration**
150 mg at diagnosis & 75 mg daily thereafter.

**Contraindication**
Hypersensitivity to aspirin, hypoprothrombinaemia, haemophilia & peptic ulceration, asthma.

**Side Effect**
Hypersensitivity, asthma, urate kidney stones, chronic gastro-intestinal blood loss, tinnitus, nausea & vomiting.

**Drug Interaction**
Oral anticoagulants, oral hypoglycemic, phenytoin, probenecid, sulphonamides.

**Use in Pregnancy & Lactation**
Aspirin should be avoided during the last 3 months of pregnancy. It should not be used by patients who are breast feeding.

**Preparation**
75 mg Tablet.



# Cavir™

**Active Ingredient**
Entecavir 0.5 mg & 1 mg Tablet.

**Indication**
Chronic hepatitis B virus infection in adults with evidence of active viral replication & either evidence of persistent elevations in serum Aminotransferase (ALT or AST) or histologically active disease.

**Dosage & Administration**
Cavir should be administered on an empty stomach (at least 2 hours after a meal or 2 hours before the next meal).
Nucleoside-treatment-naive (16 years): 0.5 mg once daily.
Lamivudine-refractory or known Lamivudine or Telbivudine resistance mutations (16 years): 1 mg once daily.
Dosage in Pediatric Patients:

Nucleoside-inhibitor-treatment-naïve and lamivudine-experienced pediatric patients at least 2 years of age and weighing at least 10 kg: dosing is based on weight.
Decompensated Liver Disease: Recommended dose is 1 mg once daily.
Renal Impairment: Dosage adjustment is recommended for patients with creatinine clearance less than 50 ml/min, including patients on hemodialysis or Continuous Ambulatory Peritoneal Dialysis (CAPD), as shown below-

*Dosage of Entecavir in patients with renal impairment:*

| **Dosage of Entecavir in patients with renal impairment** | | | | |
|---|---|---|---|---|
| Creatinine clearance ( ml/min) | ≥50 | 30 to <50 | 10 to <30 | <10, Hemodialysis or CAPD |
| Dose | 0.5 mg every 24 hrs | 0.5 mg every 48 hrs | 0.5 mg every 72 hrs | 0.5 mg every 7 days |



**Contraindication & Precaution**

Entecavir is contraindicated in patients with known hypersensitivity to Entecavir or any component of the product. Lactic acidosis: Lactic acidosis & severe hepatomegaly with steatosis, including fatal cases have been reported with the use of nucleoside analogues alone or in combination with antiretrovirals. Exacerbations of hepatitis B after discontinuation of treatment: severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy, including Entecavir.

**Side Effect**

The most common side effects are headache, fatigue, dizziness & nausea.

**Drug Interaction**

Coadministration of Entecavir with drugs that reduce renal function or compete for active tubular secretion may increase serum concentration of either Entecavir or the coadministered drug. Coadministration of Entecavir with Lamivudine, Adefovir Dipivoxil, or Tenofovir Disoproxil Fumatare did not result significant drug interactions.

**Use in Pregnancy & Lactation**

Pregnancy: USFDA pregnancy category C. There are no data on the Effect of Entecavir on transmission of HBV from mother to infant. Therefore, appropriate care should be taken.
Lactation: It is not known whether entecavir is excreted in human milk. Mothers should be instructed not to breast feed if they are taking Entecavir

**Use in Children**

Safety & Effectiveness of Entecavir in pediatric patients below the age of 02 years have not been established.

**Preparation**

0.5 mg & 1 mg Tablet.

# Ceevit®

**Active Ingredient**
Ascorbic acid & Sodium Ascorbate.

**Indication**
Scurvy, pregnancy, lactation, infection, trauma, burns, cold exposure, following surgery, fever, stress, peptic ulcer, cancer, methaemoglobinaemia haematuria, dental caries, pyorrhea, acne, infertility, atherosclerosis, fractures, leg ulcers, hay fever, vascular thrombosis prevention, levodopa toxicity, succinyl-choline toxicity, arsenic toxicity etc.

**Dosage & Administration**
1-2 tablets daily.

**Contraindication & Precaution**
There is no serious contraindication to the administration of Vitamin C.

**Side Effect**
Diarrhoea, hyperoxaluria may occur.

**Drug Interaction**
Ascorbic acid increases the apparent half-life of paracetamol & enhances iron absorption from the gastro intestinal tract.

**Use in Pregnancy & Lactation**
The drug is safe in normal doses in pregnant women, but a daily intake of 5 gm or more is reported to have caused abortion. The drug may be taken safely during lactation.

**Preparation**
250 mg Tablet.

# Ceevit® DS

**Active Ingredient**
Ascorbic acid & Sodium Ascorbate.

**Indication**
Ceevit is indicated for prevention and treatment of scurvy. It may be indicated in pregnancy, lactation, infection, trauma, burns, cold exposure, following surgery, fever, stress, peptic ulcer, cancer, methaemoglobinaemia and in infants receiving unfortified formulas. It is also prescribed for haematuria, dental caries, pyorrhea, acne, infertility, atherosclerosis, fractures, leg ulcers, hay fever, vascular thrombosis prevention, levodopa toxicity, succinyl-choline toxicity, arsenic toxicity etc.
To reduce the risk of stroke in the elderly, long-term supplementation with Ceevit is essential.

**Dosage & Administration**
For the treatment of scurvy : 1-2 tablets daily; but dose may be increased depending on the severity of the condition.
For the reduction of risk of stroke in the elderly : 1-2 tablets daily.
In other cases : 1 tablet daily or as directed by the physician.
Maximum safe dose is 2000 mg daily in divided doses.

**Contraindication & Precaution**
Ingestion of megadose (more than 1000 mg daily) of vitamin C during pregnancy has resulted in scurvy in neonates.

**Side Effect**
Vitamin C has little toxicity and only mega-doses of vitamin C may cause diarrhoea, abdominal bloating, iron over-absorption.

**Drug Interaction**
Potentially hazardous interactions :
Ascorbic acid is incompatible in solution with aminophylline, bleomycin, erythromycin, lactobionate, nafcillin, nitrofurantoin sodium, conjugated oestrogen, sodium bicarbonate, sulphafurazole diethanolamine, chloramphenicol sodium succinate, chlorthiazide sodium and hydrocortisone

sodium succinate.

**Use in Pregnancy & Lactation**
The drug is safe in normal doses in pregnant women, but a daily intake of 5 gm or more is reported to have caused abortion.
The drug may be taken safely during lactation.

**Preparation**
500 mg tablet.

C

# Ceevit® Forte

**Active Ingredient**
Vitamin C (Ascorbic acid).

**Indication**
Treatment or prevention of Vitamin C Deficiency, Scurvy, Infection, Trauma, Burns, Cold exposure, Following Surgery, Fever, Stress, Cancer, Methaemoglobinaemia & Children receiving unfortified formulas. Also indicated in Hematuria, Dental Caries, Gum Diseases, Pyorrhea, Acne, Infertility, Atherosclerosis, Fractures, Leg ulcers, Hay fever, Vascular thrombosis prevention, Levodopa toxicity, Arsenic toxicity & etc.

**Dosage & Administration**
One tablet daily with a meal or as directed by physician. Dissolve one tablet in half glass (100 ml) of water & drink instantly.

**Contraindication & Precaution**
There is no serious contraindication to the administration of Vitamin C. Diabetes, patients prone to recurrent renal calculi & those on sodium restricted diets or anticoagulant therapy should not take excessive doses of ascorbic acid over an extended period of time.

**Side Effect**
Generally ascorbic acid is well tolerated. However, few side effects including stomach upset, diarrhea, mouth sores or frequent urination may be seen.

**Drug Interaction**
Limited evidence suggests that ascorbic acid may influence the intensity & duration of action of by hydroxycoumarin.

**Use in Pregnancy & Lactation**
During pregnancy & lactation usual dose is safe.

**Preparation**
Vitamin C 1000 mg Effervescent Tablet.

# Cef-3®

**Active Ingredient**
Cefixime.

**Indication**
Urinary tract infections, upper & lower respiratory tract infections, acute otitis media, gonococcal urethritis & enteric fever.

**Dosage & Administration**
200-400 mg as a single dose or in 2 divided doses daily for 7-14 days, Child dose : 8 mg/kg daily as a single dose or in two divided doses for 7-14 days.

**Contraindication & Precaution**
Known hypersensitivity to Cephalosporin group of drugs.

**Side Effect**
Diarrhoea, nausea, abdominal pain, dyspepsia, vomiting, flatulence, headache & dizziness.

**Use in Pregnancy & Lactation**
Pregnancy Category B.
Caution should be exercised when Cefixime is administered to a nursing mother.

**Preparation**
200 mg Capsule, 400 mg Capsule, 100 mg/5 ml Suspension (30 ml, 50 ml & 75 ml), 200 mg/5ml Suspension, 25 mg/ml Paediatric Drops.

# Cefopen™

**Active Ingredient**
Cefoperazone

**Indication**
Cefopen™ is indicated for the treatment of the following infections when caused by susceptible organisms: Respiratory Tract Infections, Peritonitis & Other Intra-abdominal Infections, Bacterial Septicemia, Skin and Skin Structures Infections, Pelvic Inflammatory Disease, Endometritis & Other Infections of the Female Genital Tract, Urinary Tract Infections, Enterococcal Infections etc.

**Dose and Administration**
Sterile Cefoperazone Sodium can be administered by IM or IV injection (following dilution).
Adult: 2 to 4 grams per day administered in equally divided doses every 12 hours. In severe infections or infections caused by less sensitive organisms, the total daily dose and/or frequency may be increased. Patients have been successfully treated with a total daily dosage of 6-12 grams divided into 2, 3, or 4 administrations ranging from 1.5 to 4 grams per dose. When treating infections caused by Streptococcus pyogenes, therapy should be continued for at least 10 days.

**Contraindication & Precaution**
Cefoperazone is contraindicated in patients with known allergy to the Cephalosporin-class of antibiotics. Cefoperazone is extensively excreted in bile. The serum half-life of Cefoperazone is increased 2-4 fold in patients with hepatic disease and/or biliary obstruction. In general, total daily dosage above 4 gm should not be necessary in such patients. If higher dosages are used, serum concentrations should be monitored.

**Side Effect**
Hypersensitivity: As with all Cephalosporins, hypersensitivity manifested by skin reactions (1 patient in 45), drug fever (1 in 260), or a change in Coombs' test (1 in 60) has been reported. These reactions are more likely to occur in patients with a history of allergies, particularly to Penicillin.

**Use in Pregnancy & Lactation**
Pregnancy Category B. This drug should be used during pregnancy only if clearly needed. Only low concentrations of Cefoperazone is excreted in human milk. Although Cefoperazone passes poorly into breast milk of nursing mothers, caution should be exercised when Cefoperazone is administered to a nursing woman.

**Preparation**
1 gm & 2 gm IM/IV Injection.

# Cefotil®

**Active Ingredient**
Cefuroxime.

**Indication**
1. Upper respiratory tract infections, for example, ear, nose & throat infections such as otitis media, sinusitis, tonsillitis & pharyngitis. 2. Lower respiratory tract infections: for example, acute bronchitis, acute exacerbations of chronic bronchitis & pneumonia. 3. Skin & soft tissue infections: such as furunculosis, pyoderma, & impetigo. 4. Genito-urinary tract infections: such as pyelonephritis, urethritis, & cystitis. 5. Gonorrhoea: acute uncomplicated gonococcal urethritis, & cervicitis. 6. Early Lyme disease & subsequent prevention of late Lyme disease.



**Dosage & Administration**
Adults : 250 mg b. i.d. upto 500 mg b. i. d. should be given. For urinary tract infections a dose of 125 mg b.i.d is usually adequate. A single dose of one gram is recommended for the treatment of uncomplicated gonorrhoea. Children : The usual dose is 125 mg b. i. d., or 10 mg/kg b. i. d. to a maximum of 250 mg daily. The usual course of therapy is 7-10 days. Cefuroxime should be taken after food for optimum absorption. Parenteral Dosage : Adults : 750 mg to 1.5 g IM or IV every 8 hourly, usually 5 to 10 days. Infants & children (>3 months) : 50 to 100 mg/kg/day in equally divided doses every 6 to 8 hours.

**Contraindication & Precaution**
Known allergy to Cephalosporins. As with other antibiotics, prolonged use of Cefuroxime may result in the over growth of non-susceptible organisms (e.g. Candida, Enterococci, Clostridium difficile), which may require interruption of treatment. Pseudomonas colits has been reported with the use of broad-spectrum antibiotics, therefore, it is important to consider its diagnosis in patients who develop serious diarrhoea during or after antibiotic use.

**Side Effect**
Nausea & vomiting.

**Use in Pregnancy & Lactation**
While all antibiotics should be avoided in the first trimester if possible. Cefuroxime has been safely used in later pregnancy to treat urinary & other infections. Caution should be exercised when Cefuroxime is administered to a nursing mother.

**Preparation**
250 mg & 500 mg Tablet, 125 mg/5 ml Suspension, 750 mg IM/IV Injection, 1.5 gm IV injection.

# Cefotil™ Plus

**Active Ingredient**
Cefuroxime & Clavulanic Acid

**Indication**
Pharyngitis/Tonsillitis, Acute Bacterial Otitis Media, Acute Bacterial Maxillary Sinusitis, Acute Bacterial Exacerbations of Chronic Bronchitis & Secondary Bacterial Infections of Acute Bronchitis, Haemophilus influenzae (beta-lactamase negative strains), or Haemophilus parainfluenzae (beta-lactamase negative strains), Uncomplicated Skin & Skin-Structure Infections, Uncomplicated Urinary Tract Infections, Uncomplicated Gonorrhea, (urethral & endocervical), Early Lyme disease (erythema migrans), Septicemia, Meningitis, Switch therapy (injectable to oral) after surgery when patient's condition is improved

**Dosage & Administration**
**Pediatric Patients (03 months to 12 years,**

**who can swallow tablet whole)**

| Infection | Dosage | Duration (days) |
|---|---|---|
| Acute Otitis Media | 250 mg b.i.d. | 10 |
| Acute Bacterial Maxillary Sinusitis | 250 mg b.i.d. | 10 |

**Contraindication & Precaution**

Cefuroxime-Clavulanic Acid is contraindicated in patients with known allergy to Cephalosporins & in patients with Pseudomonas Colitis.

**Side Effect**

Generally Cefuroxime-Clavulanic Acid is well tolerated. Major adverse reactions which may occur are diarrhea, nausea, vomiting, transient elevation in AST, ALT, LDH, & eosinophilia. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, rash, itch, dysuria, sleepiness, thirst, anorexia etc.

**Drug Interaction**

Concomitant administration of probenecid with Cefuroxime-Clavulanic Acid increases the area under the serum concentration versus time curve by 50%. Drug that reduces gastric acidity may result in a lower bioavailability of Cefuroxime & tend to cancel the effect of postprandial absorption.

**Use in Pregnancy & Lactation**

All antibiotics should be avoided in the first trimester if possible. However, Cefuroxime-Clavulanic Acid can be safely used in later pregnancy to treat urinary tract & other infections. Cefuroxime-Clavulanic Acid is excreted into the breast milk in small quantities & consequently caution should be exercised when it is administered to a nursing mother.

**Preparation**

Cefotil Plus 250 Tablet: Each box contains 12 tablets in blister pack.
Cefotil Plus 500 Tablet: Each box contains 12 tablets in blister pack.
Cefotil Plus Powder for Suspension (70ml ) : Bottle containing dry powder to reconstitute 70ml suspension.

# Ceftiben™

**Active Ingredient**
Ceftibuten

**Indication**
Ceftibuten is indicated for the treatment of individuals with mild-to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:
- Acute Bacterial Exacerbations of Chronic Bronchitis
- Acute Bacterial Otitis Media
- Pharyngitis
- Tonsillitis
- Pneumonia
- Urinary Tract Infections
- Enteritis
- Gastroenteritis

C

**Dosage & Administration**
Adults: 400 mg once daily for 10 days.
Paediatric Patients: Children 6 month and above: 9 mg/kg/day once daily for 10 days

**Contraindication & Precaution**
Ceftibuten is contraindicated in patients with known allergy to the Cephalosporin group of antibiotics.

**Side Effect**
Nausea, vomiting, diarrhea, stomach upset or headache may occur.

**Use in Pregnancy & Lactation**
Pregnancy category B.
It is not known whether Ceftibuten (at recommended dose) is excreted in human milk. Caution should be exercised when Ceftibuten is administered in a nursing mother.

**Preparation**
400 mg Capsule, 60 ml PFS.

# Ceftron®

**Active Ingredient**
Ceftriaxone.

**Indication**
Renal & urinary tract infections, Lower respiratory tract infections, particularly pneumonia, Gonococcal infections, Skin & soft tissue, bone & joint infections, Bacterial meningitis, Serious bacterial infections e.g. septicemia, ENT infections, Infections in cancer patients, Prevention of postoperative infection, Perioperative prophylaxis of infections associated with surgery, Typhoid fever.

**Dosage & Administration**
Adults & children (12 years & over): 1 gm once daily. In severe infections : 2-4 gm daily, normally as a single dose every 24 hours. Children (under 12 years) : 20-50 mg/kg/day. In severe infection: up to 80 mg/kg/day may be given.

**Contraindication & Precaution**
Hypersensitivity to Cephalosporin antibiotics. It is contraindicated in premature infants during the first 6 weeks of life. Its safety in human pregnancy has not been established. Therefore it should not be used in pregnancy unless absolutely indicated. Mothers receiving Ceftriaxone should not breast-feed. In severe renal impairment accompanied by hepatic insufficiency, dosage reduction is required.

**Side Effect**
Ceftriaxone is generally well tolerated. A few side-effects such as diarrhea, nausea & vomiting, stomatitis & glossitis, rash, pruritus, urticaria, edema & erythema multiforme, eosinophilia, thrombocytopenia, leukopenia, & neutropenia, elevations of SGOT or SGPT, bilirubinemia, headache, hyperactivity, nervousness, sleep disturbances, confusion, hypertonia & dizziness.

**Drug Interaction**
A possible disulfiram-like reaction may occur with alcohol.

**Preparation**
250 mg IV, 250 mg IM, 500 mg IV, 500 mg IM, 1 gm IV, 1 gm IM & 2 gm IV Injection.

# Cerevas™

**Active Ingredient**
Vinpocetine.

**Indication**
Acute Cerebro-Vascular Accidents (Stroke): Ischemic stroke due to cerebral thrombosis, cerebral embolism, acute circulatory disorder, hypertensive crisis; the acute cardiovascular disorders, reversible ischemic neurological deficit (RIND), complete stroke (CS), multi-infarct dementia, cerebral arteriosclerosis, hypertensive encephalopathy, post-apoplectic conditions with the background of hemorrhagic strokes etc. *Geriatrics:* For relief of psychosomatic symptoms in the elderly due to cerebral insufficiency e.g. forgetfulness, memory disturbances, slow thinking, lack of concentration, dizziness, mood instability, aphasia, sleep disturbances, vasovegetative symptoms of menopausal syndrome etc.
*Ophthalmology:* Vascular disorder of the choroid & retina due to arteriosclerosis. Vasospasm, macula degenerations, arterial or venous thrombosis or embolism or glaucoma secondary to above mentioned disorders.
*Otology:* For the treatment of impaired hearing of vascular toxic (iatrogenic) origin presbyacusis. Meniere's disease, cochleovestibular neuritis, tinnitus & dizziness of labyrinth origin.

**Dosage & Administration**
1-2 tablets thrice daily, the maintenance dose is one tablet thrice daily.

**Contraindication & Precaution**
Contraindicated to pregnant & breastfeeding women. Caution should be exercised in patients with history of high blood pressure & heart disease.

**Drug Interaction**
Individuals using blood-thinning medications, including aspirin, should not use Vinpocetine.

**Side Effect**
Transient hypotension, tachycardia may occur.

**Use in Children**
No proven safety.

**Preparation**
5 mg tablet.

# Cholenak™ IV

**Active Ingredient**
Sodium Chloride 0.5% w/v, Potassium Chloride 0.1% w/v and Sodium Acetate 0.393% w/v.

**Indication**
Cholera, diarrhea, severe vomiting and fluid loss due to excessive sweating

**Dosage & Administration**
The volume and rate of infusion of Cholera Saline depends upon the requirements of the patient and the judgment of the physician. It usually varies with age, weight and clinical condition of the patient.

**Preparation**
500 ml & 1000 ml in PP bottle.



# Cilosta®

**Active Ingredient**
Cilostazol.

**Indication**
Cilosta is indicated for the reduction of symptoms of intermittent claudication, as indicated by an increased walking distance.

**Dosage & Administration**
The recommended dosage of Cilosta is 100 mg bid, taken at least half an hour before or two hours after breakfast & dinner. A dose of 50 mg bid should be considered during coadministration of Ketoconazole, Itraconazole, Erythromycin, & Diltiazem.

**Contraindication & Precaution**
Cilostazol is contraindicated in patients

with congestive heart failure of any severity. Cilostazol is also contraindicated in patients with known or suspected hypersensitivity to any of its components. There is no information with respect to the efficacy or safety of the concurrent use of Cilostazol & Clopidogrel.

**Drug Interaction**
Omeprazole & Erythromycin significantly increased the systemic exposure of Cilostazol and/or its major metabolites. Population pharmacokinetic studies showed higher concentrations of Cilostazol among patients concurrently treated with Diltiazem.

**Side Effect**
The most common side effects are headache, diarrhoea, vomiting, leg cramps, rash etc. The less frequent side effects are anorexia & oedema.

**Use in Pregnancy & Lactation**
Pregnancy: There are no adequate & well controlled studies in pregnant women. Lactation: Transfer of Cilostazol into milk has been reported in experimental animals. Because of the potential risk to nursing infants, a decision should be made to discontinue nursing or to discontinue Cilostazol.

**Preparation**
100 mg Tablet.



# Cinaron®

**Active Ingredient**
Cinnarizine.

**Indication**
Cerebral circulatory disorders: a. Prophylaxis & maintenance therapy for symptoms of cerebral vascular spasms & arteriosclerosis. b. Sequelae of cerebral & cranial trauma. c. Postapoplectic disorders d. Migraine 2. Peripheral circulatory disorders: Prophylaxis & maintenance therapy for symptoms of vascular spasms & arteriosclerosis (obliterating arteritis, thromboangiitis, Raynaud's disease, diabetes, acrocyanosis pernio, etc.) such as intermittent claudication, trophic disturbances, pregangrene, trophic & varicose ulcers, paresthesia, nocturnal cramps, cold extremities. 3. Disorders of balance.

**Dosage & Administration**
Cinaron 15 to 30 mg three times daily.

**Side Effect**
Somnolence & gastrointestinal disturbances.

**Use in Pregnancy & Lactation**
The safety of Cinnarizine in human pregnancy has not been established although studies in animals have not demonstrated teratogenic effects. Therefore, it is not advisable to administer Cinnarizine in pregnancy.

**Preparation**
15 mg Tablet.

# Cinaron® Plus

**Active Ingredient**
Cinnarizine + Dimenhydrinate.

**Indication**
Vertigo & Peripheral arterial disorders.

**Dosage & Administration**
1 tablet thrice daily.

**Contraindication & Precaution**
Not known.

**Side Effect**
Somnolence & GI disturbance.

**Drug Interaction**
Not known.

**Use in Pregnancy & Lactation**
Risk benefit ratio is considered.

**Use in Children**
Not established.

**Preparation**
Tablet.

# Ciprocin®

**Active Ingredient**
Ciprofloxacin.

**Indication**
Urinary tract infections, lower respiratory tract infections, skin & soft tissue infections, bone & joint infections, G.I. tract infections, uncomplicated gonorrhoea, Ciprocin 750 tablet is specially indicated for the treatment of pseudomonal infections of lower respiratory tract; severe infections particularly due to pseudomonas, staphylococcus & streptococci. Ciprocin750 is also indicated in surgical prophylaxis.

**Dosage & Administration**
Urinary Tract Infection : Acute Uncomplicated-100 mg or 250 mg b.i.d. 3 Days, Mild/Moderate & Severe/Complicated-500 mg b.i.d. 7 to 14 Days. Severe/Complicated 750 mg twice daily 7 to 14 Days. Lower Respiratory Tract Infection : Mild/Moderate 500 mg b.i.d., Severe/ Complicated 750 mg b.i.d 7 to 14 Days. Acute Sinusitis : Mild/Moderate 500 mg b.i.d. Infectious Diarrhea : Mild/Moderate/Severe 500 mg b.i.d. Typhoid Fever : Mild/Moderate 500 mg b.i.d. *Pediatric Dosage:* 10 mg/kg to 20 mg/kg b.i.d. (maximum 750 mg per dose) for 10 to 21 days.

**Precaution & Warning**
It should be used with caution in patients with suspected or known CNS disorders such as arteriosclerosis or epilepsy or other factors which predispose to seizures & convulsion. Do not split, crush, or chew the tablet.

**Side Effect**
Nausea & other gastrointestinal disturbances, headache, dizziness, skin rashes, Crystalluria.

**Use in Pregnancy & Lactation**
The safety & effectiveness of ciprofloxacin in pregnant & lactating women have not been established.

**Use in Children**
From 1 years & above.

**Contraindication**
Patients with a history of hypersensitivity to Ciprofloxacin or to other quinolones.

**Preparation**
Ciprocin 250 mg, 500 mg, 750 mg Tablet & 250 mg Powder for Suspension.



# Ciprocin® Eye/Ear Drops

**Active Ingredient**
Ciprofloxacin.

**Indication**
*Eye:* Corneal ulcer, bacterial Conjunctivitis.
*Ear:* Otitis externa, acute otitis media, chronic suppurative otitis media.

**Dosage & Administration**
*Eye*: The recommended dosage regimen for the treatment of corneal ulcers is two drops into the affected eye every 15 minutes for the first 6 hours & then two drops into the affected eye every 30 minutes for the remainder of the first day. On the second day, instill 2 drops in the affected eye hourly. On the third to fourteenth day, place two drops in the affected eye every four hours. Treatment may be continued after 14 days if corneal re-epithelization has not been occurred.
*Ear:* For all infections, 2 - 3 drops every 2 - 3 hours

initially.

**Contraindication & Precaution**
Hypersensitivity, overgrowth of non-susceptible organisms.

**Side Effect**
Local burning or discomfort, crusting, crystals/scales, foreign body sensation, itching, conjunctival hyperemia & a bad taste.

**Drug Interaction**
Specific drug interaction studies have not been conducted with ophthalmic Ciprofloxacin.

**Use in Pregnancy & Lactation**
Ciprofloxacin ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Preparation**
0.3% Eye/Ear Drops.

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# Ciprocin® 200 IV

**Active Ingredient**
Ciprofloxacin.

**Indication**
Ciprocin IV is indicated for the treatment of following infections caused by sensitive bacteria-

- Urinary Tract Infection
- Lower Respiratory Tract Infection
- Nosocomial Pneumonia
- Skin & Skin Structure Infection
- Bone & Joint Infection
- Complicated Intra-Abdominal Infection
- Acute Sinusitis
- Chronic Bacterial Prostatitis
- Infectious diarrhea
- Inhalational Anthrax

**Dosage & Administration**

| Indication | Severity | Dose | Frequency | Days |
|---|---|---|---|---|
| Urinary Tract | Mild to Moderate | 200 mg | q12h | 7-14 days |
| | Severe or Complicated | 400 mg | q12h | 7-14 days |

| | | | | |
|---|---|---|---|---|
| Lower Respiratory Infection | Mild to Moderate | 400 mg | q12h | 7-14 days |
| | Severe or Complicated | 400 mg | q8h | 7-14 days |
| Nosocomial Pneumonia | Mild or Moderate or Severe | 400 mg | q8h | 10-14 days |
| Skin & Skin Structure Infection | Mild to Moderate | 400 mg | q12h | 7-14 day |
| | Severe or Complicated | 400 mg | q8h | 7-14 day |
| Bone & Joint Infection | Mild to Moderate | 400 mg | q12h | ≥4-6 weeks |
| | Severe or Complicated | 400 mg | q8h | ≥4-6 weeks |
| Intra-Abdominal Infection | Complicated | 400 mg | q12h | 7-14 day |
| Acute Sinusitis | Mild to Moderate | 400 mg | q12h | 10 days |
| Chronic Bacterial Prostatitis | Mild to Moderate | 400 mg | q12h | 28 days |

**Contraindication & Precaution**
Ciprofloxacin is contraindicated in persons with a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents. Concomitant administration with tizanidine is contraindicated. Ciprocin 200 IV should be administered by slow infusion over a period of 60 minutes.



**Drug Interaction**
Concurrent administration of ciprofloxacin with theophylline may lead to elevated serum concentrations of theophylline & prolongation of its elimination half-life. This may result in increased risk of theophylline-related adverse reactions. Probenecid interferes with renal tubular secretion of ciprofloxacin & produces an increase in the level of ciprofloxacin in the serum.

**Use in Pregnancy & Lactation**
The safety & Effectiveness of Ciprofloxacin in pregnant & lactating women have not been established. Ciprofloxacin is excreted in human milk.

**Use in Children**
Ciprofloxacin is usually not recommended for use in children. However, if the benefit of ciprofloxacin therapy are considered to overweight the potential risk, the dosage should be 5-10 mg/kg/day in two divided doses, depending on the severity of the infections.

**Preparation**
200 mg/100 ml intravenous infusion.

# Citivas™

**Active Ingredient**
Citicoline 500 mg Caplet

**Indication**
Cerebrovascular disease e.g. from ischemia due to stroke, where Citicoline accelerates the recovery of consciousness & overcoming motor deficit. Treatment within the first 24 hours after onset in patients with moderate to severe stroke increases the probability of complete recovery in 3 months.
Cerebral insufficiency (e.g. dizziness, memory loss, poor concentration & disorientation) due to head trauma or brain injury.
Cognitive dysfunction due to degenerative disease (Alzheimer's disease)
Parkinson's disease- Citicoline has been shown to be effective as co-therapy for Parkinson's disease.



**Dosage & Administration**
Immediate treatment of stroke due to a clot (ischemic stroke) - 500-2000 mg of Citicoline per day, start within 24 hours of stroke.
For decline in thinking skills due to stroke- 1000-2000 mg of Citicoline per day.
Chronic cerebrovascular disease- 1000 mg daily in divided dose with or between meals for ongoing disease of the blood vessels that serve the brain.

**Side Effect**
Occasionally Citicoline may exert stimulating action of the parasympathetic system as well as a fleeting & discrete hypotensive effect.

**Precaution**
In case of persistent intracranial hemorrhage, it is recommended not to exceed the dose of 1000 mg of Citicoline daily.

**Contraindication**
Patients with hypertonic of the parasympathetic nervous system.

**Drug Interaction**
Citicoline may enhance the effects of levodopa, carbidopa & entacapone. Citicoline must not be administered with products containing meclophenoxate.

**Use in Pregnancy & Lactation**
There are no adequate & well controlled studies of Citicoline during pregnancy & lactation. Citicoline should be used during pregnancy & lactation only if the potential benefits justify the potential risks.

**Geriatric use**
No dosage adjustment is required & the usual dose can be administered.

**Preparation**
500 mg caplet.
*Caplet: Capsule shaped tablet

# Climycin™

**Active Ingredient**
Clindamycin.

**Indication**
Climycin has been shown to be Effective in the treatment of the following infections when caused by susceptible anaerobic bacteria or susceptible strains of gram positive bacteria such as streptococci, staphylococci & pneumococci: Upper respiratory tract infections, Lower respiratory tract infections, Skin & soft tissue infections, Bone & joint infections, Pelvic infections, Intra-abdominal infections, Septicemia & endocarditis, Dental infections. As an alternative therapy when used in combination with quinine or amodiaquine for the treatment of multi-drug resistant Plasmodium falciporum infection.

**Dosage & Administration**
*Adults:* Serious Infections: 150 mg - 300 mg every six hours. More severe infections: 300 mg - 450 mg every six hours.
*Pediatric Patients:* Serious Infections:
8 - 16 mg/kg/day divided into three or four equal doses.
More severe infections: 16 - 20 mg/kg/day divided into three or four equal doses.

**Contraindication & Precaution**
Clindamycin is contraindicated in patients previously found to be sensitive to Clindamycin or lincomycin or any of the ingredients of this medicine.

**Side Effect**
The adverse effects have been reported with the use of Clindamycin are abdominal pain, oesophagitis & oesophagial ulcer, nausea, vomiting & diarrhoea, pruritus, skin rashes, urticaria.

**Use in Pregnancy & Lactation**
Pregnancy: Pregnancy Category B: Clindamycin should be used in pregnancy only if clearly needed.
Lactation : Clindamycin has been reported to appear in breast milk. Therefore, it is not recommended for nursing mothers if not clearly needed.

**Use in Children**
When Clindamycin is administered to newborns & infants (birth to 16 years) appropriate monitoring of organ system functions is desirable.

**Preparation**
300 mg Capsule.

# Clinface® Gel

**Active Ingredient**
Clindamycin Phosphate & Tretinoin.

**Indication**
Clinface® Gel is indicated for the topical treatment of Acne vulgaris.

**Dosage & Administration**
*Before sleep*
- Wash the face gently with a mild soap & water, then pat the skin dry.
- Apply the Gel with finger tips through the face gently.

*In the morning*
- Apply a sunscreen after the application of Gel.
- Do not wash your face more than 2 or 3 times a day. Apply the sunscreen cream as needed.

**Contraindication & Precaution**
Clinface® Gel should not be administered to individuals who are hypersensitive to Clindamycin or Tretinoin or any other component of the Gel. Clinface® Gel should not be applied to eyes, nose, ear, lips, cut, burn & other infections. After the application of the Gel, keep away from sunlight.

**Side Effect**
Erythema, scaling, nasopharyngitis, dry skin, cough, sinusitis & diarrhea are the common side effects.

**Use in Pregnancy & Lactation**
It is not known whether Clindamycin or Tretinoin is excreted in human milk. Exercise special caution while applying Clindamycin or Tretinoin to a nursing mother.

**Preparation**
15 gm Gel.

# Clofenac®

**Active Ingredient**
Diclofenac.

**Indication**
Arthritic conditions: Rheumatoid Arthritis, Osteoarthritis, Ankylosing spondylitis, acute gout, acute musculoskeletal disorders such as periarthritis (e.g., frozen shoulder), tendinitis, tenosynovitis, bursitis, other painful conditions resulting from trauma, including fracture, low back pain, sprains, strains, dislocations, orthopaedic, dental & other minor surgery.

**Dosage & Administration**
*50 mg : Adults:* 75 - 150 mg daily in 2 to 3 divided doses, preferably after food. The recommended maximum daily dose of diclofenac is 150 mg. *Children:* In juvenile chronic arthritis, 1-3 mg of diclofenac/kg body wt. daily in divided doses. *Elderly patients:* In elderly or debilitated patients, the lowest effective dosage is recommended. *Gel:* Should be rubbed gently into the skin. Depending on the size of the affected site to be treated 2-4 gm gel should be applied 3 - 4 times daily & rubbed in lightly. *Suppository:* Should be administered rectally. *Adults:* 50 mg suppository only: 75-150 mg daily, in divided doses. *Children (1-12 years):* 12.5 mg or 25 mg suppository only: 1-3 mg/kg daily, in divided doses.

**Contraindication & Precaution**
Diclofenac is contraindicated for those patients who are hypersensitive to diclofenac. In patients with active or suspected peptic ulcer or gastrointestinal bleeding, or for those patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other NSAIDs possessing prostaglandin synthetase inhibiting activity, diclofenac is also contraindicated.

**Side Effect**
Epigastric pain, nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia. Rare: gastro-intestinal bleeding, peptic ulcer (with or without bleeding or perforation), bloody diarrhoea. In isolated cases: lower gut disorders (e.g., non-specific haemorrhagic colitis & exacerbations of ulcerative colitis or Crohn's proctocolitis), pancreatitis, glossitis, constipation, etc.

**Drug Interaction**
Lithium & digoxin, anticoagulants, antidiabetic agents, cyclosporin, methotrexate, quinolone antimicrobials, diuretics.

**Use in Pregnancy & Lactation**
Diclofenac tablets & injection should not be prescribed during pregnancy, very small quantities may be detected in breast milk but no undesirable effects on the infant are to be expected.

**Preparation**
50 mg tablet, 50 mg DT (Dispersible Tablet),100 mg SR tablet, 100 mg TR capsule, 1% Gel, 12.5 mg, 25 mg, 50 mg, Plus Inj.

# Clopirox™ 1% Cream

**Active Ingredient**
Ciclopirox Olamine

**Indication**
Dermal infections: Tinea pedis, Tinea cruris & Tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum & Microsporum canis, candidiasis (moniliasis) due to Candida albicans, & Tinea (pityriasis) versicolor due to Malassezia furfur. It is also highly effective against some gram negative & some gram positive bacteria. Owing to its anti-inflammatory effects, Ciclopirox Olamine

alone is sufficient to treat mild to moderate inflammatory fungal infections.

**Dosage & Administration**
Should be gently massaged onto the affected & surrounding skin areas twice daily for four weeks. Clinical improvement with relief of pruritus & other symptoms usually occurs within the first week of treatment. If a patient shows no clinical improvement after four weeks of treatment, the diagnosis should be redetermined. Patients with Tinea versicolor usually exhibit clinical & mycological clearing after two weeks of treatment.

**Contraindication & Precaution**
Ciclopirox Olamine cream is contraindicated in individuals who have shown hypersensitivity to any of its components.

**Side Effect**
Ciclopirox Olamine cream is well tolerated with a low incidence of adverse reactions reported in clinical trials.

**Use in Pregnancy & Lactation**
Pregnancy category B. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ciclopirox Olamine cream or is administered to nursing women.

**Use in Children**
Safety & effectiveness in children below the age of 10 years have not been established.

**Preparation**
15 gm Cream

# Clopirox™ Shampoo

**Active Ingredient**
Ciclopirox Olamine USP 10 mg.

**Indication**
Clopirox™ Shampoo is indicated in the treatment of Seborrheic dermatitis, Dandruff, Inflammation and Swelling of the scalp.

**Dosage & Administration**
Wet hair and apply approximately 1 teaspoon (5 ml) of Clopirox™ Shampoo (Ciclopirox Olamine Shampoo) to the scalp. Up to 2 teaspoons (10 ml) may be used for long hair. Lather and leave on hair and scalp for 3 minutes. A timer may be used. Avoid contact with eyes. Treatment should be repeated twice per week for 4 weeks, with a minimum of 3 days between applications.

**Contraindication**
This Shampoo is contraindicated in individuals who have shown hypersensitivity to any of its components.

**Side Effect**
Ciclopirox Olamine Shampoo is well tolerated with a low incidence of adverse reactions reported in clinical trials.

**Precaution**
Ciclopirox Olamine Shampoo is not for ophthalmic, oral, or intravaginal use.

**Use In Pregnancy**
Pregnancy category B.

**Use In Nursing Mother**
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ciclopirox Olamine Shampoo or is administered to nursing women.

**Use In Children**
No clinical trials have been conducted in subjects younger than 16 years.

**Preparation**
100 ml Shampoo.

# Clotinex™

**Active Ingredient**
Enoxaparin.

**Indication**
- Treatment of deep vein thrombosis
- Unstable angina, myocardial infarction
- Prophylaxis of venous thromboembolic disease

**Dosage & Administration**

| Indications | Recommended Dosage Schedule |
|---|---|
| Treatment of deep vein thrombosis, with or without pulmonary embolism | Subcutaneously 100 anti-Xa IU/kg twice daily for 10 days or Subcutaneously 150 anti-Xa IU/kg once daily for 10 days |
| | Oral anticoagulant therapy should be initiated when appropriate & enoxaparin sodium treatment should be continued until a therapeutic anticoagulant effect has been achieved. |
| Treatment of unstable angina & non-Q-wave myocardial infarction, administered concurrently with aspirin | Subcutaneously 100 anti-Xa IU/kg twice daily for 2 - 8 days |
| | Should be administered concurrently with oral aspirin (100 to 325 mg once daily). Treatment with enoxaparin sodium in these patients should be prescribed for a minimum of 2 days & continued until clinical stabilization. |
| Prevention of thrombus formation in extra corporeal circulation during hemodialysis | Recommended dose is 100 anti-Xa IU/kg.<br>For patients with a high risk of hemorrhage, the dose should be reduced to 50 anti-Xa IU/kg for double vascular access or 75 anti-Xa IU/kg for single vascular access. |
| | During hemodialysis, enoxaparin sodium should be introduced into the arterial line of the circuit at the beginning of the dialysis session. |
| Prophylaxis of venous thromboembolic disease in surgical patients | Patients undergoing general surgery with a moderate risk of thromboembolism (e.g. abdominal surgery):<br>Subcutaneously 2000 anti-Xa IU (0.2 ml) or 4000 anti-Xa IU (0.4 ml) once daily for 7 to 10 days. The first injection should be given 2 hours before the surgical procedure.<br><br>Patients undergoing orthopedic surgery with a high risk of thromboembolism:<br>Subcutaneously 4000 anti-Xa IU (0.4 ml) once daily for 7 to 10 days. The first injection should be given 2 hours before the surgical procedure. |
| | Longer treatment duration may be appropriate in some patients like continued therapy with 4000 anti-Xa IU once daily for 3 weeks following the initial therapy has been proven to be beneficial in orthopaedic surgery. |

| | |
|---|---|
| Prophylaxis of venous thromboembolic disease in medical patients | Subcutaneously 4000 anti-Xa IU (0.4 ml) once daily for 6 - 14 days |

*Dose in Elderly patients*
No dosage adjustment is necessary, unless kidney function is impaired.
*Dose in Renal Impairment:*
No dosage adjustment is recommended in patients with moderate & mild renal impairment. For patients with severe (creatinine clearance <30 ml/min) renal impairment, following dosage adjustments are recommended: Prophylactic dose ranges: 2000 anti-Xa IU once daily; Therapeutic dose ranges: 100 anti-Xa IU/kg once daily.
Dose in Hepatic Impairment:
Caution should be used in hepatically impaired patients.

**Contraindication & Precaution**
Contraindication: Patients with known hypersensitivity to Enoxaparin Sodium, heparin or other low molecular weight heparins. Patients with active major bleeding & conditions with a high risk of uncontrolled hemorrhage including recent hemorrhagic stroke. Precaution: Enoxaparin Sodium should be injected by deep subcutaneous route in prophylactic & curative treatment & by intravascular route during hemodialysis. Do not administer by the intramuscular route. Enoxaparin Sodium should be used with caution in conditions with increased potential for bleeding. It is recommended that the platelet counts be measured before the initiation of the treatment & regularly thereafter during treatment.



**Side Effect**
Hemorrhage (bleeding), thrombocytopenia, elevations of serum amino transferase, pain, bluish marks at injection site, skin rash at injection site, cases of neuraxial hematomas with concurrent use of enoxaparin & spinal/epidural anesthesia or spinal puncture have resulted in varying degrees of neurological injuries.

**Drug Interaction**
Agents which affect hemostasis should be discontinued prior to Enoxaparin Sodium therapy unless strictly indicated. These agents include medications such as: acetylsalicylic acid (and derivatives), NSAIDs (including ketorolac), ticlopidine, clopidogrel, dextran 40, glucocorticoids, thrombolytics & anticoagulants, other anti platelet aggregation agents including glycoprotein IIb/IIIa antagonists.

**Use in Pregnancy & Lactation**
Pregnancy category B. It should be used during pregnancy & lactation only if clearly needed.

**Use in Children**
Safety & Effectiveness have not been established.

**Preparation**
40 mg (4000 anti-Xa IU/0.4 ml) pre-filled syringe injection & 60 mg (6000 anti-Xa IU/0.6 ml) pre-filled syringe injection.

# Colicon®

**Active Ingredient**
Dicycloverine HCl.

**Indication**
Irritable bowel syndrome, Infantile colic, GIT spasm, Diverticulitis, Abdominal colic, Diarrhoea, Dysentery.

**Dosage & Administration**
Adults : 10 to 20 mg three to four times a day. Maximum recommended oral dose is 160 mg daily in divided dose. Children : Children over 6 months of age- 5 to 10 mg three times a day.

**Contraindication & Precaution**
Obstructive uropathy, obstruction disorder in GIT, severe ulcerative colitis, unstable cardiovascular status in acute hemorrhage, glucoma, myasthenia gravis, patients with hypersensitivity to dicycloverine hydrochloride.

**Side Effect**
Insomnia, headache, weakness, confusion, increased ocular tension, urinary hesitancy, palpitations etc.

**Use in Pregnancy & Lactation**
Pregnancy Category B. Dicycloverine should be used during pregnancy only if clearly needed. Dicycloverine should not be used in case of lactating mother.

**Drug Interaction**
Antiarrhythmic agents, antihistamines, antipsychotic agents, benzodiazepines, MAO inhibitors, narcotic analgesics, nitrates & nitrites, sympathomimetic agents, tricyclic antidepressants & other drugs having anticholinergic activity.

**Preparation**
10 mg Tablet & 10 mg/5 ml Syrup (50 ml).

# Colimax™

**Active Ingredient**
Colchicine USP 0.6 mg

**Indication**
Colchicine is approved by US FDA for the prevention & treatment of acute gout attack.

**Dosage & Administration**
Prophylaxis of gout flare:
0.6 mg (1 tablet) once or twice daily in adults & adolescents older than 16 years of age. Maximum dose 1.2 mg/day (2 tablets).

Treatment of acute gout attack:
• 1.2 mg (2 tablets) at first sign of a gout flare followed by 0.6 mg (1 Tablet) one hour later.
• The maximum recommended dose for treatment of acute gout attack is 1.8 mg over a 1 hour period.
• The maintenance dose will be as same as the prophylactic dose, which should be resumed after 12 hours of the acute treatment course.
Contraindication: Patients with renal or hepatic impairment should not be given Colchicine in Conjunction with permeable glycoprotein or strong CYP3A4 inhibitors (ex.: Clarithromycin or Cyclosporine)

**Side Effect**
Myelosuppression, leucopenia, granulocytopenia, thrombocytopenia & aplastic anemia have been reported. Diarrhea & pharyngolaryngeal pain may occur.

**Drug Interaction**
Co-administration of permeable glycoprotein (P-gp) and/or CYP3A4 inhibitors (e.g., clarithromycin orcyclosporine) have been demonstrated to alter the concentration of Colchicine.

**Use in Pregnancy & Lactation**
Pregnancy Category C. There are no adequate & well-controlled studies in pregnant women.

Colchicine is excreted into human milk. Caution should be exercised when administered to a nursing woman.

**Use in children**
Gout is rare in pediatric patients. Safety & effectiveness of Colchicine in pediatric patients have not been established. Patient less than 16 years of age is not recommended

**Preparation**
0.6 mg Tablet.


C

# Comet®

**Active Ingredient**
Metformin HCl.

**Indication**
Management of type 2 diabetes mellitus.

**Dosage & Administration**
Adults : Starting dose of Comet (Metformin Hydrochloride tablet) is 500 mg twice a day or 850 mg once a day, given with meals. Dosage increases should be made in increments of 500 mg weekly or 850 mg every 2 weeks, up to a total of 2000 mg per day, given in divided doses. Starting dose of Comet XR (Metformin Hydrochloride extended release tablet) is 500 mg once daily with the evening meal. Dosage increases should be made in increments of 500 mg weekly, up to a maximum of 2000 mg once daily with the evening meal. If glycemic control is not achieved on Comet XR 2000 mg once daily, a trial of Comet XR 1000 mg twice daily should be considered. Pediatrics : Starting dose of Comet is 500 mg twice a day, given with meals. Dosage increases should be made in increments of 500 mg weekly up to a maximum of 2000 mg per day, given in divided doses.

**Contraindication & Precaution**
Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels > 1.5 mg/dL [males], > 1.4 mg/dL [females] or abnormal creatinine clearance), Congestive heart failure requiring pharmacologic treatment, Known hypersensitivity to metformin hydrochloride, Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Pregnant mothers: Pregnancy Category B. Metformin should not be used during pregnancy unless clearly needed. Nursing mothers : Because the potential for hypoglycemia in nursing infants may exist, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Side Effect**
Diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, headache etc.



**Drug Interaction**
Furosemide, Nifedipine, Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin).

**Preparation**
500 mg & 850 mg Tablet, XR 500 mg & XR 1 gm tablet.

# Comprid®

**Active Ingredient**
Gliclazide

**Indication**
Indicated for the treatment of type 2 diabetes in association with dietary measures when dietary measures alone are inadequate to control blood glucose.

**Dosage & Administration**
The usual initial dose of Comprid® is 40 to 80 mg daily, gradually increased, if necessary up to 320 mg daily until adequate control is achieved. A single dose should not exceed 160 mg. When higher doses are required it should be taken twice daily, according to the main meals of the day. For extended release tablet the initial recommended dose is 30 mg daily, even in elderly patients (>65 years); the daily dose may vary from 30 to 120 mg taken orally, once daily. Comprid® XR should be taken with food because there is increased risk of hypoglycemia if a meal is taken late. It is recommended that the medication be taken at breakfast time. If a dose is forgotten, the dose taken on the next day should not be increased. Dose titration should be carried out in steps of 30 mg, according to the fasting blood glucose response. Each step should last for at least two weeks. Comprid® XR is an extended release tablet & therefore, should be neither broken nor chewed. Comprid® XR 30, can replace Gliclazide 80 mg tablets, tablet for tablet, for doses of 1 to 4 tablets per day. Elderly: Plasma clearance of Gliclazide is not altered in the elderly & steady state plasma levels are similar to those in adults under 65 years. Clinical experience in the elderly shows that it is effective & well tolerated.

**Contraindication & Precaution**
Gliclazide should not be used in juvenile onset diabetes, diabetes complicated by ketosis & acidosis, diabetes undergoing surgery, after severe trauma or during infections, patients known to have hypersensitivity to other sulfonylureas & related drugs, diabetic pre-coma & coma, severe renal or hepatic insufficiency, combination with miconazole tablets.
Care should be exercised with patients having hepatic & or renal impairment & a small starting dose should be used with careful patient monitoring. In long term clinical trials, patients with renal insufficiency have been treated satisfactorily using Gliclazide at reduced doses.

**Side Effect**
Hypoglycemia may occur in concurrent conditions such as hepatic & renal diseases, alcohol intoxication & adrenal & pituitary insufficiency. Mild gastro-intestinal disturbances including nausea, dyspepsia, diarrhea, & constipation have been reported but these types of adverse reactions can be avoided if Gliclazide is taken during a meal. Allergic dermatological reactions including rash, pruritus, erythema, bullous eruption have been reported during treatment with the drug but are not known to be directly attributable to it.

**Drug Interaction**
The hypoglycemic effect of Gliclazide may be potentiated by NSAID (in particular aspirin), phenylbutazone, sulfonamides, coumarin derivatives, MAOIs, beta-adrenergic blockers, tetracyclines, chloramphenicol, clofibrate, cimetidine & miconazole tablets.Ingestion of alcohol may also increase the hypoglycemic effect of Gliclazide. Some drugs may on the contrary, reduce its activity e.g. barbiturates, corticosteroides, thiazide diuretics, thyroid hormones, laxatives & oral contraceptives.

**Use in pregnancy & Lactation**
*Pregnancy:* Gliclazide should not be used in pregnancy. *Nursing mothers:* No study has reported its presence in human breast milk. However, other sulfonylureas have been found in milk & there is no evidence to suggest that gliclazide differs from the group in this respect.

**Use in children**
Should not be used below 18 years.

**Preparation**
Comprid® tablet: Each box containing 60 tablets in blister pack.
Comprid® XR 30 tablet: Each box containing 30 tablets in blister pack.
Comprid® XR 60 tablet: Each box containing 30 tablets in blister pack.

# Contilex®

**Active Ingredient**
Glucosamine + Chondroitin.

**Indication**
Treatment of osteoarthritis of fingers, shoulder joints & weight bearing joints of the body. As a dietary supplement to prevent Osteoarthritis.

**Dosage & Administration**
1 - 2 tablets, three times daily. Doses can tapered after 60 days as per requirement.

**Contraindication & Precaution**
Proven hypersensitivity to these ingredients is a contraindication.

**Side Effect**
No demonstrable side effects. Mild & reversible intestinal flatulence occurs rarely.

**Preparation**
(Glucosamine Sulfate 250 mg + Chondroitin Sulfate 200 mg)/Tablet.



# Cotrim®

**Active Ingredient**
Sulphamethoxazole & Trimethoprim.

**Indication**
Respiratory tract infections, genito-urinary tract infections, skin infections, acute & chronic osteomyelitis, acute brucellosis, septicaemia, nocardiosis & other infections caused by susceptible organisms.

**Dosage & Administration**
Tablet : 2 tablet twice daily. In severe cases,

3 times/day. DS Tablet : 1 tablet twice daily. Suspension : 1-2 teaspoonful twice daily.

**Contraindication & Precaution**
Hepatic & renal insufficiency, blood dyscrasias, sulphonamides sensitivity, megaloblastic anaemia, pregnancy & during nursing.

**Side Effect**
Exfoliative dermatitis, Stevens-Johnson syndrome & toxic epidermal necrolysis (Lyell's syndrome) are rare. Nausea & vomiting, diarrhoea, glossitis, stomatitis, anemia, granulocytopenia, purpura & agranulocytosis.

**Preparation**
(400 mg + 80 mg)/Tablet, (800 mg +160 mg)/ DS Tablet, (200 mg + 40 mg)/5 ml Suspension.



# Cozycol™ 800

**Active Ingredient**

Indication
Its is indicated for
• Treatment of mild to moderately active Ulcerative Colitis
• Maintenance of remission of Ulcerative Colitis
• Maintenance of remission of Crohn's disease

**Dosage and Administration**
Acute disease: 3-6 delayed release tablets (2400-4800 mg) daily in divided doses for 6 (six) weeks. Maintenance therapy: The recommended dosage is 3 delayed release tablets (2400 mg) daily in divided doses.
Maintenance of remission of Crohn's disease: 3 delayed release tablets (2400 mg) daily in divided doses.
Paediatric : Safety and effectiveness has not been established.
Elderly: Because elderly patients are more likely to have decreased renal function, care should be taken when prescribing this drug therapy. It is recommended that all patients have an evaluation of renal function prior to initiation of Mesalamine tablets. Monitor blood cell counts during drug therapy.

**Contraindication & Precaution**
Hypersensitivity to salicylates or to any other component of the formulation .
Side effect
The commonly reported adverse events are headache, nausea, dizziness, asthenia, dyspepsia, vomiting, pruritus etc.

**Drug Interaction**
Concurrent use of other known nephrotoxic agents such as NSAIDs and Azathioprine may increase the risk of renal reactions.

**Use in Special Population**
Pregnant women:
It should be given in pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactating mother: Caution is advised when it is administered to a nursing mother.
Geriatrics: Patients who are 65 years or older, caution should be taken to closely monitor blood cell counts during Mesalamine therapy.

**Preparation**
800 mg

# Daizy™

**Active Ingredients**
Dienogest 2 mg Tablet

**Indication**
Endometriosis

**Dosage & Administration**
Once daily for 3 months initially

**Contraindication**
Dienogest should not be used in women with any of the conditions listed below:
Known or suspected pregnancy, lactation, Active Venous Thromboembolic disorder, Arterial and Cardiovascular disease, Diabetes mellitus with vascular involvement, presence or history of severe hepatic disease as long as liver function values have not returned to normal, presence or history of liver tumors (benign or malignant), known or suspected sex hormone-dependent malignancies, undiagnosed abnormal vaginal bleeding, any ocular lesion arising from ophthalmic vascular disease such as partial or complete loss of vision or defect in visual fields, current or history of migraine with focal aura, hypersensitivity to Dienogest or to any ingredient in the formulation.

**Adverse effects**
The most frequently reported adverse drug reactions during treatment with Dienogest in clinical trials were headache, breast discomfort, depressed mood, and acne. The continuous administration of progestins in general leads to endometrial regression, with irregular endometrial breakthrough bleeding, particularly during the first weeks of use. Therefore changes in bleeding pattern such as spotting, irregular bleeding, or amenorrhea occurred during treatment with Dienogest.

**Pregnancy & Breastfeeding**
Contraindicated. Not recommended for breast feeding mother.

**Preparation**
2 mg Tablet

# D-balance™

**Active Ingredient**
Cholecalciferol

**Indication and Usage**
For the prevention & treatment of Vitamin $D_3$ & associated diseases like Osteomalacia, Rickets, Fractures, Preeclampsia, Eclampsia, during pregnancy & for the management of Cardiovascular & Diabetic profile

**Dosage & Administration Adults**
In Adults:
Treatment of Cholecalciferol deficiency [when 25 (OH) D level <12 ng/ml]: For rapid correction 50,000 IU of vitamin D3 once a week for 6-10 weeks.

***Each of the above dose should be followed by maintenance therapy (800-2000 IU/day). Follow-up 25 (OH) D measurements should be made approximately 3 to 4 months after initiating maintenance therapy to confirm that the target level has been achieved.

Treatment of Cholecalciferol (Vitamin D3) deficiency: 40,000 IU/week for 7 weeks, followed by maintenance therapy (1400-2000 IU/day). Follow-up 25 (OH) D measurements should be made approximately 3 to 4 months after initiating maintenance therapy to confirm that the target level has been achieved. Prevention of Vitamin D deficiency: 20,000 IU/ Month.
Children: Treatment of Vitamin D deficiency, 12-18 years: 20,000 IU, once every 2 weeks for 6 weeks. Prevention of Vitamin D deficiency, 12-18 years: 20,000 IU, once every 6 weeks.
Contraindications
Hypersensitivity to Cholecalciferol (Vitamin D3) or any of the excipients in the product.
Hypervitaminosis D, Nephrolithiasis., Diseases or conditions resulting in hypercalcemia and/ or hypercalciuria, Severe renal impairment

**Drug Interaction**
Cholecalciferol (Vitamin D3) is known to interact with Carbamazepine, Dactinomycin, Diuretics, Fosphenytoin, Miconazole, Phenobarbital, Phenytoin, Primidone.

**Adverse Effects**
The frequency of the undesirable effects listed below;
Metabolism and nutrition disorders: Uncommon (a1/1000 to <1/100): Hypercalcemia and hypercalciuria. Gastrointestinal disorders: Rare (a1/10,000 to <1/1000): Constipation, flatulence,
bloating, abdominal distension, nausea, abdominal pain, and diarrhea.
Skin and subcutaneous tissue disorders: Rare (a 1/10,000 to < 1/1,000): Pruritus, rash and urticaria



**Use in Pregnancy and Lactation**
Studies have shown safe use of doses up to 4000 IU during pregnancy. The recommended daily intake for pregnant women is 400 IU, however, in women who are considered to be Cholecalciferol (Vitamin D3) deficient a higher dose may be required. During pregnancy women should follow the advice of their medical practitioner as their requirements may vary depending on the severity of their disease and their response to treatment.
Cholecalciferol (Vitamin D3) and its metabolites are excreted in breast milk. Overdose in infants induced by nursing mothers has not been observed; however, when prescribing additional Cholecalciferol to a breast-fed child the practitioner should consider the dose of any additional Cholecalciferol (Vitamin D3) given to the mother.

**Preparation**
50000 IU Licap, 40000 IU Licap, 20000 IU Licap & 2000 IU Licap.

# Defiron®

**Active Ingredient**
Iron Sucrose Injection.

**Indication**
Defiron is indicated for the treatment of Iron deficiency in the following indications:

- Where there is a clinical need for a rapid Iron supply
- In patients who cannot tolerate oral Iron therapy or who are non-compliant
- In active inflammatory bowel disease where oral Iron preparations are ineffective
- Non-dialysis dependent-chronic kidney disease (NDD-CKD) patients receiving an erythropoietin
- Non-dialysis dependent-chronic kidney disease (NDD-CKD) patients not receiving erythropoietin
- Hemodialysis dependent-chronic kidney disease (HDD-CKD) patients receiving an erythropoietin
- Peritoneal dialysis dependent-chronic kidney disease (PDD-CKD) patients receiving an erythropoietin

It is also indicated in the treatment of Iron deficiency anaemia in patients undergoing surgical procedures, patients donating blood, postpartum patients.

**Dosage & Administration**
Administration: Defiron is exclusively to be administered intravenously by drip infusion, by slow injection or directly into the venous limb of the dialyser & is not suitable for intramuscular use & for total dose infusion (TDI), where the full dose of Iron required, representing the patient's total Iron deficit is administered in one complete infusion. Before administration of the first therapeutic dose, a test dose should be given. If any allergic reactions or intolerance

occurs during administration, the therapy must be stopped immediately.

*Normal Dosage*
Adults & Elderly: 5-10 ml Defiron (100-200 mg Iron) once to three times a week depending on the hemoglobin level.
Children: There is limited data on children under study conditions. If there is a clinical need, it is recommended not to exceed 0.15 ml Defiron (3 mg Iron) per kg body weight once to three times per week depending on the haemoglobin level.

**Contraindication & Precaution**
The use of Iron Sucrose is contraindicated in patients with evidence of Iron overload, in patients with known hypersensitivity to Iron Sucrose or any of its inactive components & in patients with anaemia not caused by Iron deficiency. It is also contraindicated in patients with history of allergic disorders including asthma, eczema & anaphylaxis, liver disease & infections.

**Side Effect**
Hypotension, cramps/leg cramps, nausea, headache, vomiting & diarrhea. Some of these symptoms may be seen in patients with chronic renal failure or on hemodialysis not receiving intravenous iron.

**Use in Pregnancy & Lactation**
Pregnancy Category-B. This drug should be used during pregnancy only if clearly needed. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Iron Sucrose is administered to a nursing woman.

**Preparation**
Iron 20 mg/ml IV Injection (5 ml).

# Deflacort™

**Active Ingredient**
Deflazacort

**Indication**
•Anaphylaxis, asthma, severe hypersensitivity reactions •Rheumatoid arthritis, juvenile chronic arthritis, polymyalgia rheumatica •Systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease (other than systemic sclerosis), polyarteritis nodosa, sarcoidosis •Pemphigus, bullous pemphigoid, pyoderma gangrenosum •Minimal change nephrotic syndrome, acute interstitial nephritis •Rheumatic carditis •Ulcerative colitis, Crohn's disease •Uveitis, optic neuritis •Autoimmune haemolytic anaemia, idiopathic thrombocytopenic purpura •Acute & lymphatic leukaemia, malignant lymphoma, multiple myeloma •Immune suppression in transplantation

**Dosage & Administration**
*Adults:* For acute disorders, up to 120 mg/day Deflacort™ (Deflazacort) may need to be given initially. Maintenance doses in most conditions are within the range 3 - 18 mg/day. *Rheumatoid arthritis:* The maintenance dose is usually within the range 3 - 18 mg/day. The smallest effective dose should be used & increased if necessary. *Bronchial asthma:* In the treatment of an acute attack, high doses of 48-72 mg/day may be needed depending on severity & gradually reduced once the attack has been controlled. For maintenance in chronic asthma, doses should be titrated to the lowest dose that controls symptoms. *Other conditions*: The dose of Deflacort™ (Deflazacort) depends on clinical need titrated to the lowest effective dose for maintenance. Starting doses may be estimated on the basis of ratio of 5mg prednisone or prednisolone to 6mg.
Hepatic Impairment: In patients with hepatic impairment, blood levels of may be increased. Therefore the dose of Deflacort™ (Deflazacort) should be carefully monitored & adjusted to the minimum effective dose. Renal Impairment- In renally impaired patients, no special precautions other than those usually

adopted in patients receiving glucocorticoid therapy are necessary.
Elderly
In elderly patients, no special precautions other than those usually adopted in patients receiving glucocorticoid therapy are necessary. The common adverse effects of systemic corticosteroids may be associated with more serious consequences in old age.
Children
There has been limited exposure of children to Deflazacort in clinical trials.
In children, the indications for glucocorticoids are the same as for adults, but it is important that the lowest effective dosage is used. Alternate day administration may be appropriate.
Doses of Deflacort™ (Deflazacort) usually lie in the range 0.25 - 1.5 mg/kg/day. The following ranges provide general guidance:
Juvenile chronic arthritis: The usual maintenance dose is between 0.25 - 1.0 mg/kg/day.
Nephrotic syndrome: Initial dose of usually 1.5 mg/kg/day followed by down titration according to clinical need.
Bronchial asthma: On the basis of the potency ratio, the initial dose should be between 0.25 - 1.0 mg/kg on alternate days.

D

**Contraindication & Precaution**
Hypersensitivity to or any of the ingredients. Patients receiving live virus immunisation.
The following clinical conditions require special caution & frequent patient monitoring is necessary: • A Cardiac disease or congestive heart failure (except in the presence of active rheumatic carditis), hypertension, thromboembolic disorders. Glucocorticoids can cause salt & water retention & increased excretion of potassium. Dietary salt restriction & potassium supplementation may be necessary. • Gastritis or oesophagitis, diverticulitis, ulcerative colitis if there is probability of impending perforation, abscess or pyogenic infections, fresh intestinal anastomosis, active or latent peptic ulcer. • Diabetes mellitus or a family history, osteoporosis, myasthenia gravis, renal insufficiency. • Emotional instability or psychotic tendency, epilepsy. • Previous corticosteroid-induced myopathy. • Liver failure. • Hypothyroidism & cirrhosis, which may increase glucocorticoid effect.
•Ocular herpes simplex because of possible corneal perforation.

**Side Effect**
The incidence of predictable undesirable effects, including hypothalamic-pituitary-adrenal suppression correlates with the relative potency of the drug, dosage, timing of administration & the duration of treatment.
•Musculoskeletal such as osteoporosis etc. •Fluid & electrolyte disturbance such as oedema & heart failure etc. •Ophthalmic such as glaucoma, papilloedema etc. •Gastrointestinal such as dyspepsia, peptic ulceration etc. •General such as anaphylaxis & rare incidence of benign intracranial hypertension. Withdrawal symptoms & signs .Too rapid a reduction of corticosteroid dosage following prolonged treatment can lead to acute adrenal insufficiency, hypotension & death.

**Drug Interaction**
Rifampicin, rifabutin, carbamazepine, phenobarbital, phenytoin, primidone, aminoglutethimide, ketoconazole, insulin, acetazolamide & carbenoxolone may interact with Deflazacort.

**The following types of medicine may interact with Deflazacort**
Estrogens, hypoglycaemics, antihypertensives, diuretics, coumarin anticoagulants, nondepolarising, muscle relaxants, salicylates, antacids, oral contraceptives, vaccines, liver enzyme inducers, liver enzyme inhibitors, betaagonists & xanthines.

**Use in Pregnancy & Lactation**
*Pregnancy* – Deflazacort does cross the placenta. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation. As with all drugs, corticosteroids should only be prescribed when the benefits to the mother & child outweigh the risks.
Nursing Mother – Corticosteroids are excreted in breast milk, although no data are available

for Deflazacort. Doses of up to 50 mg daily of Deflazacort are unlikely to cause systemic effects in the infant. Infants of mothers taking higher doses than this may have a degree of adrenal suppression but the benefits of breast feeding are likely to outweigh any theoretical risk.

**Use in Children**
Corticosteroids cause dose-related growth retardation in infancy, childhood & adolescence which may be irreversible.

**Preparation**
6 mg, 24 mg, 30 mg tablet & 60 ml suspension.

# Depram®

**Active Ingredient**
Imipramine.

**Indication**
Depression, Nocturnal enuresis

**Dosage & Administration**
Depression :1 tab 3 times daily, Nocturnal. enuresis: 1Tab/ day for children≥ 6 years of age, before bedtime.

**Contraindication & Precaution**
Recent myocardial infarction, arrhythmias (particularly heart block), not indicated in manic phase, severe liver disease

**Side Effect**
Dry mouth, less sedation, blurred vision constipation, nausea, difficulty with micturation; cardiovascular side-effects, sweating, tremors, interference with sexual function; blood sugar changes.

**Drug Interaction**
Imipramine should not be used in combination with Monoamine Oxidase Inhibitors (MAOI), anticholinergic agents, antihypertensive agents, methylphenidate, levodopa, antipsychotic drug, cimetidine, barbiturates, & TCA.

**Use in Pregnancy & Lactation**
Treatment with Imipramine should be avoided during pregnancy, unless the anticipated benefits justify the potential risk to the fetus.

**Preparation**
25 mg Tablet.



# Deprex™

**Active Ingredient**
Olanzapine.

**Indication**
Acute & maintenance treatment of schizophrenia & related psychoses where positive symptoms (e.g. delusions, hallucinations, disordered thinking, hostility & suspiciousness), acute manic or mixed episodes in bipolar disorder.

**Dosage & Administration**
The recommended starting dose for Deprex is 10 mg/day, administered as a single daily dose without regard to meals.

**Contraindication & Precaution**
Hypersensitivity, narrow-angle glaucoma, prostatic hypertrophy, or paralytic ileus & related conditions. Neuroleptic Malignant Syndrome (NMS): unexplained high fever without additional clinical manifestations of

NMS, all antipsychotic medicines, including olanzapine must be discontinued. Olanzapine should be used cautiously in patients who have a history of seizures or have conditions associated with seizures.

**Side Effect**
Frequent: somnolence & weight gain. Occasional: dizziness, asthenia, akathisia, increased appetite, peripheral oedema, orthostatic hypotension, & mild, transient anticholinergic effects including constipation & dry mouth; transient, asymptomatic elevations of hepatic transaminases, ALT, AST.

**Preparation**
5 mg & 10 mg Tablet.



# De-rash®

**Active Ingredient**
Zinc Oxide.

**Indication**
De-rash (Zinc Oxide) helps treat & prevent diaper rash while it moisturizes & nourishes the skin. The zinc oxide based formulation provides a protective barrier on the skin against the natural causes of irritation. De-rash (Zinc Oxide) spreads onto baby's skin smoothly & be wiped off easily, without causing irritation to the affected area.

**Dosage & Administration**
Change wet & soiled diapers promptly, cleanse the diaper area & allow drying. Apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

**Contraindication & Precaution**
For external use only. When using this product avoid contact with eyes stop use & ask a doctor if condition worsens or does not improve within 7 days. This may be a sign of a serious condition. Keep out of reach of children. If swallowed, get medical help immediately.

**Side Effect**
Not known.

**Use in Children**
Recommended.

**Preparation**
25 gm ointment.

# Dermasol®

**Active Ingredient**
Clobetasol Propionate.

**Indication**
Eczema, psoriasis, hypertrophic lichen planus, localized bullous disorders, keloid scarring, pretibial myxoedema, vitiligo. Suppression of reaction after cryotherapy.

**Dosage & Administration**
Once or twice daily until improvement occurs, should not be continued for more than four weeks.

**Contraindication & Precaution**
Impetigo, tinea corporis & *Herpes simplex*, scabies, acne vulgaris, rosacea, gravitational ulceration.

**Side Effect**
Adrenal suppression, prolonged & intensive treatment with a highly active corticosteroid preparation may cause atrophic changes, such as thinning, striae & dilatation of the superficial blood vessels.

**Use in Pregnancy & Lactation**
Clobetasol Propionate should be avoided during pregnancy.

**Use in Children**
Should not be used children below the age of 12 years.

**Preparation**
20 gm cream & ointment.

# Dermasol-N®

**Active Ingredient**
Clobetasol Propionate BP, Neomycin Sulphate BP & Nystatin BP.

**Indication**

• Short courses treatment of eczemas infection or fungal infection is present, suspected or likely to occur.

• Neurodermatoses

• Psoriasis (excluding widespread plaque psoriasis) where secondary bacterial infection or fungal infection is present, suspected or likely to occur.

• Other inflammatory conditions which do not respond satisfactorily to less active steroids.

**Dosage & Administration**
Adults: Apply sparingly to the affected area once or twice daily until improvement occurs. In very resistant lesion, specially where there is hyperkeratosis, the anti-inflammatory effect of Dermasol-N can be enhanced (if necessary) by occluding the treatment area with polythene. Treatment should not be continued for more than 7 days without medical supervision. If a longer course is necessary, it is recommended that treatment should not be continued for more than 4 weeks without the patient's condition being reviewed.
Elderly: Dermasol-N is suitable for use in elderly. Caution should be exercised in cases where a decrease in renal function exists & significant systemic absorption of Neomycin Sulphate may occur.
Children: Dermasol-N is suitable for use in children (2 years & over) at the same dose as adults. A possibility of increased absorption exists in very young children, thus Dermasol-N is not recommended for use in neonates & infants (younger than 2 years).

**Contraindication & Precaution**
This medication is contraindicated in rosacea, acne vulgaris & perioral dermatitis, primary cutaneous viral infection (eg-*Herpes simplex*, chicken pox) & hypersensitivity to the preparation.

**Side Effect**
Prolonged use of large amount or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercortisolism. The effect is more likely to occur in infants & children & if occlusive dressings are used. Prolonged & intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as thinning, striae, & dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or when skin folds are involved. There are reports of pigmentation changes & hypertrichosis with topical steroids.

**Use in Pregnancy & Lactation**
There is little information to demonstrate the

possible effect of topically applied Neomycin in pregnancy & lactation. However, Neomycin present in the maternal blood can cross the placenta & may give rise to a theoretical risk of foetal toxicity, thus the use of the preparation is not recommended in pregnancy & lactation. The safety of Clobetasol Propionate has not been established in lactating mothers.

**Preparation**
15 gm Cream & Ointment.



# Dermasol®-S

**Active Ingredient**
Clobetasol Propionate.

**Indication**
It is indicated in the topical therapy of recalcitrant corticosteroid-responsive dermatitis of the scalp, including recalcitrant cases of psoriasis & seborrheic dermatitis.

**Dosage & Administration**
Apply required quantity of spray once or twice daily to the affected areas of the scalp & gently rub in.

**Contraindication & Precaution**
It is contraindicated in condition like-
•Infections of the scalp
•Hypersensitivity to the preparation
•Use is not indicated in dermatitis in children under one year of age
Care must be taken to keep the preparation away from the eyes. Long-term continuous therapy with Clobetasol Propionate Scalp Solution should be avoided where possible, particularly in infants & children, as adrenal suppression can occur even without occlusion. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalized pustular psoriasis & development of local or systemic toxicity due to impaired barrier function of the skin. If used on psoriasis, careful patient supervision is important. Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy & systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, & so the skin should be cleansed before a fresh dressing is applied.

**Side Effect**
As with other corticosteroids, prolonged use of large amounts or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercortisolism. This effect is more likely to occur in infants & children, & if occlusive dressings are used. Local atrophy may occur after prolonged treatment. In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease. If signs of hypersensitivity appear with the use of Clobetasol Propionate Scalp Solution then application should be stopped immediately.

**Drug Interaction**
Drug interaction may be observed with other potential corticosteroid containing preparation.

**Use in Pregnancy & Lactation**
Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established; however, topical steroids should not used extensively in pregnancy, i.e. in large amounts for prolonged periods. The safe use of Clobetasol Propionate during lactation has not been established.

**Use in Children**
Not recommended for use in children under one year of age.

**Preparation**
Each container contains 25 ml Solution.

# Dexonex®

**Active Ingredient**
Dexamethasone.

**Indication**
Various types of dermatological disorders & allergic disorders; severe respiratory disorders like - severe bronchial asthma, non-specific chronic obstructive lung disease; primary / secondary adrenocortical insufficiency; Ocular inflammatory conditions which are unresponsive to topical corticosteroids; adjunctive therapy for various rheumatic disorders; other indications where glucocorticoid therapy is required.

**Dosage & Administration**
In general dexamethasone dosage depends on the severity of the condition & the response of the patient.
Adults: Daily oral dosages vary from 1 to 10 mg, according to individual response.
Children: Daily oral dosages vary from 0.03-0.20 mg/kg body weight, according to the individual response.

**Contraindication & Precaution**
Contraindicated in patients with gastric & duodenal ulcers; systemic & ophthalmic fungal infections; viral infections - varicella & herpes genitalis infections, viral infections of the eye; glaucoma & hypersensitivity to corticosteroids. The lowest possible dose of dexamethasone should be used to control the condition under treatment. The reduction should be gradual. Dexamethasone should be used with caution in patient with osteoporosis, cardiomyopathy, hypertension, renal insufficiency & latent tuberculosis.

**Side Effect**
Endocrine & metabolic disturbances, fluid & electrolyte disturbances, musculo-skeletal effects, gastro-intestinal effects, dermatological effects, ophthalmic effects, CNS effects & immunosuppressive effects have been associated with prolonged systemic glucocorticoid therapy.

**Use in Pregnancy & Lactation**
US FDA pregnancy category C. Glucocorticoids appear in breast milk. Mothers taking high dosages of corticosteroids should be advised not to breast-feed.

**Use in Children**
In order to minimize the potential growth effects of corticosteroids, pediatric patients should be titrated to the lowest effective dose.

**Preparation**
0.5 mg Tablet & 5 mg/ml IV or IM Injection.



# Dexonex-C™ Eye/Ear Drops

**Active Ingredient**
Dexamethasone Phosphate & Chloramphenicol.

**Indication**
*Eye:* For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated & where bacterial infection or a risk of bacterial ocular infection exists. It is also indicated in chronic anterior uveitis & corneal injury from chemical radiation or thermal burns or penetration of foreign bodies. The combination can also be used for post-operative inflammation & any other ocular inflammation associated with infection.
*Ear:* Otitis externa, Otitis media & chronic suppurative otitis media.

**Dosage & Administration**
*Eye:* Bacterial Conjunctivitis: The recommended dosage regimen for the treatment of bacterial

conjunctivitis is one or two drops instilled into the conjunctival sac(s) every two hours while awake for two days & one or two drops every four hours while awake for the next five days.
*Ear:* For all infections two to three drops every two to three hours initially. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

**Contraindication & Precaution**
Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella & in many other viral diseases of the conjunctiva & cornea. Mycobacterial infections of the eye, Fungal diseases of ocular structures. Hypersensitivity to any of the components of the medication.
The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid dosing.



**Use in Pregnancy & Lactation**
US FDA Pregnancy category C. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when Dexamethasone ophthalmic solution is administered to a nursing woman.

**Use in Children**
Safety & efficacy in pediatric patients have not been established.

**Side Effect**
Adverse reactions seen with Chloramphenicol are transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, conjunctivitis/keratitis, periocular/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness & eye pain.

**Preparation**
(Dexamethasone Sodium Phosphate 1 mg & Chloramphenicol 5 mg)/ ml sterile solution.

# Dibenol®

**Active Ingredient**
Glibenclamide.

**Indication**
For the management of Diabetes Mellitus.

**Dosage & Administration**
Half tablet (2.5 mg) to 3 tablets. Daily doses as directed by the physician & depending on blood sugar level.

**Contraindication & Precaution**
Glibenclamide is contraindicated in patients with-·Known hypersensitivity to the drug or any of its excipients
·Type 1 diabetes or diabetic ketoacidosis, with or without coma
This contraindicated should be treated with insulin.

**Side Effect**
Nausea, vomiting, epigastric pain, dizziness, weakness, paraesthesia & headache. Allergic skin reactions & haemopoietic reactions (leukopenia, thrombocytopenia, etc.).

**Drug Interaction**
Alcohol, cyclophosphamide, dicoumarol, monoamino oxidase inhibitors, phenylbutazone, propranolol & other beta-adrenergic blocking agents.

**Use in Pregnancy & Lactation**
There is no information on the use of glibenclamide in human pregnancy.

**Preparation**
5 mg Tablet.

# Diliner® DR

**Active Ingredient**
Duloxetine.

**Indication**
Depression, Anxiety, Diabetic Peripheral Neuropathic Pain, Osteoarthritis pain, Fibromyalgia.

**Dosage & Administration**
30-60 mg/day (given either once a day or as 30 mg BID) without regard to meals.

**Contraindication & Precaution**
Known hypersensitivity to Duloxetine. Concomitant use in patients taking Monoamine Oxidase Inhibitors (MAOIs) is contraindicated. Duloxetine use should be avoided in patients with uncontrolled narrow-angle glaucoma.

**Side Effect**
In Duloxetine-treated MDD patients: nausea; dry mouth; constipation; decreased appetite; fatigue; somnolence; & increased sweating. In Duloxetine-treated DPN patients: nausea; somnolence; dizziness; constipation; dry mouth; decreased appetite; & asthenia.

**Drug Interaction**
Inhibitors of CYP1A2- Fluvoxamine, quinolone antibiotics, CYP2D6 inhibitors (e.g., Paroxetine, fluoxetine, quinidine), Thioridazine, alcohol & other CNS acting drugs.

**Use in Pregnancy & Lactation**
The drug should be used during pregnancy only when the potential benefits justify the possible risk to the fetus. Women receiving the drug should not breastfeed their infants.

**Preparation**
30 mg & 60 mg DR (Delayed Release) Capsule.

# Diltizem® SR

**Active Ingredient**
Diltiazem.

**Indication**
Angina pectoris, Hypertension with tachycardia.

**Dosage & Administration**
90 - 120 mg twice daily up to 240 mg.

**Contraindication & Precaution**
Known hypersensitivity, sick sinus syndrome, second or third degree AV block, severe hypertension or acute myocardial infarction & pulmonary congestion.

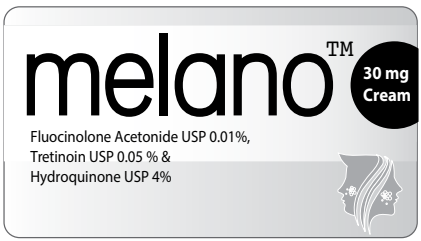
**Side Effect**
Bradycardia, sino-atrial block, atrioventricular block, hypertension, malaise, headache, hot flushes, GIT disturbances, oedema, hepatitis & depression reported.

**Drug Interaction**
Caution & careful dosage titration when diltiazem is administered concomitantly with other drugs that can affect cardiac contractility and/or conduction.

**Use in Pregnancy & Lactation**
The drug should be used during pregnancy only when the potential benefits justify the possible risk to the fetus. Women receiving the drug should not breastfeed their infants.

**Preparation**
90 mg SR Tablet.





# Dormitol®

**Active Ingredient**
Midazolam.

**Indication**
Midazolam is used as:
• Hypnotic & hence it is used for short term management of insomnia.
• Sedative & hence it relieves anxiety, tension & fear
• Pre-anaesthetics
• Anticonvulsants

**Dosage & Administration**
The duration of treatment with oral midazolam should not be more than of 2 weeks.
In certain cases extension beyond the maximum treatment period may be necessary.
*Insomnia:* Adults: -7.5 mg to 15 mg daily.
Elderly: -7.5 mg daily.
*Premedication:* 7.5 mg to 15 mg, should be given 30-60 minutes before the procedure.
*Endoscopic or Cardiovascular procedures:*
Adult: Initial dose is 2.5 mg (IV).
Elderly & debilitated patients: 1-1.5 mg (IV).
*Induction of Anesthesia:* Adult: 10-15 mg (IV) or 0.07-0.1 mg/Kg body weight, usually 5 mg (IM).
Children: 0.15-0.20 mg/Kg (IM).

**Elderly & debilitated patients**
0.025-0.05 mg/Kg (IM).
Rectal administration in children: for preoperative sedation, rectal administration of the ampoule solution is 0.35-0.45 mg/Kg, 20-30 min before induction of general anesthesia.

**Contraindication & Precaution**
Known hypersensitivity to Midazolam or other benzodiazepines, severe respiratory, insufficiency, severe hepatic insufficiency, sleep apnea syndrome, myasthenia gravis, patients with a history of alcohol or drug abuse & children.
CNS depressants, erythromycin, azole type animycotics & cimetidine may interfere the metabolism of Midazolam. So caution should be taken during the concomitant treatment with these drugs along with Midazolam. Long time use of Midazolam may increase dependency. As Midazolam is a strong sedative, it should not be taken before driving or other performance skilled tasks.

**Side Effect**
Drowsiness is the most common side Effect. Less common side effects are CNS depression, ataxia, confusion, tiredness, muscle weakness, fatigue, headache, dizziness & double vision. These effects occur predominantly at the start of treatment & usually disappear with dose adjustment or continuation of therapy.

**Use in Pregnancy & Lactation**
· Pregnancy category D
· Breastfeeding is not recommended during treatment

**Preparation**
7.5 mg tablet & 15 mg/3ml injection.

D

# Doxacil

**Active Ingredient**
Doxycycline

**Indication**
Doxacil® capsule has a very wide spectrum of activities and has been used in the treatment of a large number of infections caused by susceptible organisms. Respiratory tract infections: Pneumonia, influenza, pharyngitis, tonsillitis, bronchitis, sinusitis, otitis media and other streptococcal and staphylococcal infections where tetracycline resistance is not a problem. Genitourinary tract infections: Pyelonephritis, cystitis, urethritis, gonorrhea, epididymitis, syphilis, chancroid and granuloma inguinale. Chlamydia: Lymphogranuloma venereum, psittacosis, trachoma. Intestinal diseases: Whipples disease, tropical sprue,

blind loop syndrome. In acute intestinal amoebiasis, Doxacil® may be a useful adjunct to amoebicides. Bacillary infections: Brucellosis, tularemia, cholera, traveler's diarrhea. Acne: Acne vulgaris, acne conglobata and other forms of acne. Other infections: Actinomycosis, yaws relapsing fever, leptospirosis, typhus, rickettsial pox and Q fever, Cellulitis, furunculosis, abscess and infections caused by Mycobacterium marinum, Bordetella pertussis and Bacillus anthracis.

**Dosage & Administration**
Adults: Two capsules at a time or one capsule every 12 hours for the first day followed by one capsule per day. The dosage may be doubled on severity of the infection. Children: (Over 8 years or weighing 45 Kg or less): 4.4 mg/Kg on the first day followed by 2.2 mg/Kg daily. Acute gonococcal urethritis: 1 capsule twice daily for 2 to 4 days in male and until a cure has been obtained in female. Chlamydial infections: 1 capsule twice daily for 7 days. Syphilis: 3 capsules in divided doses for 10 days.

**Contraindication & Precaution**
It is contraindicated to patients with known hypersensitivity to any of the Tetracyclines. It is also contraindicated in severe hepatic disorder and patients with systemic lupas erythematosus. Concomitant intake of alkalis, antacids and iron may interfere with the absorption of Doxycycline. It is advisable to avoid giving doxycycline in conjunction with penicillin. Doxycycline should not be used in pregnant women unless, in the judgment of the physician, it is essential for the welfare of the patient. The use of drugs of tetracycline group during tooth development (last half of pregnancy, infancy and childhood to the age of 12 years) may cause permanent discoloration of the teeth. Tetracyclines, therefore, should not be used in this age group unless other drugs are not likely to be effective or are contraindicated.

**Side Effect**
Doxycycline may produce gastrointestinal irritation to a varying degree in some individuals. Epigastric distress, abdominal discomfort, nausea, and vomiting may occur. Long term therapy with Doxycycline may produce hematological changes. Various skin reactions including rashes, urticaria, exfoliative dermatitis may follow the use of Doxacil® but they are rare.

**Preparation**
100 mg Capusle

# Duolax™

**Active ingredient**
Magnesium Hydroxide & Liquid Paraffin.

**Indication**
Constipation, Hyperacidity with constipation, Anorectal disorder, Post-operative constipation, constipation associated with chronic cholecystitis, Hernia.

**Dosage & Administration**
The recommended oral doses are as follows-
*Adults:* 15-30ml before breakfast or at bedtime.
*Children:* Over 7 years: 7.5ml-15ml at bedtime. 3-7 years: 5-10ml at bedtime. The dose may be mixed with milk or half a glass of water if desired.

**Contraindication & Precaution**
Acute GI conditions like abdominal pain.
**Side Effect**
Rectal irritation, potassium loss (thirst, weakness, nausea & diarrhea).

**Drug Interaction**
Cimetidine, Diuretics, Famotidine & Ranitidine may cause irritation of stomach or bowel.

**Use in Pregnancy & Lactation**
Can be given to pregnant women & lactating mothers only if physician recommends.

**Use in Children**
Safe for children over 03 years. Can be given to children under 03 years if physician recommends.

**Preparation**
Each 5 ml oral emulsion contains 300 mg Magnesium Hydroxide USP & 1.25 ml liquid paraffin BP.

# Durol®



**Active ingredient**
Carvedilol

**Indication**
Congestive Heart Failure: Carvedilol is indicated for the treatment of mild or moderate heart failure of ischemic or cardiomyopathic origin, in conjunction with digitalis, diuretics and ACE inhibitors, to reduce the progression of disease as evidenced by cardiovascular death, cardiovascular hospitalization, or the need to adjust other heart failure medications. Carvedilol may be used in patients unable to tolerate an ACE inhibitor. Carvedilol may be used in patients who are or are not receiving digitalis, hydralazine or nitrate therapy. Hypertension: Carvedilol is also indicated for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents especially with thiazide type diuretics.

**Dosage & Administration**
Hypertension: Initially 12.5 mg once daily, increased after 2 days to usual dose of 25 mg once daily; if necessary may be further increased at intervals of at least 2 weeks to max.50 mg daily in single or divided doses; Elderly: Initial dose of 12.5 mg daily may provide satisfactory control. Angina: Initially 12.5 mg twice daily, increased after 2 days to 25 mg twice daily. Heart failure (under special supervision): Initially 3.125 mg twice daily (with food), dose increased at intervals of at least 2 weeks to 6.25 mg twice daily, then to 12.5 mg twice daily, then to 25 mg twice daily, increase to highest dose tolerated, maximum 25 mg twice daily in patients with severe heart failure or body-weight less than 85 kg and 50 mg twice daily in patients over 85 kg.

**Contraindication**
Carvedilol is contraindicated in patients with severe chronic cardiac failure requiring intravenous inotropic therapy, bronchial asthma or related bronchospastic conditions, second or third-degree AV block, sick sinus syndrome (unless a permanent pacemaker is in place), cardiogenic shock, or severe bradycardia. Use of carvedilol in patients with clinically manifested hepatic impairment is not recommended. Carvedilol is contraindicated in patients with hypersensitivity to the drug.

**Side Effect**
In general carvedilol is well tolerated at doses up to 50 mg daily. Most adverse events reported were of mild to moderate. These are postural hypotension, dizziness, headache, fatigue, gastro-intestinal disturbances, bradycardia, occasionally diminished peripheral circulation, peripheral oedema and painful extremities, dry mouth, dry eyes, eye irritation or disturbed vision, impotence, disturbances of micturition, influenza like symptoms, rarely angina. AV block exacerbation of intermittent claudication or Raynaud's phenomenon; allergic skin reactions, exacerbation of psoriasis, nasal stuffiness, wheezing, depressed mood, sleep disturbances, paraesthesia, heart failure, changes in liver enzymes, thrombocytopenia, leucopenia also reported.

**Drug Interaction**
Drug interactions have been seen with co-

administration of carvedilol and digoxin, resulting in an increased bioavailability of digoxin. This increase is not clinically significant and does not correlate with pharmacologic response. Pharmacokinetics studies demonstrated a lack of drug interaction between carvedilol and hydrochlorothiazide, cimetidine, torsemide and warfarin.

**Use in Pregnancy & Lactation**
There is no evidence from animal studies that carvedilol has any teratogenic effects. Embryotoxicity was observed only after large doses in rabbits. Animal studies have showed that carvedilol crosses the placental barrier and is excreted in breast milk and therefore the possible consequences of alpha and beta blockade in the human foetus and neonate should be borne in mind. Carvedilol is therefore not recommended for use in pregnancy or in breast-feeding mothers.

**Use in Children**
The safety and efficacy of carvedilol in paediatric patients have not been established.

H**Preparation**
6.25 mg tablet.

# Dyvon™

**Active Ingredient**
Calcipotriol.

**Indication**
Calcipotriol ointment is indicated for the topical treatment of chronic stable plaque type psoriasis vulgaris in adult patients.

**Dosage & Administration**
*Adults:* Calcipotriol ointment should be applied topically to the affected area twice daily (i.e. in the morning & in the evening). Less frequent application may be indicated after the initial period of treatment. After satisfactory improvement has occurred, treatment should be discontinued. If recurrence takes place after discontinuation, the treatment may be reinstituted. Experience is lacking in the use of Calcipotriol for periods longer than 1 year.

**Contraindication & Precaution**
Betamethasone & Calcipotriol Ointment is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. It is also contraindicated in patients with known disorders of calcium metabolism. Patients with severe renal insufficiency or severe hepatic disorders are also contraindicated.
The patient must be instructed on correct use of the product to avoid application and/or accidental transfer to the scalp, face, mouth or eyes. Betamethasone & Calcipotriol Ointment is not recommended for use on the face since it may give rise to itching & erythema of the facial skin. Treatment of more than 30% of the body surface should be avoided. Patients should be instructed to wash their hands after using Betamethasone & Calcipotriol Ointment, to avoid inadvertent transfer of Ointment to the face from other body areas.

**Drug Interaction**
There is no experience of concomitant therapy with other antipsoriatic drugs applied to the same skin area.

**Use in Pregnancy & Lactation**
*Pregnancy:* Safety for use in pregnancy has not been established. Therefore Calcipotriol should not be used during pregnancy unless benefits clearly outweigh the risks.
*Lactation:* It is not known whether Calcipotriol is excreted in breast milk, therefore, the drug should be used during lactation only if the

benefits clearly out weigh the risks. Calcipotriol should not be applied to the chest area during breast feeding to avoid possible ingestion by infants.

**Use in Children**
Calcipotriol Ointment should not be used in children, as there is inadequate experience with its use.

**Preparation**
20 gm Ointment.

E

# Dyvon™ Plus

**Active Ingredient**
Betamethasone Dipropionate & Calcipotriol.

**Indication**
Dyvon™ Plus Ointment & Topical Suspension is indicated for the topical treatment of plaque type psoriasis of the scalp & body.

**Dosage & Administration**
Apply required quantity of Ointment & spray of Topical Suspension once daily to the affected areas & gently rub in using the tips of the fingers. Treatment may be continued for up to 8 weeks. Treatment may be discontinued earlier, if symptoms are cleared. The maximum weekly dose should not exceed 100 gm. Shake before use. Dyvon™ Plus Ointment & Topical Suspension is not for oral, ophthalmic or intravaginal use.

**Contraindication & Precaution**
Betamethasone & Calcipotriol containing preparation is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. It is also contraindicated in patients with known disorders of calcium metabolism. Patients with severe renal insufficiency or severe hepatic disorders are also contraindicated.

Hypercalcemia & hypercalciuria have been reported. If either occurs, discontinue until parameters of calcium metabolism normalize. Topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome & unmask latent diabetes. Rate of adrenal suppression increased with treatment duration. Systemic absorption may require evaluation for HPA axis suppression. Modify use if HPA axis suppression develops. Potent corticosteroids, use on large areas, prolonged use or occlusive use may increase systemic absorption. Local adverse reactions may include atrophy, striae, irritation, acne form eruptions, hypopigmentation, & allergic contact dermatitis & may be more likely with occlusive use or more potent corticosteroids. Use is not recommended on face, axillae, groin or where atrophy is present. Children may be more susceptible to systemic toxicity when treated with topical corticosteroids.

**Side Effect**
The most common adverse reactions are folliculitis & burning sensation of skin.

**Use in Pregnancy & Lactation**
There are no adequate & well-controlled studies in pregnant women. Ointment & Suspension should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus. Systemically administered corticosteroids appear in human milk & could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topically administered calcipotriene or corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs

are excreted in human milk, caution should be exercised when Calcipotriol & Betamethasone Ointment or Suspension is administered to a nursing woman.

**Use in Children**
Dyvon™ Plus Ointment & Topical Suspension is not recommended for use in children & adolescents below the age of 18 years.

**Preparation**
20 gm Ointment & 25 ml Topical Suspension.

# Efaxim™

**Active Ingredient**
Rifaximin

**Indication**
Treatment of traveler's diarrhea by noninvasive strains of E. coli, reduction in risk of hepatic encephalopathy & bacterial over growth of irritable bowel syndrome

**Dosage & Administration**
Traveler's Diarrhea: For patients >12 years of age - 200 mg 3 times daily for 3 days.
Hepatic Encephalopathy: For patients >18 years of age - 550 mg 2 times daily.
Bacterial over growth of irritable bowel syndrome: 400 mg 3 times daily for 10 days or 550 mg 3 times daily for 14 days.
Rifaximin can be taken with or without food.

**Contraindications & Precautions**
Contraindicated in patients with a hypersensitivity to Rifaximin or to any of the rifamycin antimicrobial agents, or any components of this product.
Rifaximin is not found to be effective in patients with diarrhea complicated by fever and/or blood in the stools. Rifaximin therapy should be discontinued if diarrhea symptoms get worse or persist for more than 24-48 hours and an alternative antibiotic therapy should be considered. Pseudo membranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

**Side Effects**
Side effects include flatulence, headache, abdominal pain, rectal tenesmus, defecation urgency, nausea, constipation, pyrexia, vomiting.

**Drug Interaction**
In an invitro study has suggested that Rifaximin induces CYP3A4. However, in patients with normal liver function, Rifaximin at the recommended dosing regimen is not expected to induce CYP3A4.

**Use in Pregnancy & Lactation**
Pregnancy category C. It is not known whether Rifaximin is excreted in mother's milk or not.

**Preparation**
Efaxim™ 200 tablet: Each box contains 10's tablets in alu -alu blister.
Efaxim™ 550 tablet: Each box contains 10's tablets in alu -alu blister.

# Elorim™ cream

**Active Ingredient**
Eflornithine Hydrochloride 13.9%

**Composition**
Each gm cream contains Eflornithine Hydrochloride 139 mg as Eflornithine Hydrochloride Monohydrate INN.

**Dosage & Administration**
Apply a thin layer of ElorimTM Cream to affected areas of the face and adjacent involved areas under the chin and rub in thoroughly. Do not wash treated area for at least 4 hours. Use twice daily at least 8 hours apart or as directed by a physician.

**Contraindication & Precaution**
This preparation is contraindicated in patients with a history of sensitivity to any components of the preparation. For external use only. Transient stinging or burning may occur when applied to abraded or broken skin.

**Side Effect**
Acne, Headache, Dry Skin, itching, Rash, Folliculitis may occasionally occur.
Drug Interaction: It is not known if ElorimTM Cream has any interaction with other topically applied drug products.

**Pregnancy & Lactation**
Pregnancy Category C. It is not known whether or not Eflornithine Hydrochloride is excreted in human milk. Caution should be exercised when this Cream is administered to a nursing woman.

**Pediatric Use**
The safety and effectiveness of this product have not been established in pediatric patients less than 12 years of age.

**Preparation**
30 gm Cream.

# Emcil®

**Active Ingredient**
Pivmecillinam.

**Indication**
For treatment of infections caused by mecillinam-sensitive organisms e.g. acute cystitis, complicated urinary tract infections, salmonellosis, shigellosis, enteropathic *E.coli* diarrhoea, Gram-negative septicaemia, billiary infections.

**Dosage & Administration**
Adults: The usual dose is 1-2 tablets 3 times daily according to severity of the infection. Children: weighing less than 20 kg should be given 20-60 mg/kg divided into 3-4 daily doses. Those weighing more than 20 kg should receive normal adult dose. The tablet should be taken with at least 50-100 ml fluid.

**Contraindication & Precaution**
There have been no reports on allergy to Pivmecillinam among patients with a known history of hypersensitivity to penicillins & cephalosporins.

**Side Effect**
Generally well tolerated, gastrointestinal disturbances such as nausea, vomiting & diarrhoea or indigestion may occur when a dose has been given on an empty stomach. Skin rashes have been reported in some cases.

**Use in Pregnancy & Lactation**
Pivmecillinam in pregnancy should be prescribed when the expected benefits are considered to be greater than the potential risk. Mecillinam is not excreted into the milk of lactating mother.

**Preparation**
200 mg Tablet.

# Emolent™ Cream & Lotion

**Active Ingredient**
Light liquid paraffin and White soft paraffin

**Indication**
Cream & Lotion are used for the treatment of dry skin conditions.

**Dosage & Administration**
Light Liquid paraffin and White soft paraffin cream & lotion are used when required. Apply to the affected area and rub in well. It is specially effective after washing when the sebum content of the stratum corneum may be depleted after washing resulting in excessive moisture loss.

**Contraindication**
Hypersensitivity to any of the ingredients of this cream.

**Side Effect**
No remarkable adverse effects have been reported.

**Use in Pregnancy & Lactation**
There are no restrictions on the use during pregnancy or lactation.

**Preparation**
25 gm cream & 120 ml lotion.

# Entacyd®

**Active Ingredient**
Aluminum Hydroxide & Magnesium Hydroxide.

**Indication**
Hyperacidity, peptic ulcer, gastritis, heartburn, sour stomach & dyspepsia.

**Dosage & Administration**
Two tablets/two teaspoonful suspension 1-3 hours after meal & at bed time.

**Contraindication & Precaution**
Hypophosphatemia, hypermagnesemia.

**Side Effect**
Long term use may cause alkaluria, & nephrolithiasis.

**Preparation**
Chewable tablet & Suspension.

# Entacyd® Plus

**Active Ingredient**
Aluminum Hydroxide, Magnesium Hydroxide & Simethicone

**Indication**
Hyperacidity, peptic ulcer, gastritis, peptic oesophagitis, gastric hyperacidity, heartburn, sour stomach or hiatus hernia.

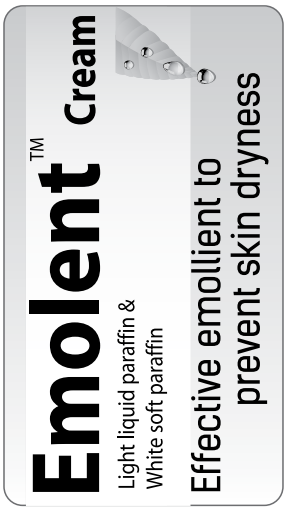
**Dosage & Administration**
1-2 tablets/1-2 teaspoonful suspension 1-3 hours after meal & at bed time.

**Contraindication & Precaution**
Renal failure or hypophosphatemia, alkalosis, hypermagnesemia.

**Side Effect**
Diarrhea, constipation or regurgitation.

**Preparation**
Chewable Tablet & Suspension.






# Epitra®

**Active Ingredient**
Clonazepam.

**Indication**
Anxiety as well as panic disorder, with or without agoraphobia. Epilepsy & other seizure disorders, alone or as an adjunct in the management of myoclonic & akinetic seizures & petit mal variant (Lennox-Gastaut syndrome).

**Dosage & Administration**
Children : Infants & children (up to 10 years of age or 30 kg of body weight)-Between 0.01 & 0.03 mg/kg/day & should not exceed 0.05 mg/kg/day given in 2 or 3 divided doses. Dosage should be increased by no more than 0.25 to 0.50 mg every third day until a maintenance dose of 0.1 to 0.2 mg/kg of body weight has been reached, unless seizures are controlled or side effects preclude further increase. Adults : Initial dose should not exceed 1.5 mg/day divided into three doses. Dosage may be increased in increments of 0.5 to 1 mg every three days until seizures are adequately controlled. Maintenance dose for adults is 8 to 10 mg/day in three divided doses.

**Contraindication & Precaution**
Significant liver disease, narrow angle glaucoma, sensitivity to benzodiazepines. Gradual withdrawal is essential when discontinuing clonazepam. When used in patients in whom several different types of seizures co-exist, clonazepam may increase the incidence or precipitate the onset of generalized tonic-clonic seizures.

**Use in Pregnancy**
The drug should be used during pregnancy & lactation if potential benefit justifies the potential risk to the fetus.

**Side Effect**
Drowsiness, Ataxia, Behaviour problems & increased salivation.

**Drug Interaction**
Alcohol, narcotics, barbiturates, nonbarbiturate hypnotics, antianxiety agents, phenothiazines, anticonvulsant drugs, mono amino oxidase inhibitors & tricyclic antidepressants.

**Preparation**
0.5 mg, 1 mg & 2 mg Tablet .

# Eporen™

**Active Ingredient**
Erythropoietin BP

**Indication**
Erythropoietin is indicated for the treatment of-
•Anemia associated with Chronic Kidney Disease.
•Anemia associated with chemotherapy in non-myeloid malignancy.
•Anemic patients scheduled to undergo elective, noncardiac , nonvascular surgery.
•Anemia associated with Zidovudine therapy in HIV patients.

**Dosage & Administration**
Dosage
Anemia in Chronic Renal Failure:
Starting dose
Adult: 50 to 100 IU/kg thrice in a week by IV or SC route
Pediatric: 50 IU/kg thrice in a week by IV or SC route
Dose adjustment: Dose should be increased if hematocrit level does not increase by 5 to 6 points after 8 weeks therapy, and hematocrit level is below suggested target range. Dose should be reduced when hematocrit level approaches 36% or hematocrit level increases >4 points in any 2 week period.
Maintenance dose: Maintenance dose must be individualized for each patient. In patients undergoing dialysis, the median maintenance dose is 75 IU/kg thrice in a week, with a range from 12.5 to 525 IU/kg thrice in a week or as directed by the physician.
If patient is not on dialysis, maintenance dose is 75 to 150 IU/kg/week.

Anemia in Cancer Patients on Chemotherapy:
Starting dose
Adult: 150 IU/kg thrice in a week by SC route or 40,000 IU/SC route weekly
Pediatric: 25 to 300 IU/kg 3 to 7 times per week by SC or IV route
Dose adjustment: If the response is not satisfactory, the dose should be increased to 300 IU/kg thrice in a week. If the hematocrit level exceeds 40%, the dose should be withheld until the hematocrit level falls to 36%. The dose should be reduced to 25% when treatment is resumed and titrated to maintain the desired hematocrit level.
Zidovudine-treated HIV-infected Patients:
Starting dose
Adult: 100 IU/kg as an IV or SC injection thrice in a week for 8 weeks
Pediatric: 50 to 400 IU/kg 2 to 3 times per week by SC or IV route
Dose adjustment: If the response is not satisfactory, the dose should be increased by 50-100 IU/kg thrice in a week. Response should be evaluated every 4 to 8 weeks thereafter and the dose should be adjusted accordingly by 50 to 100 IU/kg increments thrice in a week.
Maintenance dose: The dose requires titration to maintain the hematocrit level between 33-36%.
Surgery Patients:
300 IU/kg/day by SC route for 10 days before surgery, on the day of surgery, and for 4 days after surgery. An alternate dose schedule is 600 IU/kg by SC route once weekly (21,14, and 7 days before surgery) & a fourth dose on the day of surgery.

Administration
a) Do not shake. It is not necessary to shake Eporen. Prolonged vigorous shaking may denature any glycoprotein, rendering it

biologically inactive. b) Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. c) Administer as intravenous injection over 1-2 minutes. In patients on dialysis, the injection should follow the dialysis procedure. Slow injection over 5 minutes may be beneficial to those who experience flu-like symptoms. d) Do not administer by intravenous infusion or in conjunction with other drug solutions. e) For the subcutaneous route, a maximum of 1 mL at one injection site should generally not be exceeded. In the case of larger volumes, more than one site should be chosen for the injection.

**Contraindication & Precaution**

Erythropoietin is contraindicated in patients with: • Uncontrolled hypertension; • Known hypersensitivity to mammalian cell-derived products; • A history of hypersensitivity to Erythropoietin or any component of the preparation.

Erythropoietin should be used with caution in those patients with controlled hypertension, ischaemic vascular disease, history of seizures, or suspected allergy to the product. Iron evaluation: Prior to and during Eporen therapy, the patient's iron stores, including transferrin saturation and serum ferritin, should be evaluated. Transferrin saturation should be at least 20%, and ferritin should be at least 100 ng/m l. virtually all patients will require supplemental Iron to increase or maintain transferrin saturation to levels that will adequately support erythropoiesis.

**Side Effect**

General: Headache, dizziness, fever, malaise, arthralgia and occasionally hyperkalemia. Cardiovascular: Hypertension is the most common side effect, palpitations. Gastrointestinal: Nausea, vomiting, anorexia and diarrhea may occur occasionally. Allergic reactions.

**Use in Pregnancy & Lactation**

Pregnancy Category C. Since there are no controlled studies of erythropoietin in pregnant women, and because animal reproduction studies are not always predictive of human responses, erythropoietin should be used during pregnancy only if clearly needed. Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when erythropoietin is administered to a nursing woman.

**Preparation**

Eporen™ 3000 IU: Each box contains 1 Pre-filled syringe containing 3000 IU of Recombinant Human Erythropoietin Alpha in Alu-PVC blister pack.

Eporen™ 5000 IU: Each box contains 1 Pre-filled syringe containing 5000 of Recombinant Human Erythropoietin Alpha in Alu-PVC blister pack.

# Equra®

**Active Ingredient**
Urea.

**Indication**
Ichthyosis & dry skin conditions, eczemas, psoriasis.

**Dosage & Administration**
Twice daily.

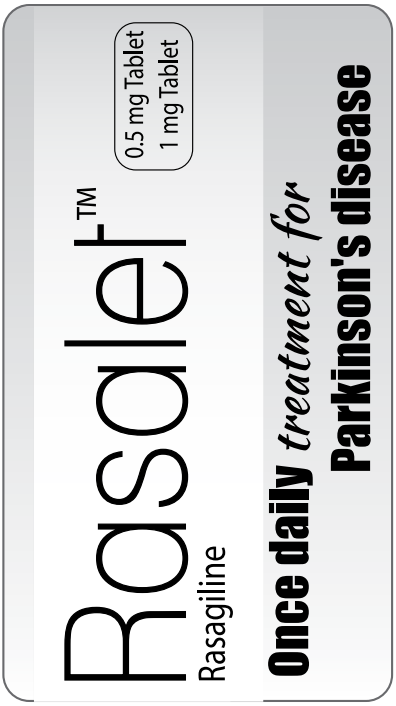
**Side Effect**
Burning & irritation, if applied to inflamed, broken or exudative skin eruptions.

**Use in Pregnancy & Lactation**
Equra cream can be used during pregnancy & lactation. Equra can be used in all age groups.

**Contraindication & Precaution**
Local irritation & edema, when applied to sensitive skin. If the condition is aggravated or there is no improvement the doctor should be consulted.

**Preparation**
10% Cream.





# Erian®

**Active Ingredient**
Cinchocaine Hydrochloride + Hydrocortisone + Framycetin Sulphate + Esculin.

**Indication**
Internal & external haemorrhoids; Haemorrhoids post-partum; Anal pruritus, peri-anal eczema, anal fissures & proctitis; Post-haemorrhoidectomy application to relieve pain & discomfort.

**Dosage & Administration**
***(1) Ointment:*** Apply the ointment in small quantity with the finger, on the painful or pruritic area, morning & evening and after each defecation. For deep application attach applicator/cannula (supplied) to tube, insert to full extent & squeeze tube gently from lower end whilst withdrawing.
(2) ***Suppository:*** one suppository at morning , one at evening & after each defecation.

**Contraindication & Precaution**
Known hypersensitivity to any of the four ingredients, during pregnancy, herpes simplex, vaccinia or varicella, or tuberculous infection of the anal region. Discontinue use if sensitization occurs. The possibility, however rare, that prolonged use of this preparation might produce systemic corticosteroid effects.

**Side Effect**
Long-term continuous treatment causes atrophic changes in the skin leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasia & ecchymoses.

**Use in Pregnancy & Lactation**
During pregnancy, it should not be used unnecessarily on extended areas, in large amounts or for prolonged periods of time.

**Drug Interaction**
Proper data is not available.

**Use in Children**
Not recommended.

**Preparation**
Ointment.

# Eromycin®

**Active Ingredient**
Erythromycin.

**Indication**
Alternative to a penicillin in penicillin-sensitive patients, penicillin-resistant staphylococcal infections, alternative to a tetracycline in mycoplasma pneumonia, pertussis, diphtheria-especially in treatment of the carrier state, rheumatic fever prophylaxis, chronic bronchitis, otitis media & chronic prostatitis.

**Dosage & Administration**
Adults : 1-2 gm daily in divided doses. Children : 30-50 mg/kg/day.

**Contraindication & Precaution**
Hypersensitivity to Erythromycines, impaired hepatic function.

**Side Effect**
Nausea, gastrointestinal disturbances & allergy being the commonest ( 0.5-5%) adverse effects.

**Drug Interaction**
Theophylline, Carbamazepine, Digoxin, Warfarin, Ergotamine.

**Use in Pregnancy & Lactation**
There is no evidence that the use of Erythromycin is hazardous in pregnancy though it does cross the placental barrier.

**Preparation**
500 mg Tablet, 125 mg/5 ml Dry Powder for Syrup & 200 mg/5 ml Paediatric Drops.

# Eromycin® Lotion

**Active Ingredient**
Erythromycin.

**Indication**
Acne, pimples & bacterial skin infections susceptible to Erythromycin.

**Dosage & Administration**
Apply in morning & evening to the affected areas.

**Contraindication & Precaution**
Hypersensitivity to any of its ingredients.

**Side Effect**
Erythema, desquamation, burning sensation, eye irritation, tenderness, dryness or oily skin.

**Drug Interaction**
Clindamycin interacts with Erythromycin.

**Use in Pregnancy & Lactation**
Use with caution.

**Preparation**
25 ml Lotion.

# Esloric®

**Active Ingredient**
Allopurinol.

**Indication**
Primary & secondary gout.

**Dosage & Administration**
Allopurinol should be introduced at low dosage e.g. 100mg/day to reduce the risk of adverse reactions & increased only if the serum urate response is unsatisfactory. Extra caution should be exercised if renal function is poor. The following dosage schedules are suggested:
- 100 to 200 mg daily in mild conditions,
- 300 to 600 mg daily in moderately severe conditions,
- 700 to 900 mg daily in severe conditions.

If dosage on a mg/kg body weight basis is required, 2 to 10 mg/kg body weight per day should be used.
*Dosage in Children:* Children under 15 years: 10 to 20 mg/kg body weight per day up to a maximum of 400 mg daily.
*Dosage in the elderly:* In the absence of specific data, the lowest dosage which produces satisfactory urate reduction should be used.
*Dosage in renal impairment:* In severe renal insufficiency, it may be advisable to use less than 100 mg /day or to use single doses of 100 mg at longer intervals than one day.

**Side Effect**
Pruritic maculopapular skin eruptions, fever, chill, arthralgias, cholestatic jaundice, eosinophilia & mild leukocytosis or leukopenia.

**Drug Interaction**
Anticoagulant, Diuretic, Cytotoxic agent.

**Use in Pregnancy & Lactation**
This drug should be used during pregnancy only if clearly indicated, caution should be exercised when Allopurinol is administered to a lactating mother.

**Preparation**
100 mg Tablet.

# Evit®

**Active Ingredient**
α-Tocopheryl Acetate (Vitamin E)

**Indication**
Vitamin E deficiency.

**Dosage & Administration**
Betterment of Cardiovascular health: 400 mg - 800 mg / day.
Deficiency syndrome in adults: 400 mg / day.
Thalassemia: 800 mg / day.
Sickle-cell anemia: 400 mg / day.
Betterment of Skin & Hair: 400 mg / day (Topical use is also established for beautification).

**Contraindication & Precaution**
No absolute contraindication.

**Side Effect**
Fatigue, diarrhea or myopathy.

**Drug Interaction**
Vitamin A, K & Warfarin.

**Use in Pregnancy & Lactation**
Vitamin E is safe in pregnancy & lactation, when used as recommended doses. Higher doses are not established.

**Preparation**
400 mg & 200 mg Licap.


# Eyevi®

**Active Ingredient**
Vitamin C + Vitamin E + Zinc + Copper + Lutein

**Indication**
Age-related Eye Disease.

**Dosage & Administration**
One Eyevi capsule, one or two times daily or as directied by the physician.

**Contraindication & Precaution**
Hyperoxaluria, anticoagulants, estrogens, vitamin-K.

**Side Effect**
Diarrhea, abdominal pain, & other gastrointestinal disturbances, fatigue & weakness.

**Preparation**
Capsule.

# Ezex®

**Active Ingredient**
Clobetasone Butyrate.

**Indication**
Eczema, dermatitis & otitis externa.

**Dosage & Administration**
Up to 4 times daily.

**Contraindication & Precaution**
Skin lesions caused by infection with viruses (e.g. *Herpes Simplex*, chicken pox), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo), hypersensitivity to the preparations. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye as

glaucoma might result.

**Side Effect**
Hypersensitivity, transient adrenal suppression, local atopic changes, hypertrichosis, exacerbation of symptoms may occur.

**Use in Pregnancy & Lactation**
There is inadequate evidence of safety in human pregnancy & lactation.

**Preparation**
25 gm Cream & Ointment.

# Facticin™

**Active Ingredient**
Gemifloxacin 320 mg

**Indication**
Acute exacerbations of chronic bronchitis, Community-acquired pneumonia.

**Dosage & Administration**
In Acute Exacerbations of Chronic Bronchitis (AECB) once daily for 5 days. For Community-Acquired Pneumonia (CAP) in mild to moderate severity once daily for 5 days & in severe cases once daily for 7 days.

**Contraindication & Precaution**
Known hypersensitivity to Gemifloxacin & other quinolones, Patients who have previously suffered tendon damage with fluoroquinolones. Adequate hydration of patients receiving Gemifloxacin should be maintained to prevent the formation of a highly concentrated urine & crystalluria.
Side Effect: Generally well tolerated. The most side effects include abdominal pain, diarrhea, headache, nausea, rash & vomiting.

**Drug Interaction**
Gemifloxacin absorption is significantly reduced when aluminium- or magnesium-containing antacids & iron salts are concomitantly administered. Gemifloxacin should be taken at least 2 hours before or 3 hours after these agents. Gemifloxacin should be taken at least 2 hours before sucralfate administration.

**Use in Pregnancy & Lactation**
Gemifloxacin should not be used in pregnant or lactating women. The safety & efficacy of Gemifloxacin in pregnant or lactating women have not been established.

**Use in Children**
Not recommended below 18 years of age.

**Preparation**
Facticin Tablet: Box containing 1x6's Alu-Alu blister packs.



# Famotack®

**Active Ingredient**
Famotidine.

**Indication**
Duodenal ulcer, Gastric ulcer, Gastro-oesophageal reflux disease & Zollinger-Ellison syndrome, Gastritis.

**Dosage & Administration**
20 mg twice daily or 40 mg at night. Maintenance therapy as Famotack 20 one tablet at night.

**Contraindication & Precaution**
Hypersensitivity

**Side Effect**
Headache, dizziness, constipation & diarrhoea, nausea and/or vomiting, abdominal discomfort or distention, anorexia, fatigue, rash.

**Use in Pregnancy & Lactation**
Should be prescribed only if clearly needed. It is best avoided by nursing mothers.

**Preparation**
20 mg Tablet.

# Favinil™

**Active Ingredient**
Favipiravir INN

**Indication**
Treatment of novel or re-emerging pandemic influenza virus infections

**Dosage & Administration**
The usual adult dosage is 1600 mg of Favipiravir administered orally twice daily on Day-1 followed by 600 mg orally twice daily from Day 2 to Day 5.The total treatment duration should be 5 days.

**Side Effect**
Most common side effects are Diarrhea and increase of blood uric acid levels.

**Precaution**
Favipiravir should not be given in pregnant women, requirement of the confirmation of non-pregnancy in women of childbearing potential before use, thorough contraception measures from the start of the treatment to 7 days after the end of the treatment. Caution should be taken for Hepatic and renal impaired patient or use Favipiravir as per the direction of registered Physician

**Contraindication**
Favipiravir is contraindicated for pregnant women and women who may possibly be pregnant

**Use In Pregnancy & Lactation**
Favipiravir may cause delayed development or death of embryos during the early stage of pregnancy. Should not be given during pregnancy.

**Preparation**
200 mg Tablet

# Femastin™

**Active Ingredients**
Estriol

**Indication**
Due to lack of estrogen, marked physiological changes like vaginal dryness & itching, hot flashes, osteoporosis, vaginal discharge may occur. Femastin Cream is widely used to treat these estrogen deficiencies effectively.

**Dosage & Administration**
*Vaginal Atrophy*
Once daily for 2 months.
*Pre- and post-operative therapy in postmenopausal women undergoing vaginal surgery*
Once daily for 2 weeks before surgery and twice weekly up to 2 weeks after surgery.
*Labial adhesions*
1-2 times daily for two months.

**Contraindication**
Pregnancy, Known or suspected estrogen dependent tumors, undiagnosed vaginal bleeding, untreated endometrial hyperplasia, known or suspected breast cancer.

**Side Effect**
Breast tension or pain, nausea, spotting, fluid retention & cervical hyper secretion may occasionally occur & be indicative of too high dosage. Headache, hypertension, leg cramps & vision disturbances are seldom observed. In general, most of these adverse reactions disappear after the 1st week of treatment
Drug Interaction
There are strong indications that estrogens, estriol included, can increase the pharmacologic effects of certain corticosteroids. If necessary, the dosage of the corticosteroid should be reduced. There are also some indications, mainly obtained with other estrogens or oral contraceptives, that concurrent use of estriol with activated charcoal, barbiturates, hydantoins & rifampicin may possibly decrease the effectiveness of estriol.

**Use in Pregnancy & Lactation**
Use Femastin in breastfeeding women only if really needed, as estriol is excreted in the milk & it may decrease the quality & quantity of the milk production.

**Preparation**
0.1% Cream

# Fentizol™ VT 600

**Active Ingredient**
Fenticonazole Nitrate

**Indication**
Genital candidiasis (vulvovaginitis, colpitis, infectious fluor)
-Trichomoniasis
-Vaginal infections sustained by mixed forms of Trichomonas vaginalis & Candida albicans.

**Dosage & Administration**
Used in Trichomonas or mixed (Trichomonas & Candida albicans) vaginal infections:
• One 600 mg VT (followed by a second administration 24 hours later, if necessary).
Candida albicans infections:
• One single 600 mg VT administration in the evening. Should the symptoms persist, a second administration may be repeated after three days.
• The tablet must be introduced deep into the vagina & pushed well up to the fornix. To avoid re-infection, it is recommended that the partner undergoes concurrent treatment with Fenticonazole Cream or similar Azole Cream.

**Contraindication & Precaution**
Contraindicated in case of hypersensitivity to Fenticonazole & other Imidazoles. As systemic absorption is very low, the possibility of overdose is rare. In case of accidental swallowing, emesis or gastric lavage should be done. After vomiting, active charcoal along with water/lemon juice & laxative should be given to the patient.

**Side Effect**
After intravaginal administration slight transient burning (which usually disappears rapidly) may occasionally happen. Prolonged topical application may cause sensitisation reactions. Fenticonazole is generally well tolerated by the mucous membranes; only exceptionally mild & transient erythematous reactions have been reported. After topical application or intravaginal administration, a slight burning sensation may occur, usually subsiding soon. Should more persistent irritation occur or resistant micro-organism develop, suspend the treatment & seek the doctor's advice. Due to poor absorption of Fenticonazole, no systemic effects should occur, provided the above instructions are carefully observed.

**Use in Pregnancy & Lactation**
It is not recommended in pregnancy. Safety in breastfeeding has not been established.
**Use in Children**
Fenticonazole Nitrate is not recommended for children.

**Preparation**
1 vaginal Tablet in Alu-Alu blister with an applicator.

# Fexo™

F

**Active Ingredient**
Fexofenadine.

**Indication**
Seasonal & perennial allergic rhinitis & Chronic idiopathic urticaria.
**Dosage & Administration**

| Patient Population | Fexo Tablet | Fexo Oral Suspension | **In case of decreased renal function** |
|---|---|---|---|
| Adults & Children 12 years & older | 60 mg twice daily or 120 mg once daily or 180 mg once daily | ----- | 60 mg once daily is recommended as the starting dose |
| Children 6 to 11 years | 30 mg twice daily or 60 mg once daily | 30 mg (5 ml) twice daily | 30 mg (5 ml) once daily is recommended as the starting dose |
| Children 2 to 5 years | ----- | 30 mg (5 ml) twice daily | 30 mg (5 ml) once daily is recommended as the starting dose |
| Children 6 months to less than 2 years | ----- | 15 mg (2.5 ml) twice daily | 15 mg (2.5 ml) once daily is recommended as the starting dose |

**Contraindication & Precaution**
Fexofenadine is contraindicated in patients with known hypersensitivity to any of the ingredients.

**Side Effect**
Generally well tolerated.

**Use in Pregnancy & Lactation**
There are no adequate & well controlled studies in pregnant women. Fexofenadine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
It is not known if Fexofenadine is excreted in human milk. Caution should be exercised when Fexofenadine is administered to a nursing woman. In case of decreased renal function, care should be taken in dose selection & it may be useful to monitor renal function.

**Preparation**
60 mg, 120 mg, 180 mg Tablet & 30 mg / 5 ml Suspension.

# Filfresh®

**Active Ingredient**
Melatonin INN 3 mg.

**Indication**
Filfresh® is used for numerous conditions but is showing the most promise in short-term regulation of sleep patterns, including jet lag.
Insomnia Filfresh® helps to induce sleep in people with disrupted circadian rhythms (such as those suffering from jet lag or poor vision or those who work the night shift) low melatonin levels (such as some elderly and individuals with schizophrenia) children with learning disabilities who suffer from insomnia.
Osteoporosis Filfresh® stimulates cells called osteoblasts that promote bone growth.
In Menopause Filfresh® helps peri- or postmenopausal women to regulate sleep patterns. Eating disorders Filfresh® levels may play a role in the symptoms of anorexia. Sarcoidosis Attention Deficit Hyperactivity Disorder (ADHD) It may be effective in managing sleep disturbances in children with this condition.

**Dosage & Administration**
Adult :
Insomnia : 3-6 mg one hour before bedtime
Jet lag : 0.50 to 5 mg one hour prior to bedtime at final destination or, 1 to 5 mg 1 hour before bedtime for 2 days prior to departure and for 2 to 3 days upon arrival at final destination.
Eastbound travel - Take a preflight early evening treatment followed by treatment at bedtime for 4 days after arrival.
Westbound travel- Take for 4 days at bedtime when in the new time zone.
Sarcoidosis : 20 mg per day for 4 to 12 months.
Depression : 0.125 mg twice in the late afternoon, each dose 4 hours apart.
Difficulty falling asleep : 5 mg 3 to 4 hours before an imposed sleep period over a 4-weeks period.
Children (6 months to 14 years of age with sleep disorders) : 0.30 mg/day

**Contraindication**
Melatonin should not be used by patients who have autoimmune diseases.

**Pregnancy & Lactation**
Information regarding safety and efficacy in pregnancy and lactation is not available.

**Precautions**
Caffeine and fluvoxamine may increase the effects of melatonin, while melatonin may decrease the antihypertensive effect of nifedipine.

**Side Effect**
Possible adverse effects include headache and depression. Drowsiness may be experienced within 30 minutes after taking melatonin and may persist for 1 hour and thus may affect driving skills.

**Overdose**
There is little or no evidence of any major toxicities with melatonin, even at high doses.

**Preparation**
Tablets.

# Filwel™ Gold

**Active Ingredient**
Vitamin A, C, D, E, K, Thiamine, Riboflavin, Niacin, Vitamin B6, Folic Acid, Vitamin B12, Biotin, Pantothenic acid, Calcium, Iron, Phosphorous, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Chloride, Potassium, Boron, Nickel, Silicon, Tin, Vanadium & Lutein.

**Indication**
Treatment of vitamin & mineral deficiencies.

**Dosage & Administration**
One tablet daily with food.

**Contraindication & Precaution**
Known hypersensitivity, large dose of vitamin A may increase the risk of osteoporosis.

**Side Effect**
Diarrhorea, skin may assume slightly yellow discoloration, other gastrointestinal disturbances.

**Use in Pregnancy & Lactation**
Recommended by the consultation with physician.

**Preparation**
Tablet.



# Filwel™ Kids

**Active Ingredient**
Cod Liver Oil, Vitamin A, Vitamin D, Vitamin C, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin E & Nicotinamide.

**Indication**
Filwel Kids Syrup helps preventing vitamin deficiencies in children & adult. It stimulates appetite & improves digestion; good vision, strong bones & healthy teeth; increases resistance against coughs, colds, chest & bronchial troubles; helps maintain healthy muscles & nervous system & helps optimizing brain development.

**Dosage & Administration**
Infants (<1 year): Half teaspoonful daily.
Children (1 - 4 years): One teaspoonful daily.
Children (> 4 years): One & half teaspoonful daily.
It can be taken with water or milk if desired.

**Contraindication & Precaution**
The product is contraindicated in patients with a known hypersensitivity to any of the ingredients of this product. In the long term use, this medicine may accumulate in the body which may cause hypervitaminosis of the related fat soluble vitamins. Then, it should not be used over dosage or be used continuously except recommended by the physicians.

**Side Effect**
Generally well tolerated.

**Use in Pregnancy & Lactation**
Recommended.

**Use in Children**
Recommended.

**Preparation**
100 ml Syrup.

# Filwel™ Silver

**Active Ingredient**
Vitamin A, C, D, E, K, Thiamine, Riboflavin, Niacin, Vitamin B6, Folic acid, Vitamin B12, Biotin, Pantothenic acid, Calcium, Phosphorous, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Chloride, Potassium, Boron, Nickel, Silicon, Vanadium & Lutein.

**Indication**
Treatment of vitamin & mineral deficiencies above the age of 45 years.

**Dosage & Administration**
One tablet daily with food. Not formulated for use in children.

**Side Effect**
Diarrhorea, skin may assume slightly yellow discoloration, other gastrointestinal disturbances.

**Contraindication & Precaution**
Known hypersensitivity, large dose of vitamin A may increase the risk of osteoporosis in postmenopausal women.

**Use in Pregnancy & Lactation**
Recommended by the consultation with physician.

**Drug Interaction**
No drug interactions have been reported.

**Preparation**
Tablet.

# Filwel™ Teen hm

**Active Ingredient**
Each film coated tablet contains: Vitamin A 2500 IU, Vitamin C 120 mg, Vitamin D 400 IU, Vitamin E 30 IU, Vitamin K 25 mcg, Thiamin (B1) 3.75 mg, Riboflavin (B2) 4.25 mg, Niacin 30 mg, Vitamin B6 5 mg, Folic Acid 400 mcg, Vitamin B12 15 mcg, Biotin 300 mcg, Pantothenic Acid 10 mg, Calcium 200 mg, Iron 9 mg, Magnesium 100 mg, Zinc 15 mg, Selenium 20 mcg, Copper 2 mg, Manganese 2 mg and Chromium 120 mcg.

**Indication**
Indicated for teenage boys (age from 13 to 19) as comprehensive nutritional supplements.
- Boosts up immunity, guarantees disease free teenage
- Accelerates the physical and mental growth of the boys
- For the proper growth of bone and teeth
- Healthy immune system with Vitamin C and E, Beta-Carotene, Zinc, Iron and Selenium
- Healthy muscle function with Magnesium
- Improves mood to enjoy the spirit of teenage
- Ensures quality daily nutrition to all Teenage boys
- Energy through the conversion of food to fuel with vitamins B6 and B12, Thiamine, Riboflavin & Niacin

**Dosage & Administration**
For teen boys, one tablet daily with food.

**Side Effect**
Constipation, diarrhea or upset stomach may occur. These effects are usually temporary and may disappear as your body adjust to this medication

**Contraindication & Precaution**
Contraindicated in patients with a known hypersensitivity to any of the ingredients. Folic Acid alone is improper therapy in the treatment of pernicious anaemia and other.

**Drug Interaction**
No such drug interactions have been reported.

**Preparation**
Tablet

# Filwel™ Teen hr

**Active Ingredient**
Each film coated tablet contains: Vitamin A 2500 IU, Vitamin C 120 mg, Vitamin D 800 IU, Vitamin E 30 IU, Vitamin K 25 mcg, Thiamin (B1) 2.3 mg, Riboflavin (B2) 2.6 mg, Niacin 30 mg, Vitamin B6 3 mg, Folic Acid 400 mcg, Vitamin B129 mcg, Biotin 300 mcg, Pantothenic Acid 10 mg, Calcium (elemental) 300 mg, Iron 18 mg, Magnesium 50 mg, Zinc 15 mg, Selenium 20 mcg, Copper 2 mg, Manganese 2 mg and Chromium 120 mcg.

**Indication**
Indicated for teenage girls (age from 13 to 19) as comprehensive nutritional supplements.
- Development and maintenance of bone & teeth
- Boosts up immunity
- Supplying energy through breaking down of carbohydrates, protein & fat
- Prevents Acne and smoothens the skin
- Supports skin structure through Synthesis of Collagen and Elastin
- Defends the skin from free radical mediated damage
- Restores hormonal balance
- Reduces Anxiety & Depression

**Dosage & Administration**
For teen girls, one tablet daily with food.

**Side Effect**
Constipation, diarrhea or upset stomach may occur. These effects are usually temporary and may disappear as your body adjust to this medication

**Contraindication & Precaution**
This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Folic Acid alone is improper therapy in the treatment of pernicious anaemia and other megaloblasticanaemia where Vitamin B12 is deficient.

**Drug Interaction**
No such drug interactions have been reported.

**Use in pregnancy and lactation**
Not indicated for use by pregnant & lactating mothers.

**Preparation**
Tablet

# Flacol®

**Active Ingredient**
Simethicone.

**Indication**
Flatulence, abdominal distention, fullness, gas & windy colic, large bowel preparation.

**Dosage & Administration**
Children (<2 years) : 20 mg (0.3 ml) 4 times daily; Children (2-12 years) : 40 mg (0.6 ml) 4 times daily; Adults: 40-80 mg (0.6 ml - 1.2 ml) 4 times daily. Chewable tablet: Chew 1-3 tabets after meals & at bed time.

**Contraindication & Precaution**
Do not exceed 12 doses per day without physician's recommendation.

**Side Effect**
No adverse effect has been noted after oral ingestion.

**Preparation**
67 mg/ml Paediatric Drops & 40 mg Chewable ablet.

# Flexi®

**Active Ingredient**
Aceclofenac.

**Indication**
Osteoarthritis, Rheumatoid Arthritis & Ankylosing Spondylitis.

**Dosage & Administration**
100 mg twice daily or 200 mg SR tablet once daily.

**Contraindication & Precaution**
Peptic ulcer or gastric-intestinal bleeding. It should not be given to patients with moderate to severe renal impairment. Close medical surveillance is also imperative in patients suffering from severe impairment of hepatic function. It should not be prescribed during pregnancy, unless there are compelling reasons for doing so.

**Side Effect**
Dyspepsia, abdominal pain, nausea & diarrhea, dizziness. Dermatological complaints including pruritus & rash & abnormal hepatic enzyme levels & raised serum creatinine have occasionally been reported.

**Drug Interaction**
Lithium, digoxin, diuretics, anticoagulants, methotrexate.

**Use in Pregnancy & Lactation**
The regular use of NSAIDs during the last trimester of pregnancy may increase uterine tone & contraction. The use of Aceclofenac should therefore be avoided in pregnancy & lactation unless the potential benefits to the mother outweigh the possible risks to the fetus

**Use in Children**
No clinical data on the use of Aceclofenac in Children is available.

**Preparation**
100 mg Tablet & 200 mg Sustained Release (SR) Tablet.

# Flexilax®

**Active Ingredient**
Baclofen.

**Indication**
Flexilax is indicated for the treatment of muscle spasm, muscle contraction, spasticity resulting from multiple sclerosis, spinal cord injuries & other spinal cord diseases, muscle spasm of cerebral origin especially infantile cerebral palsy, cerebrovascular accidents or neoplastic or degenerative brain disease, tension-type headache.

**Dosage & Administration**
Flexilax (Baclofen) should be given in divided doses preferably 3 times daily for adults & 4 times daily for children. The lowest dose compatible with an optimal response is recommended. The dosage shall be started from 5 mg three times a day to a maximum of 20 mg three times a day.

**Contraindication & Precaution**
Baclofen is contraindicated in patients with previously demonstrated hypersensitivity to any of the components of the product.

**Side Effect**
The most common adverse reactions associated with Baclofen are transient drowsiness, daytime sedation, dizziness, weakness & fatigue.

**Use in Pregnancy & Lactation**
Pregnancy category B. Baclofen is excreted in breast milk however evidence to date suggests that the quantities are so small that no undesirable effects on the infant would be expected.

**Preparation**
5 mg & 10 mg Tablet

# Flindof™

**Active Ingredient**
Doxofylline.

**Indication**
Doxofylline is indicated for the treatment of bronchial asthma, pulmonary disease with spastic bronchial component and Chronic Obstructive Pulmonary Disease (COPD).

**Dosage & Administration**
• Adults: 400 mg tablet two or three times daily or as prescribed by a physician.
• Elderly: 200 mg tablet two or three times daily
• Maximum Daily Dose: 1,200 mg.
• <12 yr: 6-9 mg/kg body wt bid.
Doxofylline may be taken with or without food.

**Adverse Effects**
After xanthine administration, nausea, vomiting, epigastric pain, cephalalgia, irritability, insomnia, tachycardia, and occasionally hyperglycemia and albuminuria, may occur. If a potential oral overdose is established, the patient may present with severe arrhythmias and seizure; these symptoms could be the first sign of intoxication. Adverse reactions may cause the withdrawal from treatment; a lower dose rechallenge may start only after the advice of physician.

**Precautions**
Caution is advised for those patients with hypoxemia, hyperthyroidism, liver disease, renal disease, in those with history of peptic ulcer and in elderly. Frequently, patients with congestive heart failure have markedly prolonged drug serum levels following discontinuation of the drug.

**Contraindication**
Doxofylline is contraindicated in individuals who have shown hypersensitivity to the drug and its components. It is also contraindicated in patients with Acute MI, hypotension, arrhythmia, duodenal ulcer, epilepsy and convulsions.

**Drug Interaction**
Doxofylline should not be administered together with other xanthine derivatives, including beverages and foods containing caffeine. Toxic synergism with ephedrine has been documented for xanthines. Concomitant therapy with erythromycin, troleandomycin, lincomycin, clindamycin, allopurinol, cimetidine, propranolol and anti-flu vaccine may decrease the hepatic clearance of xanthines causing an increase in blood levels.

**Use in Pregnancy & Lactation**
Animal reproduction studies indicate that Doxofylline does not cause fetal harm when administered to pregnant animals nor can affect reproduction capacity. However, since there are limited experiences in humans during pregnancy, xanthines should be given to pregnant women only if clearly needed. Doxofylline is contraindicated in nursing mothers.

**Preparation**
200 & 400 mg tablets.

# Flonasin™

**Active Ingredient**
Azelastine Hydrochloride BP & Fluticasone Propionate BP

**Pharmacology**
Azelastine hydrochloride is H1-receptor antagonist & Fluticasone propionate is a synthetic corticosteroid with anti-inflammatory activity.

**Indications**
Seasonal allergic rhinitis in patients 12 years of age and older

**Dosage and administration**
For adults and adolescents (12 years and older): One spray per nostril twice daily.

**Contraindication & Precaution**
Avoid driving or operating machinery. Avoid concurrent use of alcohol or other central nervous system (CNS) depressants with Flonasin . Hypercorticism and adrenal suppression with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue the spray slowly.

**Side Effect**
Dysgeusia, epistaxis, and headache.

**Use in Pregnancy & Lactation**
Pregnancy category C. It should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the fetus. Caution should be exercised when administered to a nursing woman.

**Pediatric use**
Not recommended under 12 years.

**Overdose**
There have been no reported over dosages with Azelastine Hydrochloride. Acute Azelastine Hydrochloride overdosage by adults with this dosage form is unlikely to result in clinically significant adverse events, other than increased somnolence. Chronic Fluticasone Propionate overdosage may result in signs/symptoms of hypercorticism.

**Storage**
Store below $25^0$ C. Protect from light & moisture. Keep out of the reach of children.

**Preparation**
120 sprays, which each metered spray delivers Azelastine Hydrochloride BP 137 mcg and Fluticasone Propionate BP 50.00 mcg.

# Flonaspray®

**Active Ingredient**
Fluticasone Propionate.

**Indication**
Prophylaxis & treatment of allergic rhinitis.

**Dosage & Administration**
Adults: 02 sprays in each nostril once daily, preferably in the morning. Children (4 to 11 years of age) 01 spray in each nostril once daily.

**Contraindication & Precaution**
Hypersensitivity to any of its components. Care must be taken while transferring patients from systemic steroid to Fluticasone nasal spray if there is any reason to suppose that their adrenal function is impaired.

**Side Effect**
Nasal irritation & stinging. Nasal septum perforation, dryness of nose & throat, unpleasant taste & smell & epistaxis reported rarely.

**Drug Interaction**
None is yet known.

**Preparation**
50 mcg/spray, Nasal Spray.

F

# Flugal®

**Active Ingredient**
Fluconazole.

**Indication**
Candidiasis, Cryptococcal infections (including

meningitis), Tinea pedis, corporis, cruris, versicolor & dermal candidiasis.

**Dosage & Administration**
Acute or recurrent vaginal candidiasis: a single dose of 150 mg. Mucosal candidiasis (except vaginal): 50 mg daily (100 mg daily in unusually difficult infections) given for 7-14 days in oropharyngeal candidiasis ; for 14-30 days in other mucosal infections (e.g. oesophagitis, candiduria). Systemic candidiasis & cryptococcal infections (including meningitis) 400 mg initially then 200 mg daily, increased if necessary to 400 mg daily ; treatment continued according to response.
Child over 1 year - superficial candidal infections, 1-2 mg/kg daily; systemic candidiasis & cryptococcal infections (including meningitis) - 3-6 mg/kg daily (in serious life threatening infections up to 12 mg/kg daily has been given to children aged 5-13 years - max. 400 mg daily).



**Contraindication & Precaution**
Hypersensitivity, advanced liver disease, renal impairment, children below the age of one year.

**Side Effect**
Nausea, abdominal discomfort, diarrhoea & flatulence, occasionally abnormalities of liver enzyme, rarely rash, angioedema & anaphylaxis reported.

**Drug Interaction**
Rifampicin , Warfarin, Phenytoin.

**Use in Pregnancy & Lactation**
Caution should be taken.

**Preparation**
200 mg, 150 mg & 50 mg Capsule, 50 mg/5 ml Suspension, 2mg/ml IV Infusion.

# Flurizin®

**Active Ingredient**
Flunarizine.

**Indication**
- Prophylaxis of classic (with aura) or common (without aura) migraine
- Symptomatic treatment of vestibular vertigo
- Peripheral Vascular Disease (PVD)
- Motion sickness

**Dosage & Administration**
Migraine Prophylaxis:
Starting Dose: 10 mg at night in patients less than 65 years of age & 5 mg daily in patients older than 65 years.
Maintenance Treatment: If a patient is responding satisfactorily & if a maintenance treatment is needed, the dose should be decreased to 5 days treatment at the same daily dose with two successive medicine free days every week. Even if the prophylactic maintenance treatment is successful & well tolerated, it should be interrupted after 6 months & it should be re-initiated only if the patient relapses.
Peripheral Vascular disease: 10 mg twice daily, up to 30 mg per day if required.
Vertigo & motion sickness: 10-20 mg daily for adults & 5 mg daily for children (> 40 kg).

**Contraindication & Precaution**
Hypersensitivity to Flunarizine. Flunarizine is contra-indicated in patients with a history of depressive illness, or with pre-existing symptoms of Parkinson's disease or other extrapyramidal disorders. Flunarizine may lead to drowsiness which is aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be cautioned against driving motor vehicles or performing other potentially hazardous tasks where a loss of mental alertness may lead to accidents.

**Side Effect**
Drowsiness and/or fatigue, as well as weight gain and/or increased appetite may occur.
.Infrequently reported adverse reaction are:

heartburn; nausea; gastralgia; insomnia; anxiety; galactorrhoea; dry mouth; muscle ache; skin rash.

**Use in Pregnancy & Lactation**
Safety in pregnancy & lactation has not been established.

**Preparation**
5 mg & 10 mg Tablet.

# Fodexil™

**Active Ingredient**
Cefadroxil 500 mg Capsule, 1 gm Tablet.

**Indication**
- Upper respiratory tract infections caused by *Streptococcus pyogenes* (Group A beta-hemolytic Streptococci) & *Streptococcus pneumoniae*.
- Urinary tract infections caused by *E. coli*, *Proteus mirabilis*, & *Klebsiella species*.
- Skin & soft tissue infections caused by Staphylococci (including penicillinase producing strains) & Streptococci.

**Dosage & Administration**
Infections of upper respiratory tract:Adult - pharyngitis & tonsillitis: 1 g/day in single or divided doses for 10 days, Children- 30 mg/kg/day in equally divided doses every 12 hour for at least 10 days. Uncomplicated lower urinary tract infections: Adult- 1-2 g daily as a single or 2 divided doses, Children- >6 year: 500 mg bid; 1-6 year: 250 mg bid; <1 year: 25 mg/kg daily in divided doses. Skin & soft tissue infections: Adult- 1 g/day in single or divided doses, Children- 30 mg/kg/day in equally divided doses every 12 hour

**Contraindication & Precaution**
Cefadroxil is contraindicated in patients with a history of hypersensitivity to any of the ingredients
Cefadroxil should be used with caution in the presence of markedly impaired renal function (creatinine clearance rate of less than 50 ml/min). For patients considering creatinine clearance of ml/min/1.73 sqm, starting dose 1000 mg & maintenance dose 500 mg should be administered as per following table:

| Creatinine clearance (ml/min) | Dosing interval |
|---|---|
| 1-10 | 36 hr. |
| 11-25 | 24 hr. |
| 26-50 | 12 hr. |
| >50 | No need to adjust |

Cefadroxil can be excreted from body by hemodialysis. Prolonged use of Cefadroxil may result in the overgrowth of nonsusceptible organisms. Cefadroxil should be prescribed with caution in individuals with history of gastrointestinal disease, particularly colitis.

**Side Effect**
The most commonly reported side effects are gastrointestinal disturbances & hypersensitivity phenomena. Side effects including nausea, vomiting, diarrhoea, dyspepsia, abdominal discomfort, fever, dizziness, headache, arthralgia may also occur.

**Drug Interaction**
Prothrombin time prolonged; bleeding may occur when taken with anticoagulants. Decreased elimination with probenecid is also reported.

**Use in Pregnancy & Lactation**
Pregnancy category B. But it should be used only if clearly needed. Caution should be exercised when Cefadroxil is administered to nursing mother.

**Use in Children**
Please see dosage & Administration

**Preparation**
Fodexil 500 mg Capsule : Each box contains 18 capsules in blister pack.
Fodexil 1gm Tablet : Each box contains 12 Tablets in blister pack.

# Fona®

**Active Ingredient**
Adapalene.

**Indication**
Acne.

**Dosage & Administration**
Fona® 0.1% Cream: Once daily at night-time.
Fona® 0.3% Gel: Once daily in the evening.

**Contraindication & Precaution**
Hypersensitivity to Adapalene. Adapalene should not be applied to cuts, abrasions, eczematous or sunburned skin.

**Side Effect**
Erythema, scaling, dryness, pruritus, burning sensation, skin irritation, stinging sunburn, acne flares.

**Drug Interaction**
Concomitant use of other potentially irritating topical products (medicated or abrasive soaps & cleaners, soaps & cosmetics that have a strong drying effect, products with high concentrations of alcohol, astringents, spices or lime) should be approached with caution. Exercise particular caution in using preparations containing sulfur, resorcinol or salicylic acid in combination with Adapalene.

**Use in Pregnancy & Lactation**
Use adapalene during pregnancy only if the potential benefit justifies the potential risk to the foetus. Exercise caution when administering Adapalene to a nursing mother. Safety & effectiveness in children below 12 years of age have not been established.

**Preparation**
10 gm Cream & Gel.

# Fona™ Plus Gel

**Active Ingredient**
Adapalene & Benzoyl Peroxide

**Indication**
Fona Plus Gel is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

**Dosage & Administration**
Apply a thin film of FonaTM Plus Gel to affected areas of the face and/or trunk once daily after washing. Use a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek). Avoid the eyes, lips and mucous membranes. FonaTM Plus Gel is not for oral, ophthalmic, or intravaginal use.

**Contraindication & Precaution**
Should not be administered to individuals who are hypersensitive to any of its component. Avoid exposure to sunlight and sunlamps. Wear sunscreen when sun exposure cannot be avoided.

**Side Effect**
Erythema, scaling, dryness, and stinging/ burning may occur. Most commonly reported adverse events are dry skin, contact dermatitis, application site burning, application site irritation, and skin irritation.

**Use in Pregnancy and Lactation**
There are no well-controlled trials in pregnant women treated with Adapalene and Benzoyl peroxide. Caution should be exercised when administered to a nursing woman.

**Preparaion**
10 gm gel.


# Fosfomax™

**Active Ingredient**
Fosfomycin Trometamol EP granules for oral solution equivalent to 3 g Fosfomycin.

**Indication**
It is indicated only for the treatment of acute cystitis (uncomplicated urinary tract infection) in women due to susceptible strains of Escherichia coli and Enterococcus faecalis.

**Dosage & Administration**
The recommended dosage for women 18 years of age and older for acute cystitis is one sachet of FosfomaxTM with or without food. This medicine should not be used in children.

**Preparation**
Pour the entire content of the Fosfomax sachet into half glass of water then stir gently to dissolve. Hot water should not be used. Fosfomax should be taken immediately after dissolving in water.

**Contraindication**
Fosfomycin is contraindicated in patients with known hypersensitivity to the drug and patients with severe renal insufficiency and patients undergoing hemodialysis.

**Precautions**
Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Fosfomycin. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile. Do not use more than one single dose of Fosfomycin to treat a single episode of acute cystitis. Repeated daily doses of Fosfomycin did not improve the clinical success or microbiological eradication rates compared to single dose therapy, but did increase the incidence of adverse events.

**Adverse Effect**
In clinical trials, the most frequently reported adverse events occurring in > 1% of the study population regardless of drug relationship were: diarrhea 10.4%, headache 10.3%, vaginitis 7.6%, nausea 5.2%, rhinitis 4.5%, back pain 3.0%, dysmenorrhea 2.6%, pharyngitis 2.5%, dizziness 2.3%, abdominal pain 2.2%, pain 2.2%, dyspepsia 1.8%, asthenia 1.7%, and rash 1.4%. The following adverse events occurred in clinical trials at a rate of less than 1%, regardless of drug relationship: abnormal stools, anorexia, constipation, dry mouth, dysuria, ear disorder, fever, flatulence, flu syndrome, hematuria, infection, insomnia, lymphadenopathy, menstrual disorder, migraine, myalgia, nervousness, paresthesia, pruritus, SGPT increased, skin disorder, somnolence, and vomiting.



**Use in Pregnancy and Lactation**
Pregnancy category: B This drug should not be used during pregnancy unless the benefit outweighs the risk. A decision should be made to discontinue breastfeeding or to not administer the drug, taking into account the importance of the drug to the mother.

**Drug Interaction**
Metoclopramide: When co-administered with Fosfomycin, metoclopramide, a drug which increases gastrointestinal motility, lowers the serum concentration and urinary excretion of Fosfomycin. Other drugs that increase gastrointestinal motility may produce similar effects.

**Preparation**
Box containing 1 sachet of Fosfomycin Trometamol EP granules for oral solution equivalent to 3 g Fosfomycin.

# Frabex®

**Active Ingredient**
Tranexamic Acid

**Indication**
Tranexamic Acid is indicated for short term use for haemorrhage or risk of haemorrhage in those with increased fibrinolysis or fibrinogenolysis. Local fibrinolysis as occurs in the following conditions:
Local fibrinolysis-
a) Prostatectomy and bladder surgery
b) Menorrhagia
c) Epistaxis
d) Conisation of the cervix
e) Traumatic hyphaema
Management of dental extraction in haemophiliacs. Hereditary angioneurotic oedema.

**Dosage & Administration**
Adults: Local Fibrinolysis: The recommended standard dose is 15-25 mg/kg body weight two to three times daily. For the indications listed below the following doses may be used:
a. Prostatectomy: Prophylaxis and treatment of haemorrhage in high risk patients should commence pre- or post-operatively with tranexamic acid injection; thereafter 1 gm three to four times daily until macroscopic haematuria is no longer present.
b. Menorrhagia: Recommended dosage is 1 gm 3 times daily as long as needed for up to 4 days. If very heavy menstrual bleeding, dosage may be increased. A total dose of 4g daily should not be exceeded. Treatment with Tranexamic acid should not be initiated until menstrual bleeding has started.
c. Epistaxis: When repeated bleeding is anticipated oral therapy (1 gm three times daily) should be administered for 7 days.
d. Cervix Conisation: 1.5 gm three times daily.
e. Traumatic Hyphaema: 1-1.5gm three times daily. The dose is based on 25mg/kg three times a day. Haemophilia: In the management

of dental extractions 1-1.5 gm every eight hours. The dose is based on 25mg/kg.
Hereditary angioneurotic oedema: Some patients are aware of the onset of illness; suitable treatment for these patients is intermittently 1-1.5 gm two to three times daily for some days. Other patients are treated continuously at this dosage.
Paediatric population: In children the dosage is in the region of 20 mg/kg/day. However, data on efficacy, posology and safety for these indications are limited.

**Contraindication**
Tranexamic Acid is contraindicated in patients with a history of thromboembolic disease.

**Drug Interaction**
Clinically important interactions have not been observed with tranexamic acid tablets. Because of the absence of interaction studies, simultaneous treatment with anticoagulants must take place under the strict supervision of a physician experienced in this field.

**Use in Pregnancy and Lactation**
Pregnancy category B. Tranexamic acid passes into breast milk to a concentration of approximately one hundredth of concentration in the maternal blood. An antifibrinolytic effect in the infant is unlikely.

**Side Effect**
Diarrhoea; Eyesight problems.

**Preparation**
500 mg Capsule & 500 mg/5 ml IV Injection.

# Fungidal®

**Active Ingredient**
Miconazole Nitrate.

**Indication**
Skin & nail infections due to dermatophytes, yeasts & other fungi such as: Tinea capitis, corporis, manuum, pedis, barbae, cruris, unguium or onychomycosis. Pityriasis versicolor, candidiasis of skin & nails, stomatitis angularis, otitis externa, mycoses secondarily infected with bacteria.

**Dosage & Administration**
Twice daily.

**Contraindication & Precaution**
No contraindication is known.

**Side Effect**
Topical application of Miconazole Nitrate has almost no side Effect.

**Use in Pregnancy & Lactation**
Miconazole Nitrate should be used with caution during pregnancy.

**Preparation**
10 gm Cream.

# Fungidal-HC®

**Active Ingredient**
Miconazole Nitrate & Hydrocortisone.

**Indication**
Inflamed dermatoses such as intertrigo &

infected eczema, primary irritant or contact allergic eczema or seborrheic eczema including that associated with acne. perianal & genital dermatitis.

**Dosage & Administration**
Two or three times daily.

**Contraindication & Precaution**
Hypersensitivity. It should be used with caution when applied to extensive surface areas or under occlusive dressings including baby napkins.

**Side Effect**
Local sensitivity may occur. Corticosteroids can be absorbed sufficient amount to produce systemic effects.

**Drug Interaction**
Amphotericin antagonises effect of Miconazole.
**Use in Pregnancy & Lactation**
Topical steroids should not be extensively used in pregnancy.

**Preparation**
10 gm Cream.



# Fusid®

**Active Ingredient**
Furosemide.

**Indication**
Cardiac, pulmonary, hepatic & renal oedema, peripheral oedema & hypertension.

**Dosage & Administration**
Tablet : In mild cases, 20 mg daily or 40 mg on alternate days. In resistant cases, 80 mg/day. Children- 1 to 3 mg/kg/day, max. 40 mg/day. Injection : 20-50 mg/day IM/IV. Children- 0.5-1.5 mg/kg/day. max. 20 mg/day.

**Contraindication & Precaution**
Anuria, electrolyte deficiency & pre-comatose states associated with liver cirrhosis. Hypersensitivity to furosemide or sulphonamides.

**Side Effect**
Alkalosis, uric acid retention & may rarely produce acute gout. Fusid may provoke hyperglycemia & glycosuria.

**Drug Interaction**
ACE inhibitors, lithium. The toxic effects of nephrotoxic antibiotics may be increased by concomitant administration of potent diuretics such as furosemide.

**Use in Pregnancy & Lactation**
Fusid should be cautiously used in cardiogenic shock complicated by pulmonary oedema & in the first trimester of pregnancy. Blood pressure & pulse during rapid diuresis should be monitored. Should be used with caution during lactation.

**Preparation**
40 mg Tablet & 20 mg/2 ml Injection.

# Fusid® Plus

**Active Ingredient**
Spironolactone + Furosemide.

**Indication**
Essential hypertension, Chronic

congestive heart failure, Hepatic cirrhosis with ascites, Swelling due to excess fluid retention (edema), Hyperaldosteronism, resistant edema associated with secondary hyperaldosteronism.

**Dosage & Administration**
Fusid plus: 1 to 4 tablets daily, Fusid 40 plus: one to two tablets daily.

**Contraindication & Precaution**
Anuria, acute renal insufficiency, rapidly deteriorating or severe impairment of renal function (creatinine clearance: < 30 ml/ min), hyperkalaemia, Addison's disease, & in patients who are hypersensitive to spironolactone, furosemide or sulphonamides. Caution should be taken in patients liable to electrolyte deficiency. Used with caution in diabetes, enlarged prostate, hypotension & in hypovolemia.

**Side Effect**
Headache & drowsiness, gastrointestinal distress including cramp & diarrhoea, ataxia, mental confusion, skin rashes, gynaecomastia, hirsutism, deepening of the voice, menstrual irregularities, impotence, hyponatremia, hyperkalemia, dehydration & reduction in blood volume with circulatory collapse, cardiac arrhythmias.

**Drug Interaction**
ACE inhibitors, potassium salts, cardiac glycosides, corticosteroids, indomethacin & other non-steroidal anti-inflammatory drugs (NSAIDs), aminoglycoside antibiotics, sucralfate.

**Use in Pregnancy**
Furosemide should only be used in women in child bearing age when appropriate contraceptive measures are taken or if the potential benefits justify the potential risks to the foetus.

**Use in Lactation**
If use of Spironolactone is considered essential, an alternative method of infant feeding should be instituted. Furosemide is excreted in breast milk & breast-feeding should be discontinued if treatment is essential.

**Preparation**
(Spironolactone 50 mg & Furosemide 20 mg)/ Tablet, (Spironolactone 50 mg & Furosemide 40 mg)/ Tablet.

# Fusitop-HC™



**Active Ingredient**
Fusidic Acid BP & Hydrocortisone Acetate BP.

**Indication**
Following dermatitis associated with bacterial infections:-
- Primary irritant dermatitis
- Contact allergic dermatitis
- Eczema (atopic, infantile, discoid, stasis)
- Seborrhoeic dermatitis
- Lichen simplex & pruritus ani
- Flexural psoriasis

**Dosage & Administration**
Fusitop-HC™ Cream should be applied to the affected area in a thin film 2-3 times daily & massaged gently onto the skin. Treatment is generally continued for a period of 7 days. As the skin rash improves, the frequency of application should be gradually reduced. As topical steroids exhibit tachyphylaxis, it may be better to omit therapy for several days every fortnight.

**Contraindication & Precaution**
Known hypersensitivity to any of the components, severe hepatic failure, ulcers (delayed wound healing), and infants under 1 year. Precaution should be taken for long-term use, especially in face, flexure, folding areas and children.

**Drug Interaction**
Fusidic Acid may inhibit the metabolism of drugs which undergo extensive bio-transformation in the liver, but no evidence for this is available. Food may delay absorption of Fusidic Acid. No hazardous drug interactions are reported with topical Hydrocortisone Acetate.

**Use in Pregnancy & Lactation**
Fusidic Acid & Hydrocortisone Acetate should not be used during pregnancy. Both of them have been detected in the breast milk, so nursing mothers are advised not to use the drug.

**Preparation**
10 gm Cream.

G

# Gabastar®

**Active Ingredient**
Gabapentin.

**Indication**
Gabastar (Gabapentin) is indicated for
• Neuropathic Pain
• Adjunctive therapy in partial seizure & secondary generalized seizure

**Dosage & Administration**
Neuropathic Pain: The treatment may be initiated as a single 300 mg dose on Day-1, than 300 mg twice on Day-2 & 300 mg thrice on Day-3. The dose can be subsequently be titrated up as needed for pain relief to a daily dose of 1800 mg (divided TID).
Epilepsy: Patients over 12 years of age - the Effective dose of Gabastar® is 900 to 1800 mg/day given in three divided doses. The starting dose is 300 mg three times a day.
Paediatric patients age 3-12 years- the starting dose should range from 10-15 mg/kg/day in 3 divided doses, & the Effective dose reached by upward titration over a period of approximately three days.
In case of renal impaired patients Gabapentin doses must be reduced.
Gabapentin can be taken orally with or without food.

**Contraindication & Precaution**
Gabapentin is contraindicated in patients who have known hypersensitivity to the drug. Patients should not drive a car or operate complex machinery until they have gained sufficient experiences about Gabapentin whether or not it affects their mental and/ or motor performance adversely.

**Side Effect**
Fatigue, Dizziness, ataxia, weight gain, peripheral edema, dry mouth & somnolence may occur.

**Use in Pregnancy & Lactation**
Pregnancy category C. Gabapentin may be secreted through the breast milk. So it should be used during lactation only if potential benefits justifies the potential risk to the baby.

**Preparation**
100 mg & 300 mg Tablet.


**Drug Interaction**
Terfenadine, Astemizole, Mizolastine, Cisapride, Triazolam, oral midazolam, dofetilide, quinidine, pimozide, simvastatin & lovastatin.

**Use in Pregnancy & Lactation**
Miconazole Oral Gel should be avoided in pregnant women if possible. The potential hazards should be balanced against the possible benefits. Caution should be exercised when prescribing Miconazole Oral Gel to nursing mothers.

**Preparation**
20 mg/gm Oral Gel.

# Gelora®

**Active Ingredient**
Miconazole.

**Indication**
Treatment & prevention of fungal infections of the oropharynx & gastrointestinal tract, & of super infections due to Gram-positive bacteria.

**Dosage & Administration**
Adults : 1-2 teaspoonfuls of gel four times daily, Children aged 6 years & over: 1 tea-spoonful of gel four times daily, Children aged 2-6 years: 1 tea-spoonful of gel twice daily , Infants under 2 years : ½ tea-spoonful of gel twice daily.

**Side Effect**
Nausea, vomiting, diarrhoea, allergic reactions.

**Contraindication & Precaution**
Known hypersensitivity to the active drug.If the concomitantuseofMiconazole&anticoagulants is envisaged, the anti-coagulant effect should be carefully monitored & titrated. It is advisable to monitor Miconazole & Phenytoin levels, if they are used concomitantly. Particularly in infants & young children, caution is required to ensure that the gel does not obstruct the throat.

# Genacyn® Ointment

**Active Ingredient**
Gentamicin.

**Indication**
Burns, eczema, seborrheic dermatitis, ecthyma, excoriation, folliculitis, furunculosis, insect bites & stings, lacerations & abrasions, paronychia, pyoderma gangrenosum, skin cysts & abscesses, stasis ulcers & infected skin ulcers, bacterial, fungal or viral superinfection, sycosis barbae, minor surgical wounds, infected contact dermatitis caused by susceptible organisms.

**Dosage & Administration**
Apply 3-4 times daily. Before application the area should be washed with soap & water & dried thoroughly. The treated area may be covered with gauze dressing if desired. If crusts present, it should be removed before application of ointment to provide maximum contact with the infecting organisms.

**Precaution**
It should not be used to patients with hypersensitivity to Gentamicin.

**Side Effect**
Itching, redness, swelling or other signs of irritation.

**Preparation**
0.1% Ointment.

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**Use in Pregnancy & Lactation**
Not applicable for the intended patient population.

Precaution
For external use only. Do not inject or swallow. Keep out of the eyes and ears and do not use over large areas of the body. If the product comes into contact with the eyes, wash out promptly and thoroughly with clean water. There have been reports of hypersensitivity and skin irritation after topical administration of Chlorhexidine, including generalized allergic reactions and anaphylactic shock. The prevalence of Chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. The application of this product should be discontinued and immediate medical help should be sought in case of any symptoms which may indicate an allergic reaction. If skin irritation or redness occurs, prompt medical advice should be sought.

**Preparation**
Each HDPE container contains 10 ml solution.

# Germicord™

**Active Ingredient**
Chlorhexidine Gluconate 7.1% w/v equivalent to 35.52 ml Chlorhexidine Gluconate Solution BP or 4% w/v Chlorhexidine Solution

**Indication**
Germicord™ 7.1% Solution is indicated for prophylaxis of omphalitis (infection of the umbilical cord) in newborn.

**Dosage & Administration**
Immediately after cutting the cord, Germicord™ should be applied to the tip of the cord, the stump and around the base of the stump.

# Germisol® Hand Rub

**Active Ingredient**
Chlorhexidine Gluconate

**Indication**
For the disinfection of clean & intact skin. For pre-operative surgical hand disinfection, hand disinfection on the ward prior to aseptic procedures or after handling contaminated materials.
For disinfection of the patients' skin prior to

surgery or other invasive procedures.

**Dosage & Administration**
For external use only.
Adults:
*Pre-operative surgical hand disinfection:* Dispense 5 ml of solution & spread thoroughly over both hands & forearms, rubbing vigorously. When dry apply a further 5 ml & repeat the procedure.
*Antiseptic hand disinfection on the ward:* Dispense 3 ml of solution & spread thoroughly over the hands & wrists rubbing vigorously until dry.
*Disinfection of patients' skin:* Prior to surgery apply the solution to a sterile swab & rub vigorously over the operation site for a minimum of 2 minutes. Chlorhexidine Gluconate is also used for preparation of the skin prior to invasive procedures such as venepuncture.
Elderly & children: There are no special dosing regimes for children & the elderly.

**Contraindication & Precaution**
Chlorhexidine Gluconate is contraindicated for persons who have previously shown a hypersensitivity to Chlorhexidine. However, such reactions are extremely rare.
Avoid contact with the brain, meninges or middle ear. Do not use for injection. Do not use in body cavities. The solution is irritant to the eyes & mucous membranes. Keep out of contact with eyes. If chlorhexidine solutions come into contact with the eyes, wash out promptly & thoroughly with water. The preparation is flammable due to its alcohol content. When use is to be followed by diathermy do not allow pooling of the fluid to occur, & ensure that the skin & surrounding drapes are dry. Prolonged skin contact with alcoholic solutions should be avoided, allow drying before proceeding.

**Side Effect**
Irritative skin reactions can occasionally occur. Generalised allergic reactions have also been reported but are extremely rare.

**Drug Interaction**
Chlorhexidine is incompatible with soaps & other anionic agents. Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with chlorhexidine solutions.

**Use in Pregnancy & Lactation**
No untoward effects are known.

**Preparation**
0.5% w/v Chlorhexidine Gluconate in 70% v/v Isopropyl Alcohol.



# Geston®

**Active Ingredient**
Allylestrenol.

**Indication**
- Threatened abortion
- Habitual abortion
- Threatened premature delivery
- IUGR

**Dosage & Administration**
Threatened abortion: 1 tablet three times daily until symptoms disappear.
Habitual abortion : 1 - 2 tablets daily as soon as pregnancy is diagnosed. The administration should be continued for at least one month after the end of the critical period.
Threatened premature delivery : Dosage must be determined individually. High dosages (up to 40mg daily) have been used.
IUGR: 1 tablet three times daily for at least two months. The dose is to be reduced if symptoms improved
Missed dose: In case of a missed dose it should be taken as soon as the patient remembers

& she should continue the regular dosing schedule. A double dose is not recommended.

**Contraindication & Precaution**
Hypersensitivity; thrombophleobitis; undiagnosed vaginal bleeding, incomplete abortion, hormone-dependent carcinoma, cerebral apoplexy, as a diagnostic test for pregnancy; severe hepatic impairment.

**Side Effect**
Treatment with Allylestrenol (especially a long term treatment with it) is known to cause some gastrointestinal complaints such as vomiting, nausea, & sometimes epigastric discomfort.

**Use in Pregnancy & Lactation**
Specially designed for pregnancy. Should not be used during lactation.



**Use in Children**
It should not be used for children younger than 16 years old.

**Preparation**
5 mg tablet.

## Glysup® Suppository

**Active Ingredient**
Glycerin

**Indication**
For the relief of occasional constipation.

**Dosage & Administration**
Children under 2 years: Consult with a physician. Children (2 to 6 years): Only 1 Glysup 1.15 suppository per 24 hours or as directed by the physician.
Adults & Children (From 6 years): only 1 Glysup 2.30 suppository per 24 hours or as directed by the physician. Insert suppository well up into rectum. Suppository needs to melt completely to produce laxative action.

**Contraindication & Precaution**
Sensitivity to the ingredients. Do not use unless the patient needs to be treated (when constipated).

**Side Effect**
Glycerin when used rectally may cause rectal discomfort or a burning sensation.

**Use in Pregnancy & Lactation**
There are no controlled data in human pregnancy.

**Preparation**
1.15 gm & 2.30 gm Suppository

## Gol™

**Active Ingredient**
Macrogol & Electrolytes

**Pharmacology**
Macrogol (3350) exerts an osmotic action in the gut, which induces a laxative effect. Macrogol (3350) increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the soften stools and a facilitation of the defecation. Electrolytes combined with Macrogol (3350) are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted without net gain or

loss of sodium, potassium and water. Macrogol (3350) is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract.

**Indication**
For use in adults and children over 12 years of age for effective relief from constipation and treatment of chronic constipation. Also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and colon.

**Dosage & Administration**
Measure 25 mL of GOL™ oral solution with measuring cup provided, then add this to 100 mL of water. Any unused diluted solution should be discarded within 24 hours.
Adults:
Constipation: 25 mL of GOL™ oral solution added to 100 mL of water once daily (to make a total volume of 125 mL). This may be increased to 2 – 3 doses of 25 mL daily (each 25 mL dose added to 100 mL of water), if required according to individual response.
Fecal Impaction: 8 doses of 25 mL daily (each 25 mL dose added to 100 mL of water). A course of treatment for faecal impaction does not normally exceed 3 days.
Children (12 -18 years): 25 mL of GOL™ oral solution added to 100 mL of water once daily.

**Contraindication**
Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon. Hypersensitivity to the active substances.

**Precaution**
This medicinal product contains 8.125 mmol of sodium in each dose of 25 ml. The sodium content of GOL™ oral solution should be taken into consideration when administering the product to patients on a controlled sodium diet.

**Side Effect**
In the treatment of chronic constipation, diarrhoea or loose stools normally respond to a reduction in dose. Diarrhoea, abdominal distension, anorectal discomfort and mild vomiting are more often observed during the treatment for fecal impaction. Vomiting may be resolved if the dose is reduced or delayed.

**Use In Pregnancy & Lactation**
Clinically, no effects during pregnancy are anticipated, since systemic exposure to Macrogol (3350) is negligible. GOL™ oral solution can be used during pregnancy.
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Macrogol (3350) is negligible. GOL™ oral solution can be used during breast-feeding.

**Drug Interaction**
There is a possibility that the absorption of other medicinal products could be transiently reduced during use with GOL™ oral solution. There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

**Overdose**
Extensive fluid loss by diarrhea or vomiting may require correction of electrolyte disturbances.

**Preparation**
100 ml solution.



# Grastim™

**Active Ingredient**
Filgrastim Concentrated Solution.

**Indication**
a. Cancer patients receiving myelosuppressive chemotherapy
b. Patients with Acute Myeloid Leukemia,

receiving Induction or consolidation chemotherapy
c. Cancer patients receiving bone marrow transplant
d. Patients undergoing peripheral blood Progenitor cell collection and therapy
e. Patients with severe chronic neutropenia

**Side Effect**
Neutropenia, vomiting, leukopenia, anaemia, thrombocytopenia, pyrexia, back pain, abdominal pain, diarrhoea, cough, pain, nausea, pain in extremity, headache, constipation, stomatitis, asthenia, mucosal inflammation, alopecia.
Contraindications
Filgrastim is contraindicated in patients hypersensitive to the drug, any ingredient in the formulation, or proteins derived from Escherichia coli.



**Pediatric precautions**
Filgrastim has been used in children 3 months to 18 years of age without unusual adverse effect. However, safety and efficacy of the drug in neonates or patients with autoimmune neutropenia of infancy have not been established

**Use in Pregnancy & Lactation**
Pregnancy category: C. although there are no adequate and controlled studies to date in humans, Filgrastim has been shown to adversely affect pregnancy and the fetus in animals. Filgrastim should be used during pregnancy only when the potential benefits justify the possible risks to the fetus. It is not known whether Filgrastim is distributed into milk. Because many drugs are distributed into milk, Filgrastim should be used with caution in nursing women.

**Drug Interaction**
The safety and efficacy of concomitant administration of doses of Filgrastim with doses of myelosuppressive antineoplastic agents have not been established. Because transient decreases in platelet counts have been reported in some patients receiving Filgrastim, it is recommended that the drug should be used with caution in patients receiving other drugs known to decrease the platelet count.

**Dosage and administration**
As directed by the physician.

**Preparation**
Each 0.5 ml Pre-filled syringe contains sterile Filgrastim Concentrated Solution BP (GCSF) 300 mcg (30 MU).

# Gutfix™

**Active Ingredient**
Lubiprostone INN

**Indication**
• Irritable Bowel Syndrome with Constipation (IBS-C).
• Chronic Idiopathic Constipation (CIC) in adults.
• Opioid-Induced Constipation (OIC) in adult patients with chronic, non-cancer pain.

**Dosage & Administration**
Irritable Bowel Syndrome with Constipation:
The recommended dose is 8 mcg twice daily orally with food and water.

Chronic Idiopathic Constipation and Opioid-Induced Constipation:
The recommended dose is 24 mcg twice daily orally with food and water.

**Contraindications**
Lubiprostone is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

**Side Effects**
Diarrhea, full or bloated feeling or pressure in

the stomach, nausea, stomach pain, swelling of abdominal or stomach area, dyspnea.

**Use in Pregnancy & Lactation**
May be used in pregnancy only if it is clearly needed by the assessment of risk benefit ratio.

Caution should be exercised when Lubiprostone is administered to a nursing woman.

**Drug Interaction**
There is a possibility of a dose-dependent decrease in the efficacy of Lubiprostone in patients using diphenylheptane opioids.

**Prepparation**
8 mcg and 24 mcg Capsule

# Gynepro®

**Active Ingredient**
Metronidazole, Neomycin Sulphate, Polymyxin B Sulphate, Nystatin.

**Indication**
Vaginal trichomoniasis, vaginal leucorrhoeas, mixed vaginal infections (Fungal or Bacterial).

**Dosage & Administration**
One suppository in vagina at bedtime for 12 days, or as directed by the physician.

**Contraindication & Precaution**
Contraindicated to the patients who are hypersensitive to Metronidazole, Neomycin Sulphate, Polymyxin B Sulphate & Nystatin. Caution should be taken in case of renal impairment.



**Side Effect**
Skin rash, urticaria may occur rarely.

**Use in Pregnancy & Lactation**
Caution should be practiced in pregnancy & lactation.

**Preparation**
Each box contains 2 x 6's vaginal suppositories.

# Halobet™

**Active Ingredient**
Halobetasol Propionate.

**Indication**
Halobet (Halobetasol Propionate) cream & ointment are a super-high potency corticosteroid indicated for the relief of the inflammatory & pruritic manifestations of corticosteroid-responsive dermatitis.

**Dosage & Administration**
Apply a thin layer to the affected skin once or twice daily, as directed by your physician & rub in gently & completely. Halobet(Halobetasol Propionate) is a super-high potency topical corticosteroid; therefore, treatment should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. Halobet should not be used with occlusive dressings.

**Contraindication & Precaution**
Halobetasol Propionate is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, & glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, & the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol & ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt & complete upon discontinuation of the drug. Infrequently, signs & symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

**Side Effect**
In controlled clinical trials, the most frequent adverse events reported for Halobet included

stinging, burning or itching in 4.4% of the patients. Less frequently reported adverse reactions were dry skin, erythema, skin atrophy, leukoderma, vesicles & rash. The following additional local adverse reactions are reported infrequently with topical corticosteroids, & they may occur more frequently with high potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folulicilitis, hypertrichosis, acneiform eruptions,hypopigmentation, perioral dermatitis, allergic contact dermatitis, seconday infection, striae & miliaria.

**Drug Interaction**
No such report has been founded.

**Use in Pregnancy & Lactation**
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate & well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

**Use in Children**
Not recommended for use in children.

**Preparation**
Halobet 0.05% Cream - Each pack has a laminated tube containing 20 gm cream.
Halobet 0.05% Ointment - Each pack has a laminated tube containing 20 gm ointment.

# Hemorif®

**Active Ingredient**
Micronised Diosmin & Hesperidin

**Indication**
Acute hemorrhoidal attacks, Chronic hemorrhoidal disease, organic & functional chronic venous insufficiency of the lower limbs with the following symptoms: heavy legs, pain, nocturnal cramps.



**Dosage & Administration**
*Acute hemorrhoidal attacks:* 3 tablets twice daily for 4 days, then 2 tablets twice daily for three days & if required then 1 tablet twice daily.
*Chronic hemorrhoids :* 1 tablet twice daily, *Chronic venous insufficiency :* 1 tablet twice daily initially for seven days. Duration may be increased depending on severity.

**Side Effect**
Gastric disorder & neurovegetative disorders (feeling of discomfort).

**Use in Pregnancy & Lactation**
Experimental studies in animal have not demonstrated any teratogenic effects & no harmful effect have been reported in women to date.
Breast feeding is not recommended during treatment.

**Preparation**
(Diosmin 450 mg + Hesperidin 50 mg)/Tablet.

# Hemorif® DS

**Active Ingredient**
Diosmin BP 900 mg & Hesperidin USP 100 mg

**Indication**
Used for poor circulation in the legs (Chronic Venous Insufficiency, CVI),
hemorrhoids, leg ulcers from poor circulation (venous stasis ulcers), also have
some evidence for the treatment of bleeding gums, bleeding/hemorrhage in
the eye, preventing damage to the liver, varicose veins).

**Dosage & Administration**
Acute Hemorrhoid: 1 tablet thrice daily for first 4 days, followed by 1 tablet
twice daily for 3 days & then 1 tablet once daily as maintenance dose.
Relapse of Internal Hemorrhoid & Chronic Hemorrhoid: 1 tablet once daily for
3 months.
CVI: 1 tablet once daily for 2-6 months.
Leg Wounds: 1 tablet once daily for 2 months.

**Contraindication**
CVI and its complications should be diagnosed and management monitored
by a physician. It is contraindicated for anyone having a hypersensitivity to
any ingredient in the product.

**Adverse Effects**
The most common adverse reactions reported in subjects receiving
combination therapy were gastrointestinal disturbances, headache, rash,
cramps in lower limb, phlebitis, venous thrombosis.

**Use In Pregnancy & Lactation**
Pregnant Women: Experimental studies have not shown any teratogenic
effect in animals. In human beings, no harmful effect has so far been reported.
Nursing Women: In the absence of data concerning excretion into breast milk,
breast feeding is not recommended during treatment.

**Preparation**
30 tablets.

# Hemosol™ -A

**Active Ingredient**
Bicarbonate Hemodialysis Solution (Acidic Component)

**Indication**
i. Acute & Chronic renal failure
ii. To correct electrolyte and acid-base imbalance
iii. In the treatment of poisoning

**Dosage & Administration**
HemosolTM-A & Hemosol™-B to be used in the dilution ratio of HemosolTM-A (Acidic Solution): Hemosol™-B (Basic Solution): Purified Water BP = 1: 1.83: 34. Hemodialysis needs to be performed 2-3 times a week. Each session lasts for 3-6 hrs.

**Preparation**
10 Liter Solution.

# Hemosol™ -B

**Active Ingredient**
Bicarbonate Hemodialysis Solution (Basic Component)

**Indication**
i. Acute & Chronic renal failure
ii. To correct electrolyte and acid-base imbalance
iii. In the treatment of poisoning

**Dosage & Administration**
HemosolTM-A & HemosolTM-B to be used in the dilution ratio of HemosolTM-A (Acidic Solution): HemosolTM-B (Basic Solution): Purified Water BP = 1: 1.83: 34. Hemodialysis needs to be performed 2-3 times a week. Each session lasts for 3-6 hrs.

**Preparation**
10 Liter Solution.

# Heplol™

**Active Ingredient**
Heplol™: Each Tablet contains 150 mg L-Ornithine L-Aspartate.

**Indication**
• Treatment of hyperammonemia as a result of acute and chronic liver diseases such as liver cirrhosis, fatty liver, hepatitis; especially for the treatment of incipient disturbances of consciousness (pre-coma) or neurological complications (hepatic encephalopathy).
• Treatment of concomitant diseases and sequelae of acute and chronic liver diseases (e.g. liver cirrhosis) with the symptoms of latent and manifest hepatic encephalopathy.

**Dosage & Administration**
Adults and children over 7 years of age: 150 mg-300 mg (1 to 2 tablets) 3 times a day taken with a small amount of water. The course of treatment is determined individually.

**Side Effects**
• Nausea
• Vomiting
• Stomachache
• Flatulence
• Diarrhea

**Use In Pregnancy & Lactation**
It is not known whether there are harmful e_ ects from use of the product during pregnancy or while breastfeeding. Caution needed for pregnant and breastfeeding women.

**Contraindication**
• Hypersensitivity to L-Ornithine L-Aspartate or any other excipients in these products.
• Severe renal insu_ciency (a serum creatinine value exceeding 3mg/100 ml is regarded as reference value).

**Drug Interaction**
Not known

**Preparation**
150 mg tablet.

# Imotil®

**Active Ingredient**
Loperamide.

**Indication**
Acute & chronic diarrhoea, IBS (Diarrhoea predominant).

**Dosage & Administration**
Acute diarrhoea: The initial dose is 2 capsules for adults & 1 capsule for children older than eight; in addition 1 capsule should be taken at any subsequent loose stool. The daily dose, however should not exceed 8 capsules for adults, for children 4-6 capsules according to age. Chronic diarrhoea Initial dose: Adults: 2 capsules daily. Children: Older than eight: 1 capsule daily.

**Contraindication & Precaution**
It should not be used in children less than 4 years of age.

**Side Effect**
Paralytic ileus, abdominal cramps & bloating urticaria, nausea, vomiting, constipation, tiredness, drowsiness, dizziness & dry mouth.

**Use in Pregnancy & Lactation**
Although studies in animal did not demonstrate any teratogenic Effect of loperamide, it should not be administered during pregnancy. The fraction of loperamide secreted in the human milk is very low, but caution is advised if it is to be administered to nursing mothers.

**Preparation**
2 mg Capsule.

# Infudex™

**Active Ingredient**
Dextrose Anhydrous.

**Indication**
Simple dehydration, Carbohydrate depletion, hypoglycemic coma, General weakness etc.

**Dosage & Administration**
Dose is variable. It depends on the clinical condition, age and body surface area of the patients.

**Preparation**
Infudex 5 IV Infusion, 500 ml: Each 100 ml solution contains 5 gm Dextrose Anhydrous USP. Infudex 5 IV Infusion, 1000 ml: Each 100 ml solution contains 5 gm Dextrose Anhydrous USP. Infudex 10 IV Infusion, 500 ml: Each 100 ml solution contains 10 gm Dextrose Anhydrous USP. Infudex 10 IV Infusion, 1000 ml: Each 100 ml solution contains 10 gm Dextrose Anhydrous USP.

# Intimate™

**Active Ingredient**
Tadalafil.

**Indication**
Erectile Dysfunction (ED) & the signs & symptoms of Benign Prostatic Hyperplasia (BPH).

**Dosage & Administration**
Erectile Dysfunction
***For Use as Needed***
• The recommended starting dose of Tadalafil for use as needed in most patients is 10 mg, taken prior to anticipated sexual activity.

• The dose may be increased to 20 mg or decreased to 5 mg, based on individual efficacy & tolerability. The maximum recommended dosing frequency is once per day in most patients.
***For Once Daily Use***

• The recommended starting dose of Tadalafil for once daily use is 2.5 mg, taken at approximately the same time every day, without regard to timing of sexual activity.
• The Tadalafil dose for once daily use may be increased to 5 mg, based on individual efficacy & tolerability.

***Use with Food***

Tadalafil may be taken without regard to food.
ild (creatinine clearance 51 to 80 mL/min): No dose adjustment is required.
•Moderate (creatinine clearance 31 to 50 mL/min): A starting dose of 5 mg not more than once per day is recommended, & the, maximum dose should be limited to 10 mg not more than once in every 48 hours.
•Severe (creatinine clearance <30 mL/min & on hemodialysis): The maximum recommended dose is 5 mg not more than once in every 72 hours

Tadalafil for Once Daily Use
•Mild (creatinine clearance 51 to 80 mL/min): No dose adjustment is required.
•Moderate (creatinine clearance 31 to 50 mL/min): No dose adjustment is required.
•Severe (creatinine clearance <30 mL/min & on hemodialysis): Tadalafil for once daily use is not recommended.
Hepatic Impairment:
Tadalafil for Use as Needed: Mild or moderate : The dose of Tadalafil should not exceed 10 mg once per day. The use of Tadalafil once per day has not been extensively evaluated in patients with hepatic insufficiency & therefore, caution is advised.
Severe : The use of Tadalafil is not recommended
Tadalafil for Once Daily Use
•Mild or moderate : Tadalafil for once daily use has not been extensively evaluated in patients with hepatic insufficiency. Therefore, caution is advised if Tadalafil for once daily use is prescribed to these patients.
•Severe : The use of Tadalafil is not recommended.
Geriatrics:
No dose adjustment is required in patients >65 years of age.

**Contraindication**

*Nitrates*

Administration of Intimate to patients who are using any form of organic nitrate, either regularly and/or intermittently, is contraindicated. In clinical pharmacology studies, Intimate was shown to potentiate the hypotensive effect of nitrates.

*Hypersensitivity Reactions*

Intimate is contraindicated in patients with a known serious hypersensitivity to tadalafil. Hypersensitivity reactions have been reported, including Stevens-Johnson syndrome & exfoliative dermatitis.

**Side Effect**

Body as a whole: Hypersensitivity reactions including rash, urticaria, facial edema, Stevens-Johnson syndrome, & exfoliative dermatitis.
Cardiovascular & cerebrovascular: Serious cardiovascular events, including myocardial infarction, sudden cardiac death, unstable angina pectoris, ventricular arrhythmia, stroke, transient ischemic attacks, chest pain, palpitations, & tachycardia, may occur. Most of the patients in whom these events have been reported had pre-existing cardiovascular risk factors. However, it is not possible to definitively determine whether these events are related directly to these risk factors, to Tadalafil, to sexual activity, or to a combination of these or other factors. Hypotension (more commonly reported when tadalafil is given to patients who are already taking antihypertensive agents), hypertension, & syncope.

Skin & subcutaneous tissues: Hyperhidrosis (sweating).
Gastrointestinal: Abdominal pain & gastroesophageal reflux.
Nervous system: Migraine, transient global amnesia
Respiratory system: Epistaxis (nose bleed)
Special senses: Blurred vision, nonarteritic anterior ischemic optic neuropathy, retinal vein occlusion, visual field defect.

Otologic: Cases of sudden decrease or loss of hearing have been reported.

**Pregnancy & Lactation**
Intimate is not indicated for use in newborn, children or women.

**Precaution**
Evaluation of erectile dysfunction & BPH should include an appropriate medical assessment to identify potential underlying causes, as well as treatment options. Before prescribing Intimate, it is important to note the following: Cardiovascular status of the patient, Interaction with other medicines (Nitrates, alpha-blocker, anti-hypertensive & potent inhibitors of CYP3A4) & with substantial consumption of alcohol, sudden loss of vision, sudden hearing loss, renal insufficiency & hepatic impairment.



**Overdosage**
Adverse events were similar to those seen at lower doses. In case of overdose, standard supportive measure should be adopted as required. Hemodialysis contributes negligible to tadalafil elimination

**Preparation**
5, 10 & 20 mg Tablet.

## Iprex™ Respirator Solution

**Active Ingredient**
Ipratropium Bromide.

**Indication**
Maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis & emphysema.

**Dosage & Administration**
Adults - 0.4-2 ml (100-500 mcg) of Ipratropium bromide should be diluted to a final volume of 2.0-4.0 ml with normal saline 0.9% administered four times daily. Children (over 3 years) - The same mode of administration is applicable to children. 0.4-2 ml of the prepared solution administered 3 times daily.

**Contraindication & Precaution**
Contraindicated in patients with a history of hypersensitivity to soya lecithin or related food products such as soybean & peanut, known or suspected cases of hypersensitivity to ipratropium bromide, or to atropine & its derivatives. Ipratropium bromide should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy or bladder-neck obstruction.

**Side Effect**
Dry mouth through inhibition of salivary flow, dryness of the oropharynx; cough, exacerbation of symptoms, & irritation from aerosol; headache; nausea, dizziness, blurred vision/difficulty in accommodation & drying of secretions, tachycardia, nervousness, paresthesias, drowsiness, coordination difficulty, itching, hives, flushing, alopecia, constipation, tremor & mucosal ulceration, worsening of narrow-angle glaucoma, acute eye pain, hypotension, Allergic-type reactions such as skin rash, angio-oedema of tongue, lips & face, urticaria (including giant urticaria), laryngospasm & anaphylactic reaction.

**Drug Interaction**
There are no studies fully evaluating the interaction Effects of Ipratropium.

**Use in Pregnancy & Lactation**
Pregnancy Category B., Ipratropium bromide should be used during pregnancy only if clearly needed. It is not known whether ipratropium bromide is excreted in human milk.

**Preparation**
250 mcg/ml Respirator Solution.

# Iracet™

**Active Ingredient**
Levetiracetam

**Indication**
Iracet (Levetiracetam) is indicated as an adjunctive therapy for Partial Onset Seizures, Myoclonic Seizures in Patients with Juvenile Myoclonic Epilepsy, Primary Generalized Tonic-Clonic Seizures

**Dosage & Administration**
Iracet (Levetiracetam) can be initiated with either intravenous or oral administration.
For tablet & oral solution: Treatment should be initiated with a daily dose of 1000 mg/day, given as twice-daily dosing (500 mg twice daily). Additional dosing increments may be given (1000 mg/day additional every 2 weeks) to a maximum recommended daily dose of 3000 mg.

**Use in Pediatric Patients**

| Age/weight | Initial dose (Daily) | Incremental dose (Daily) |
|---|---|---|
| 1 Month To < 6 Months | 7 mg/kg twice daily | 21 mg/kg twice daily |
| 6 Months To < 4 Years | 10 mg/kg twice daily | 25 mg/kg twice daily |
| 4 Years To < 16 Years | 10 mg/kg twice daily | 30 mg/kg twice daily |
| Adolescent with 20- 40 kg body weight | 250 mg twice daily | 750 mg twice daily |

*The daily dose should be increased every 2 weeks.

*Weight-Based Dosing Calculation For Pediatric Patients:*
Total daily dose (mL/day) = Daily dose (mg/kg/day) x patient weight (kg)/100 mg/mL
*Injection:*
Iracet (Levetiracetam) injection is for intravenous use only & must be diluted prior to administration. Iracet™ (Levetiracetam) injection (500 mg/5 mL) should be diluted in 100 mL of compatible diluents & administered intravenously as a 15-minute IV infusion. Product with particulate matter or discoloration should not be used.

**Dosing Instructions**
Preparation & Administration

| Dose | Withdraw Volume | Volume of Diluent | Infusion Time |
|---|---|---|---|
| 500 mg | 5 ml (one 5 ml ampoule) | 100 ml | 15 minutes |
| 1000 mg | 10 ml (two 5 ml ampoules) | 100 ml | 15 minutes |
| 1500 mg | 15 ml (three 5 ml ampoules) | 100 ml | 15 minutes |

For example, to prepare a 1000 mg dose, dilute 10 ml of Iracet (Levetiracetam) injection in 100 ml of a compatible diluents & administer intravenously as a 15-minute infusion.
*Compatibility & Stability*
Levetiracetam injection was found to be physically compatible & chemically stable when mixed with the following diluents & antiepileptic drugs for at least 24 hours & stored in polyvinyl chloride (PVC) bags at controlled room temperature 15-30°C (59-86°F).
*Diluents*
• Sodium chloride (0.9%) injection, USP
• Lactated Ringer's injection
• Dextrose 5% injection, USP
Other Antiepileptic Drugs
• Lorazepam
• Diazepam
• Valproate sodium

**Contraindication & Precaution**
None

**Side Effect**
Dizziness, drowsiness, irritability, sore throat, tiredness, weakness are some common adverse effects. In rare cases severe allergic reaction may happen.

**Drug Interaction**
No potential drug interaction has been reported

**Use in Pregnancy & Lactation**
Pregnancy category C.

**Lactation**
No data on the use of Levetiracetam in breast-feeding women are available. Data from animals indicate that Levetiracetam is secreted into milk. Therefore Levetiracetam is contraindicated during breast-feeding

**Use in Children**
The safety & effectiveness of Levetiracetam in the adjunctive treatment of partial onset seizures in pediatric patients' age 1 month to 16 years old with epilepsy have been established.

**Preparation**
250 mg & 500 mg, 500 mg XR Tablet, Injection: 50 ml oral solution.

# Isodex™ IV

**Active Ingredient**
Dextrose Anhydrous USP 4.30% w/v & Sodium Chloride BP 0.18% w/v

**Indication**
It is indicated in water and sodium depletion. It provides Dextrose as a nutrient in a suitable medium of Sodium Chloride or it may also be employed as a source of Sodium Chloride. It is usually used in the maintenance and replacement of fluid, electrolyte and carbohydrate in patients who are in nothing by mouth regimen during pre & post operative stage.

**Dosage & Administration**
The volume and rate of infusion of the solution depends on the clinical condition, age and body surface area of the patient and judgment of the physicians.

**Contraindication & Precaution**
It is contraindicated in patients with hypernatremia, acidosis, hypokalemia and fluid overload.

**Use in Pregnancy & Lactation**
It is also not known whether Dextrose and Sodium Chloride Infusion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose & Sodium Chloride Infusion is administered to a nursing woman.

**Preparation**
Isodex™ IV, 1000 ml: Each 1000 ml PP bottle contains solution of Sodium Chloride BP 0.18% w/v and Dextrose Anhydrous USP 4.30% w/v.

# Isovent®

**Active Ingredient**
Misoprostol.

**Indication**
Labor induction (in unfavorable cervical conditions) & in the prevention & treatment of Post Partum Hemorrhage (PPH).

**Dosage & Administration**
Induction of Labor: 25 mcg vaginally 6 hourly

or, 50 mcg orally 4 hourly.
Postpartum Hemorrhage (PPH) prophylaxis: 400 mcg to 600 mcg orally or rectally immediately following delivery of the child.
Postpartum Hemorrhage (PPH) treatment: 1000 mcg rectally or, 200 mcg orally with 400 mcg sublingually.

**Side Effect**
Spotting, cramps, hypermenorrhea, menstrual disorder & dysmenorrhea. Postmenopausal vaginal bleeding may be related to Misoprostol administration.

**Contraindication & Precaution**
Precaution should be taken in conditions where hypertension might precipitate severe complications (e.g. Cerebrovascular & cardiovascular disease).

**Drug Interaction**
No evidence of clinically significant interaction between Misoprostol & cardiac, pulmonary & CNS drugs & NSAIDs. Bioavailability of Misoprostol is decreased with high doses of antacid.

**Use in Pregnancy & Lactation**
Because of the abortifacient property of the Misoprostol component, it is contraindicated in women who are pregnant.

**Preparation**
200 mcg & 600 mcg Tablet.



# Itra®

**Active Ingredient**
Itraconazole.
**Indication**
Candidiasis, Pityriasis Versicolor, Tinea, histoplasmosis, systemic candidiasis, aspergillosis, cryptococcosis, in AIDS patients to prevent relapse of underlying fungal infections & in the prevention of fungal infection during prolonged neutropenia.

**Dosage & Administration**
100 mg -200 mg daily.

**Side Effect**
Nausea, abdominal pain, dyspepsia, constipation, headache, dizziness, raised liver enzymes, menstrual disorders, allergic reactions (including pruritus, rash, urticaria & angioedema), hepatitis & cholestatic jaundice, peripheral neuropathy & Stevens-Johnson syndrome reported. On prolonged use hypokalaemia, oedema & hair loss reported.

**Contraindication & Precaution**
Known hypersensitivity, severe hepatic disease.

**Drug Interaction**
The drugs like terfenadine, astemizole, cisapride, HMG-CoA reductase inhibitors such as simvastatin, oral midazolam or triazolam should not be given concurrently with Itraconazole. Significant interactions also observed during co-administration of rifampin, phenytoin, phenobarbital, digoxin, & calcium channel blockers.

**Use in Pregnancy & Lactation**
Itraconazole is contraindicated in pregnancy. Breast feeding while receiving Itraconazole is not recommended.

**Preparation**
100 mg Capsule.

# Ivanor™

**Active Ingredient**
Ivabradine Hydrochloride.

**Indication**
Symptomatic treatment of chronic stable angina pectoris in coronary artery disease patients with normal sinus rhythm. **Ivanor**™ is indicated:

- In patients unable to tolerate or with a contra-indication to the use of beta-blockers, or
- In combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose & whose heart rate is > 60 bpm.

**Dosage & Administration**
The usual recommended starting dose of Ivabradine is 5 mg twice daily which may be increased after 3-4 weeks of treatment to 7.5 mg twice daily, depending on therapeutic response. Usual dose is 1 tablet in the morning & 1 tablet in the evening during meals.

**Contraindication & Precaution**
History of hypersensitivity to Ivabradine or any of the excipients, resting heart rate below 60 bpm before treatment, cardiogenic shock, acute myocardial infarction, severe hypotension (<90/50 mmHg), severe hepatic insufficiency, sick sinus syndrome, sino-atrial block, heart failure, pacemaker dependent, unstable angina, 3rd degree AV block, combination with strong cytochrome P450 3A4 inhibitors (such as azole antifungals, macrolide antibiotics, HIV protease inhibitors).
Mild to moderate hypotension, Atrial fibrillation, Patients with congenital QT syndrome or treated with QT wave prolonging medicinal products, Moderate hepatic insufficiency, Severe renal insufficiency.

**Side Effect**
Visual symptoms, blurred vision, bradycardia, 1st degree AV block, ventricular extrasystoles, headaches, & dizziness.

**Drug Interaction**
QT wave prolonging medicinal products is not recommended.

- Cardiovascular QT wave prolonging medicinal products (e.g. quinidine, disopyramide, bepridil, sotalol, ibutilide, amiodarone). Non cardiovascular QT wave prolonging medicinal products (e.g. pimozide, ziprasidone, sertindole, mefloquine, halofantrine, pentamidine, cisapride, intravenous erythromycin).
- The concomitant use of cardiovascular & non cardiovascular QT wave prolonging medicinal products with Ivabradine should be avoided since QT wave prolongation may be exacerbated by heart rate reduction. If the combination appears necessary, close cardiac monitoring is needed.

**Use in Pregnancy & Lactation**
Fertility: Studies in rats have shown no Effect on fertility in males & females
Pregnancy: There are no or limited amount of data from the use of Ivabradine in pregnant women. Therefore, Ivabradine is contra-indicated during pregnancy.
Breast-feeding: Animal studies indicate that Ivabradine is excreted in milk. Therefore, Ivabradine is contra-indicated during breast-feeding.

**Use in Children**
Not recommended.

**Preparation**
5 mg & 7.5 mg Tablet.

# Iventi® Eye Drops

**Active Ingredient**
Moxifloxacin.

**Indication**
Bacterial conjunctivitis.

**Dosage & Administration**
One drop in the affected eye 3 times a day for 7 days.

**Contraindication & Precaution**
In patients with a history of hypersensitivity to Moxifloxacin, to other quinolones, or to any of the components in this medication. As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use & institute alternative therapy. Patients should be advised not to wear contact lenses if they have signs & symptoms of bacterial conjunctivitis.

**Drug Interaction**
Drug-drug interaction studies have not been conducted with Moxifloxacin Hydrochloride ophthalmic solution.

**Side Effect**
Ocular: Conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, & tearing. Non-ocular: fever, increased cough, infection, otitis media, pharyngitis, rash, & rhinitis.

**Use in Pregnancy & Lactation**
Moxifloxacin Hydrochloride ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when Moxifloxacin hydrochloride ophthalmic solution is administered to a nursing mother.

**Preparation**
0.5% Eye Drops.

# Iventi-D™ Eye Drops

**Active Ingredient**
Moxifloxacin & Dexamethasone

**Indication**
Steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists. The combination can also be used for post-operative inflammation and any other ocular inflammation associated with infection.

**Dosage & Administration**
One or two drops instilled into the conjunctival sac(s), every 4 to 6 hours. During the initial 24 to 48 hours, the dosage may be increased to 1 or 2 drops every two hours. Frequency must be decreased gradually or warranted by improvement in clinical signs. Care should be taken not to discontinue the therapy prematurely.
Prevention of Post-Surgery Ocular Inflammation and Infection: Instill 1 drop, 4 times/day in the eye to be operated, starting 1 day before the surgery and during 15 days after the surgery.
Treatment of Ocular Infections Caused by Susceptible Organisms: Instill 1 drop 4 times/day during 7 days, or as directed by the doctor. Observe the appearance of the medicine before using it.
Patients Submitted to Cataract Surgery: Instil the solution immediately after the surgery.
Patients Submitted to Refractive Surgery by LASIK: Instill the solution within 15 min after the surgery.

**Contraindication & Precaution**
This ophthalmic solution is contraindicated in epithelial herpes simplex keratitis (Dendritic keratitis), vaccinia, varicella, and in many other viral diseases of the conjunctiva and cornea, Mycobacterial infection of the eye and fungal diseases of ocular structures and in individuals

hypersensitive to any of the components of the medication. Prolonged use of steroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation.

**Side Effect**
The most frequently reported drug-related undesirable effects seen with Moxifloxacin are conjunctival irritation, increased lacrimation, keratitis and papillary conjunctivitis.

**Use in Pregnancy & Lactation**
There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when Dexamethasone ophthalmic solution is administered to a nursing woman.

**Preparation**
Each LDPE bottle contains 5 ml of Moxifloxacin BP 0.5% and Dexamethasone Phosphate BP 0.1% of sterile solution.

# Iventi® 400 IV

**Active Ingredient**
Moxifloxacin 0.16% w/v.

**Indication**
Acute Bacterial Sinusitis, Acute Bacterial Exacerbation of Chronic Community Acquired Pneumonia, Uncomplicated Skin & Skin Structure Infection.

**Dosage & Administration**

| Infection | Dose | Duration |
|---|---|---|
| Acute Bacterial Sinusitis | 400 mg OD | 10 days |
| Acute Bacterial Exacerbation of Chronic Bronchitis | 400 mg OD | 5 days |
| Community Acquired Pneumonia | 400 mg OD | 10 days |
| Uncomplicated Skin & Skin Structure Infection | 400 mg OD | 7 days |
| | | |

**Contraindication & Precaution**
Moxifloxacin is contraindicated in persons with a history of hypersensitivity to Moxifloxacin or any member of the quinolone class of antimicrobial agents.

**Side Effect**
Iventi is generally well tolerated. The most common side effects caused by Iventi, which are usually mild, include nausea, vomiting, stomach pain, diarrhea, dizziness & headache. You should be careful about driving or operating machinery until you are sure Iventi is not causing dizziness.

**Pregnancy & Lactation**
The safety & effectiveness of Moxifloxacin in pregnant women, & lactating women have not been established.

**Preparation**
250 ml intravenous infusion.

# Iventi® Tablet

**Active Ingredient**
Moxifloxacin.

**Indication**
Moxifloxacin is indicated for the treatment of adults (>18 years of age) in Acute Bacterial Sinusitis, Acute Bacterial Exacerbation of Chronic Bronchitis, Community Acquired Pneumonia, Uncomplicated & Complicated Skin and Skin Structure Infections, Complicated Intra-Abdominal Infections.

**Dosage & Administration**

| Type of Infection | Dosage | Duration (days) |
|---|---|---|
| Acute Bacterial Sinusitis | 400 mg Once Daily | 10 |
| Acute Bacterial Exacerbation of Chronic Bronchitis | 400 mg Once Daily | 5 |
| Community Acquired Pneumonia | 400 mg Once Daily | 7-14 |
| Uncomplicated Skin and Skin Structure Infections (uSSSI) | 400 mg Once Daily | 7 |
| Complicated Skin and Skin Structure Infections (cSSSI) | 400 mg Once Daily | 7-21 |
| Complicated Intra-Abdominal Infections | 400 mg Once Daily | 5-14 |

**Contraindication**
Known hypersensitivity to moxifloxacin or any member of the quinolone class of antimicrobial agents.

**Precaution**
Discontinue if pain or inflammation in a tendon occurs or any hypersensitivity reactions and QT Prolongation observe.

**Side effect**
Iventi is generally well tolerated. The most common side effects caused by Iventi, which are usually mild, include nausea, vomiting, diarrhea, dizziness & headache.

**Use in Pregnancy & Lactation**
Moxifloxacin is a pregnancy category C drug and it may be excreted in human milk. So it should be used only if the potential benefit justifies the potential risk.

**Drug interactions**
Iventi tablet should be administered at least 4 hours before or 8 hours after products containing magnesium, aluminum, iron or zinc, including antacids, sucralfate, multivitamins. NSAID may increase the risk of CNS stimulation. Warfarin may increase the risk of bleeding.

**Preparation**
400 mg tablet.

# Ketoral®

**Active Ingredient**
Ketoconazole.

**Indication**
Superficial & deep mycoses.

**Dosage & Administration**
200 mg one tablet once daily.

**Contraindication & Precaution**
Pregnancy & patients with acute liver pathology. In patients with a previous history of liver disease, liver enzyme levels should be monitored during treatment.

**Side Effect**
Nausea, itching, an idiosyncratic liver reaction may occur (incidence 1:10,000).

**Drug Interaction**
Acyclovir have shown dose-dependent, synergistic, antiviral activity against herpes simplex virus type 1 & 2 in in-vitro replication studies. Ketoconazole & vidarabine showed interference, indifference or antagonism in vitro against these viruses.

**Use in Pregnancy & Lactation**
Ketoconazole is contraindicated in pregnancy. Breast-feeding is contraindicated in patients taking this drug.

**Preparation**
200 mg Tablet.



# K-one® MM

**Active Ingredient**
Phytomenadione.

**Indication**

- Prophylaxis & treatment of haemorrhagic disease in the newborn.
- Haemorrhage or risk of haemorrhage as a result of severe hypoprothrombinemia" (i.e. deficiency of clotting factors II, VII, IX & X) of various etiologies, including over dosage of courmarin-type anticoagulants, their combination with phenylbutazone, & other forms of hypovitaminosis K (e.g. in obstructive jaundice as well as liver & intestinal disorders, & after prolonged treatment with antibiotics, sulphonamides or salicylates).
- Prevention & treatment of bleeding due to vitamin K deficiency.

**Dosage & Administration**
Prophylaxis: Mild Hemorrhage or hemorrhagic tendency: The usual dose for neonates is 2 mg orally at or just after birth. Then 2 mg on 4th - 5th day & another 2 mg on 28th - 30th day orally.
If the oral route is unsuitable then 2 mg of drug can be administered by IM or IV route. Children over 1 year of age are could be given 5-10 mg orally. A single 1 mg (0.1ml) dose IM is recommended in children who are not assured of receiving a second oral dose or, in the case of breast-fed children, who are not assured of receiving a third oral dose.
To ensure a total protection of the newborns, 3 prophylactic doses of Vitamin K should be administered orally following the dosing schedule mentioned above.

Therapy: Initially, 1 mg by intravenous injection, with further doses as required, based on the clinical picture & coagulation status.
Neonates with special risk factors (Pre-maturity, birth asphyxia (inadequate intake of oxygen by

the baby during birth process), obstructive jaundice, inability to swallow, maternal use of anticoagulants or anti-epileptics]: 1 mg intramuscularly or intravenously at birth or shortly after birth if the oral route is unsuitable.

Intramuscular & intravenous doses should not exceed 0.4 mg/kg in premature infants weighing less than 2.5 kg. The size & frequency of further doses should be based on coagulation status.

**Side Effect**
There are isolated unconfirmed reports on the possible occurrence of anaphylactoid reactions & venous irritation or phlebitis after parenteral use of Phytomenadione injections.

**Precaution & Contraindication**
Careful monitoring of the coagulation parameters is necessary for patients with severely impaired liver function after administration of Phytomenadione. It is contraindicated in patients with known hypersensitivity to any of its constituents.

**Use in Pregnancy & Lactation**
Though Vitamin K1 does not readily cross the placental barrier & only a small fraction of administered Vitamin K1 enters into the breast milk, it is not recommended for Phytomenadione to be given to expectant mothers as prophylaxis of hemorrhagic disease in the newborn. Vitamin K1 should be given to pregnant women only if the benefit to the mother outweighs the risk to the fetus.

**Preparation**
Phytomenadione 2 mg / 0.2 ml Oral / IM / IV



# Kop™

**Active Ingredient**
Ketoprofen.

**Indication**
Ankylosing Spondylitis, Osteoarthritis, & Rheumatoid Arthritis, Bursitis & Tendinitis, Dysmenorrhoea or postoperative pain & acute gout or soft-tissue disorders.

**Dosage & Administration**
*SR Capsule:* 100-200 mg once daily.*Elderly:* As with other medications it is generally advisable in the elderly to begin ketoprofen therapy at the lower end of the dose range.

**Contraindication & Precaution**
Ketoprofen is contraindicated in patients with known hypersensitivity to the drug. Ketoprofen is contraindicated in patients in whom asthma, urticaria, or other sensitivity reaction is precipitated by aspirins or other NSAIDs. Adverse GI effects should be considered in patients receiving Ketoprofen.

**Side Effect**
Dyspepsia, nausea, abdominal pain, diarrhoea, constipation, flatulence, anorexia, vomiting, stomatitis, headache, dizziness, malaise, depression, nervousness, dreams, tinnitus, visual disturbance, rash, impairment of renal function, signs or symptoms of urinary-tract irritation.

**Drug Interaction**
Anticoagulant or thrombolytic agent, hydrochlorothiazide, salicylates, methotrexate.

**Use in Pregnancy & Lactation**
It is recommended to avoid medication during pregnancy, should not be used during breast feeding unless unavoidable.

**Preparation**
100 mg SR Tablet.

# Lactoring™ IV

**Active Ingredient**
Hartmann's solution

**Indication**
Lactoring™ IV is used to treat hypovolemia caused by surgery, hemorrhage and trauma. Excessive sweating, severe diarrhea or vomiting, excess loss of fluid by nephritic kidneys, inadequate intake of fluid and electrolytes etc. that may lead to typical hypovolemic shock may be corrected with Lactoring™. Severe plasma loss caused by intestinal obstruction, burns or other denuding conditions of the skin may be treated with Lactoring.

**Dosage & Administration**
The volume and rate of infusion will depend upon the requirements of the patients and the judgment of the physician. It usually varies with age, weight and clinical condition of the patient. The recommended flow rate is up to 100 drops/minute/70 kg body weight.

**Contraindication & Precaution**
As for other calcium-containing infusion solutions, concomitant administration of Ceftriaxone and Compound Sodium Lactate solution is contraindicated in newborns (≤28 days of age), even if separate infusion lines are used (risk of fatal Ceftriaxone-calcium salt precipitation in the neonate's bloodstream).
Compound of Sodium Lactate solution is also contraindicated in patients with
• A known hypersensitivity to sodium lactate.
• Extracellular hyperhydration or hypervolemia
• Severe renal insufficiency
• Hyperkalemia
• Hypercalcaemia
• Metabolic alkalosis
• Severe metabolic acidosis
• Conditions associated with increased lactate levels (hyperlactatemia) including lactic acidosis

**Use in Pregnancy & Lactation**
Can be used safely during pregnancy and lactation as long as the electrolyte- and fluid balance is controlled.
It is reminded that calcium crosses the placenta and is distributed into breast milk.

**Preparation**
Lactoring™ IV 500 ml: Each 500 ml PP bottle contains solution of 0.6% w/v of Sodium Chloride, 0.04% w/v of Potassium Chloride, 0.027% w/v of Calcium Chloride, and 0.32 % w/v of Sodium Lactate.
Lactoring™ IV 1000 ml: Each 1000 ml PP bottle contains solution of 0.6% w/v of Sodium Chloride, 0.04% w/v of Potassium Chloride, 0.027% w/v of Calcium Chloride, and 0.32 % w/v of Sodium Lactate.

# Lamicet™

**Active Ingredient**
Lamotrigine.

**Indication**
Lamicet™ 50 tablet: Each Film-coated tablet contains Lamotrigine USP 50 mg.
Pharmacology
Lamotrigine controls epileptic seizures by inhibiting voltage-sensitive sodium channels, thereby stabilizes neuronal membranes and consequently inhibits presynaptic excitatory neurotransmitter (e.g., glutamate and aspartate) release.
Indications and usage
Lamotrigine is an antiepileptic drug (AED) indicated for:
•Epilepsy—monotherapy in patients aged 16 years and older •Epilepsy—adjunctive therapy in patients aged 2 years and older:
— Partial-onset seizures.
— Primary generalized tonic-clonic seizures.

—Generalized seizures of Lennox-Gastaut syndrome.
•Bipolar disorder in patients aged 18 years and older

**Dosage & administration**
1. Monotherapy of seizures (adult and child over 16 years):
Initially 25 mg once daily for 14 days, then 50 mg once daily for further 14 days, then increased by maximum 50 mg/day every 7-14 days; usual maintenance dose 225-375 mg/day in 1-2 divided doses.
2. a. Adjunctive therapy of seizures with Valproate (adult and child over 12years):
Initially 25 mg on alternate days for 14 days, then 25 mg once daily for further 14 days, thereafter increased by maximum 25-50 mg/day every 7-14 days; usual maintenance,
100-200 mg/day in 1 -2 divided doses.
Child 2-12 years:
Initially 150 micrograms/kg/day in 1-2 divided doses for 14 days (those weighing under 13 kg may receive 2 mg on alternate days for first 14 days), then 300 micrograms/kg/day in 1 -2 divided doses for further 14 days, thereafter increased by maximum 300 micrograms/kg/day every 7-14 days; usual maintenance 1-3 mg/kg/day in 1-2 divided doses.
b. Adjunctive therapy of seizures (with enzyme inducing drugs e.g., Carbamazepine, Phenytoin, Phenobarbital, or Primidone) without Valproate (adult and child over 12 years):
Initially 50 mg once daily for 14 days, then 50 mg twice daily for further 14 days, thereafter increased by maximum 100 mg/dayinevery 7-14 days; usual maintenance 300-500 mg daily In 2 divided doses.
Child 2-12 years:
Initially 600 micrograms/kg/day in 2 divided doses for 14 days, then 1.2 mg/kg/day in 2 divided doses for further 14 days, thereafter increased by maximum 1.2 mg/kg/day in every 7-14 days; usual maintenance 5-15 mg/kg/day in 2 divided doses (maximum 400 mg/day in 2 divided doses).
3. a. Monotherapy therapy of bipolar disorder (without enzyme inducing Drugs) without Valproate (adult over 18 years):
Initially 25 mg once daily for 14 days, then 50 mg once daily for further 14 days, then 100 mg once daily for further 7 days; usual maintenance dose 200 mg once daily; maximum 200 mg daily.
3. b. Adjunctive therapy of bipolar disorder with valproate (adult over 18 years):
Initially 25 mg on alternate days for 14 days, then 25 mg once daily for further 14 days, then 50 mg once daily for further 7 days; usual maintenance dose 100 mg daily; maximum 100 mg daily.
3. c. Adjunctive therapy of bipolar disorder (with enzyme inducing drugs with enzyme inducing drugs e.g., Carbamazepine, Phenytoin, Phenobarbital, or Primidone) without Valproate (adult over 18 years):
Initially 50 mg once daily for 14 days, then 50 mg twice daily for further 14 days, then 100 mg twice daily for further / days, then 150 mg twice daily for further 7 days; usual maintenance 200 mg twice daily.
Adverse reactions
Adult: Dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, Sharyngitis, and rash.
hildren: Vomiting, diarrhea, infection, fever, abdominal pain, and tremor.

**Special warnings & precautions**
• Discontinue at the first sign of rash.
•Blood dyscrasias (e.g., neutropenia, thrombocytopenia, pancytopenia): May occur, either with or without an associated hypersensitivity syndrome. Monitor for signs of anemia, unexpected infection, or bleeding.
• Suicidal behavior and ideation: Monitor for suicidal thoughts or behaviors.
• Aseptic meningitis: Monitor for signs of meningitis.
Contraindications
Hypersensitivity (e.g., rash, angioedema, acute urticaria, extensive pruritus, mucosal ulceration) to the drug or its ingredients.

**Drug Interaction**
Valproate increases lamotrigine concentrations more than 2-fold. Carbamazepine, phenytoin, phenobarbital, primidone, and rifampin

decrease lamotrigine concentrations by approximately 40%. Estrogen-containing oral contraceptives decrease lamotrigine concentrations by approximately 50%. Protease inhibitors lopinavir/ritonavir and atazanavir/ lopinavir decrease lamotrigine exposure by approximately 50% and 32%, respectively.

**Use in Pregnancy & Lactation**
Pregnancy: Pregnancy category C.
Nursing Mothers: Lamotrigine is present in milk from lactating women taking Lamotrigine. Hepatic impairment: Dosage adjustments required in patients with moderate and severe liver impairment Renal impairment: Reduced maintenance doses may be effective for patients with significant renal impairment.

**Preparation**
20 tablets in blister pack.



# Lanso®

**Active Ingredient**
Lansoprazole.

**Indication**
Duodenal ulcer, gastric ulcers, erosive esophagitis, Zollinger-Ellison Syndrome, *H. pylori eradication*.

**Dosage & Administration**
30 mg daily dose.

**Contraindication & Precaution**
Known hypersensitivity.

**Side Effect**
Gastrointestinal disturbances, headache, dizziness, malaise, dry or sour mouth or throat.

**Use in Pregnancy & Lactation**
USFDA Pregnancy category B.

**Preparation**
30 mg Capsule.

# Lanso D™

**Active Ingredient**
Dexlansoprazole.

**Indication & Uses**
Lanso D™ (Dexlansoprazole) is a Proton Pump Inhibitor (PPI) used to treat-
• Relief of heartburn
• Healing of all grades of Erosive Esophagitis
• Maintenance of healed Erosive Esophagitis
• Treatment of non-erosive GERD

**Dosage & Administration**
Lanso D™ (Dexlansoprazole) capsule is administered orally. The recommended doses of Dexlansoprazole for adults are as follows:

| Indications | Dose | Duration |
|---|---|---|
| Relief of heartburn | 30 mg once daily | Up to 6 months |
| Healing of Erosive Esophagitis | 60 mg once daily | Up to 8 weeks |
| Maintenance of healed Erosive Esophagitis | 30 mg once daily | Up to 6 months |
| Symptomatic Non-Erosive GERD | 30 mg once daily | 4 weeks |

**Side Effect**
Adverse events are rarely seen; such as diarrhea, abdominal pain, nausea, vomiting, flatulence etc.

**Use in Pregnancy & Lactation**
There are no studies with dexlansoprazole use in pregnant women to inform a drug-associated risk..

**Contraindication**
Dexlansoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

**Drug Interaction**
Dexlansoprazole may interfere with the absorption of drugs for which gastric pH is important for bioavailability (e.g., Ampicillin esters, Digoxin, Iron salts, Ketoconazole).

**Overdose**
There have been no reports of significant overdose of Dexlansoprazole. Multiple doses of Dexlansoprazole 120 mg and single dose of Dexlansoprazole 300 mg did not result in any severe adverse events.

**Preparation**
30 mg & 60 mg Capsule.

# Larsulin™

**Active Ingredient**
Insulin Glargine (rDNA)

**Indication**
Larsulin™ is indicated to improve glycemic control in adults and children with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus

**Dosage & Administration**
Larsulin™ exhibits a relatively constant glucose-lowering profile over 24 hours that permits once-daily dosing. Potency of insulin glargine is approximately the same as human insulin.
Larsulin™ is recommended for once daily subcutaneous administration & may be administered at any time during the day. However, once started should be administered at the same time every day. The dose of Larsulin™ must be individualized based on clinical response. Blood glucose monitoring is essential in all patients with diabetes. In patients with type 1 diabetes, Larsulin™ must be used in regimens with short-acting insulin. Larsulin™ is not recommended for intravenous administration. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia.
*Initiation of Larsulin™ therapy:*
The recommended starting dose of Larsulin™ in patients with type 1 diabetes should be approximately one-third of the total daily insulin requirements. Short-acting, premeal insulin should be used to satisfy the remainder of the daily insulin requirements.
The recommended starting dose of Larsulin™ in patients with type 2 diabetes who are not currently treated with insulin is 10 units (or 0.2 Units/kg) once daily, which should subsequently be adjusted to the patient's needs.
*Converting to Larsulin™ from other insulin therapies:*
If changing from a treatment regimen with an intermediate-or long-acting insulin to a regimen with Larsulin™ , the amount and timing of shorter-acting insulins and doses of any oral anti-diabetic drugs may need to be adjusted.
• If transferring patients from once-daily NPH insulin to once-daily Larsulin™, the recommended initial Larsulin™ dose is the same as the dose of NPH that is being discontinued.
• If transferring patients from twice-daily NPH insulin to once-daily Larsulin™, the recommended initial Larsulin™ dose is 80% of the total NPH dose that is being discontinued.

**Side Effect**
Side effects of Insulin glargine are

hypoglycemia, allergic reactions, injection site reaction, lipodystrophy, pruritus, and rash.

**Use in Pregnancy & Lactation**
Pregnancy: Pregnancy category C. Insulin glargine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactation: It is unknown whether insulin glargine is excreted in human milk. Because many drugs, including human insulin, are excreted in human milk, caution should be exercised when Insulin glargine is administered to a nursing woman. Lactating women may require adjustments in insulin dose & diet.

**Precaution**
•Dose adjustment and monitoring: Blood glucose should be monitored in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision.
•Administration: Insulin glargine must not be diluted or mixed with any other insulin or solution. It should not be administered subcutaneously via an insulin pump or intravenously because severe hypoglycemia can occur.
•Renal or hepatic impairment: Reduction in the Insulin glargine dose may require in these cases.

**Contraindication**
Insulin glargine is contraindicated in patients with hypersensitivity to Insulin glargine or one of its excipients.

**Storage**
Store at 2° C to 8° C in a refrigerator. Do not freeze. In case of insulin for recent use need not to be refrigerated, try to keep it in a cool place and keep away from heat and light. The insulin in use can be kept under the room temperature for a month.

**Preparation**
Larsulin™ Injection: Each vial contains 3 ml solution.
Larsulin™ Pen Cartridge: Each cartridge contains 3 ml solution.



# Laxyl®

**Active Ingredient**
Bromazepam.

**Indication**
Laxyl is indicated for the treatment of anxiety & anxiety related disorders like emotional disturbance, functional disturbance in the gastrointestinal system, functional disturbance in the genitourinary system, psychosomatic disorders.

**Dosage & Administration**
3 mg to 18 mg daily in divided doses.

**Contraindication & Precaution**
Patients with known hypersensitivity to benzodiazepines; acute pulmonary insufficiency; respiratory depression; phobic or obsessional states; chronic psychosis. In patients with chronic pulmonary insufficiency, & in patients with chronic renal or hepatic disease, dosage may need to be reduced.

**Use in Pregnancy & Lactation**
Not recommended.

**Side Effect**
Common adverse effects include drowsiness, sedation, unsteadiness & ataxia.

**Preparation**
3 mg Tablet.

# Lebac®

**Active Ingredient**
Cephradine

**Indication**
Pharyngitis, sinusitis, otitis media, tonsilitis, laryngotracheo-bronchitis, acute & chronic bronchitis, lobar & bronchopneumonia, cystitis, urethritis, pyelonephritis, abscess, cellulitis, furunculosis, impetigo, bacillary dysentery, enteritis, peritonitis. bone & joint infection, surgical prophylaxis.

**Dosage & Administration**
1-2 gm daily in 2 to 4 divided doses.

**Contraindication & Precaution**
Hypersensitivity to any Cephalosporin antibiotic.

**Side Effect**
Nausea, vomiting, diarrhoea & abdominal discomfort, allergic reactions, skin rashes, urticaria, eosinophilia, angioedema & anaphylaxis, elevation of hepatic enzyme values, neutropenia, Super-infection with resistant microorganisms, particularly candida, pseudomembranous colitis. Thrombophlebitis.

**Use in Pregnancy & Lactation**
The drug should be used during pregnancy only when clearly indicated, the drug should be used with caution in nursing mother.

**Preparation**
250 mg & 500 mg Capsule, 125 mg/5 ml Powder for Suspension, 250 mg/5 ml Forte Powder for Suspension, 125 mg/1.25 ml Powder for Paediatric Drops, 500 mg IM/IV Injection.

# Lerozol®

**Active Ingredient**
Letrozole.

**Indication**
Infertility, ER positive breast cancer.

**Dosage & Administration**
ER positive (+) breast Cancer: The recommended dose is one 2.5 mg tablet administered once a day, regardless to meals
Infertility: 1 Tablet daily from 3 to 7 days of menstrual cycle

**Precaution**
Since fatigue & dizziness have been observed with the use of letrozole & somnolence was uncommonly reported, caution is advised when driving or using machinery.

**Drug Interaction**
Co-administration of letrozole & tamoxifen 20 mg daily results reduction of plasma levels of Letrozole.

**Use in Pregnancy & Lactation**
Pregnancy Category D.
Caution should be exercised when letrozole is administered to a nursing woman.

**Pediatric Use**
Not recommended

**Preparation**
2.5 mg Tablet.

# Levocar®

**Active Ingredient**
Levocarnitine.

**Indication**
Heart Diseases , Congestive Heart Failure, Kidney

Disease, Chronic Fatigue Syndrome, High Cholesterol, Intermittent Claudication, Dementia & memory impairment, Down Syndrome, Male infertility & Hyperthyroidism.

**Dosage & Administration**
Adults: 1 to 2 gm per day in divided doses.
Infants & children: Between 50 & 100 mg/kg/day in divided doses, with a maximum of 3 g/day. Dosage should begin at 50 mg/kg/day. The exact dosage will depend on clinical response.

**Contraindication & Precaution**
No known contraindication.

**Side Effect**
Generally well tolerated.

**Use in Pregnancy & Lactation**
Pregnancy Category B. It is not known whether Levocarnitine is excreted in human milk. Supplemental Levocarnitine is not advised for nursing mothers.

**Preparation**
330 mg Tablet.



# Levostar™

**Active Ingredient**
Levosalbutamol

**Indication**
Treatment or prevention of bronchospasm in adults, adolescents, & children 6 years of age & older with reversible obstructive airway disease.

**Dosage & Administration**
Levostar 1 & 2 mg Tablets: Adults & adolescents above 12 years: 1-2 mg three times daily, Children (upto 11 years): 1 mg three times daily. Levostar Syrup: Adults: 5-10 ml three times daily, Children (upto 11 years): 5 ml three times daily.

**Contraindication & Precaution**
Hypersensitivity to any of the components of the formulation. Potentially serious hypokalemia may result from $ß_2$ agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia & by concomitant treatment with xanthine derivatives, steroids & diuretics. Oral Levosalbutamol should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias or hypertension.

**Drug Interaction**
Short-acting sympathomimetic bronchodilators or epinephrine & if additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects.

**Side Effect**
Hypokalaemia, palpitation, fine tremors of the skeletal muscle (particularly the hand), muscle cramps, nausea, vomiting, burning substernal or epigastric pain, diarrhoea, nervousness, headache, dizziness, fatigue & sleeplessness.

**Use in Pregnancy & Lactation**
Use of oral Levosalbutamol in pregnant or nursing mothers should be considered only if the expected benefit to the mother is greater than any possible risk to the foetus or the infant.

**Preparation**
1 mg, 2 mg Tablet.

# Liglimet™

**Active Ingredient**
Linagliptin and Metformin Hydrochloride

**Indication**
LiglimetTM is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Linagliptin and Metformin is appropriate.

**Dosage & Administration**
Dose of this combination should be individualized on the basis of the patient's current regimen, effectiveness, and tolerability while not exceeding the maximum recommended daily dose of 2.5 mg Linagliptin and 1000 mg Metformin twice daily.
Linagliptin/Metformin combination should generally be given twice daily with meals, with gradual dose escalation, to reduce the gastrointestinal (GI) side effects due to Metformin.The recommended starting dose in patients currently not treated with Metformin, initiate treatment with 2.5 mg Linagliptin/500 mg Metformin Hydrochloride twice daily. The recommended starting dose in patients already treated with Metformin, start with 2.5 mg Linagliptin and the current dose of Metformin taken at each of the two daily meals. The starting dose in Patients already treated with Linagliptin and Metformin individual components may be switched to Liglimet containing the same doses of each component.

**Contraindications & Precaution**
The combination of Linagliptin & Metformin is contraindicated in patients with:
• Severe renal impairment (eGFR below 30 mL/min/1.73 m2 )
• Acute or chronic metabolic acidosis, including diabetic ketoacidosis
• A history of hypersensitivity reaction to Linagliptin or Metformin

**Side Effects**
Most common adverse effects are nasopharyngitis and diarrhea. Hypoglycemia is more common in patients treated with this combination and sulfonylureas.

**Use in pregnancy & Lactation**
*Pregnancy Category B.*
Nursing mothers: It is not known whether Linagliptin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when the combination of Linagliptin & Metformin is administered to a nursing woman.

**Preparation**
2.5/500 & 2.5/850 Tablet

# Linita™

**Active Ingredient**
Linagliptin INN

**Indication**
**Linita**™ is indicated as an adjunct to diet & exercise to improve glycemic control in patients with type 2 diabetes mellitus.

**Dosage & Administration**
The recommended dose of **Linita**™ is 5 mg once daily. No dosage adjustment is required for hepatic or kidney impaired patients. Contraindication & precaution: History of a serious hypersensitivity reaction to Linagliptin, such as anaphylaxis or angioedema. When used with an insulin secretagogue (e.g. sulfonylurea), consider lowering the dose of the insulin secretagogue to reduce the risk of hypoglycemia.

**Side Effect**
Side effects includes: Hypoglycemia, headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, stuffy or runny nose & sore throat.

**Drug Interaction**
P-glycoprotein/CYP3A4 inducer: The efficacy of Linagliptin may be reduced when administered in combination (e.g., with

rifampin). Use of alternative treatments is strongly recommended.

**Use in Pregnancy & Lactation**
Pregnancy: Pregnancy Category-B. There are no adequate & well-controlled studies in pregnant women. Linagliptin tablets should be used during pregnancy only if clearly needed. Nursing Mothers:It is not known if whether Linagliptin passes into breast milk or not. Caution should be exercised when Linitagliptin is administered to a nursing woman

**Use in Children**
Safety & effectiveness of Linagliptin in pediatric patients under 18 years of age have not been established.

**Preparation**
5 mg Tablet.



# Lipired™

**Active Ingredient**
Fenofibrate.

**Indication**
Hyperlipidemia.

**Dosage & Administration**
One 200 mg capsule daily.

**Contraindication**
Hepatic or severe renal dysfunction, including primary biliary cirrhosis, & patients with unexplained persistent liver function abnormality. Preexisting gallbladder disease. Hypersensitivity to fenofibrate.

**Side Effect**
Hepatitis, cholelithiasis, cholecystitis, hepatomegaly, myalgia, myasthenia, rhabdomyolysis, photosensitivity, eczema, peripheral edema, angina, palpitations, tachycardia, & migraine.

**Drug Interaction**
Oral Anticoagulants, Resins, Cyclosporine.

**Preparation**
200 mg Capsule.

# Livwel®

**Active Ingredient**
Vitamin A (as Retinol Palmitate & Beta Carotene), C, D3, E, B1, B6, B12, Riboflavin, Niacin, Folic Acid, Biotin, Pantothenic Acid, Calcium, Iodine, Magnesium, Zinc, Selenium, Manganese, Chromium, Potassium, Para-Amino Benzoic Acid, Inositol, Choline

**Indication**
Livwel Syrup is indicated in multivitamin & multimineral deficiencies in: Adults (especially who cannot intake supplements in solid dosage forms e.g. tablet & who suffer gastrointestinal side effects after taking solid dosage forms). Children of all ages & infants.

**Dosage & Administration**
For adults: 3 - 4 teaspoonful daily
For children of 4 - 12 years: 2 - 3 teaspoonful daily; For children of 1 - 4 years: 1-2 teaspoonful daily: For infants up to 1 year: 1 teaspoonful daily or as directed by the physician.

**Contraindication & Precaution**
Supplement should not be used in over dosage or should not be used long time without the recommendation by a physician.

**Side Effect**
Generally the product is well tolerated.

**Use in Pregnancy & Lactation**
The specific information is not available in this respect.

**Preparation**
100 ml & 200 ml Syrup.

# LNC™

**Active ingredient**
Cilnidipine

**Indication**
Hypertension

**Dosage & Administration**
Adults: 5-10 mg once daily after breakfast. Maximum dose: 20 mg once daily. The safety of Cilnidipine in pediatric patients has not been established.
Use in the elderly: Since the elderly may be more susceptible to hypotension, therapy should be initiated with the lowest possible dose (5 mg).

**Contraindication & Precaution**
Cilnidipine is contraindicated in patients with known sensitivity to Cilnidipine or any of the excipients or patients having cardiogenic shock, recent MI or acute unstable angina and severe aortic stenosis.
Cilnidipine should be administered with care in the following patients: patients with serious hepatic dysfunction, patients with a history of serious adverse reactions to calcium antagonists. During the discontinuation, the dosage should be gradually decreased under close observation.

**Side Effect**
The most common side effects of Cilnidipine are: dizziness, flushing, headache, hypotension, peripheral edema, palpitation, GI disturbances, increased micturition frequency, lethargy, eye pain & depression.

**Use in Pregnancy & Lactation**
Cilnidipine should not be administered in pregnant woman or woman having possibilities of being pregnant. It is also advisable to avoid the administration of Cilnidipine to nursing mothers. However, if the administration is indispensable, the patient should be instructed to discontinue lactation.

**Preparation**
5 mg & 10 mg Tablet



# Loracef®

**Active Ingredient**
Cefaclor.

**Indication**
Pneumonia, bronchitis, pharyngitis, tonsillitis sinusitis, otitis media, Skin & soft tissue infections, urinary tract infections including pyelonephritis & cystitis.

**Dosage & Administration**
250 mg every eight hours. Children : 20 mg/kg/day in divided doses every 8 hours.

**Contraindication & Precaution**
Hypersensitivity, caution in the presence of markedly impaired renal function, overgrowth of non-susceptible organisms.

**Side Effect**
Diarrhoea, nausea & vomiting, eruptions, pruritis & urticaria, Serum sickness, Eosinophilia, thrombocytopenia, transient lymphocytosis & leucopenia. Transient hepatitis & cholestatic

jaundice, slight elevation in AST, ALT or alkaline phosphate. Reversible interstitial nephritis, Reversible hyperactivity, nervousness, confusion, hypertonia, dizziness, hallucinations & somnolence have been reported rarely.

**Drug Interaction**
The nephrotoxicity of aminoglycoside antibiotics such as gentamicin & tobramycin may enhanced by any Cephalosporin.

**Use in Pregnancy & Lactation**
Caution is recommended in the use of the drug in early pregnancy. Caution should be exercised when Cefaclor is administered to a nursing women.

**Preparation**
125 mg/5 ml Suspension & 125 mg/1.25 ml Paediatric Drops.



# Loratin®

**Active Ingredient**
Loratadine.

**Indication**
Allergic rhinitis, Skin allergies including Chronic Idiopathic Urticaria (CIU).

**Dosage & Administration**
Adult & child over 6 years: One Loratin 10 mg tablet or two teaspoonful (10 ml) Loratin suspension once daily. Children aged 2-5 years: 5 ml or 1 teaspoonful (5 mg) suspension once daily. Loratadine is not recommended for children under 2 years of age.

**Contraindication**
Loratadine is contraindicated in patients who have shown hypersensitivity to its ingredients or idiosyncrasy.

**Side Effect**
Anticholinergic effects, fatigue, nausea, headache, tachycardia & syncope.

**Use in Pregnancy & Lactation**
Loratadine should be used during pregnancy only if clearly needed. Loratadine should not be administered to lactating mother.

**Preparation**
10 mg Tablet & 5 mg/5 ml Suspension

# Lubgel™ Eye Drops

**Active Ingredient**
Carboxymethylcellulose Sodium 1%.

**Indication**
Lubgel™ 1% Eye Drops is indicated for the long-lasting relief of burning, irritation, and discomfort due to dryness of the eye or exposure to wind or sun.

**Dosage & Administration**
Instill 1 or 2 drops in the affected eye(s) as needed or as directed by physician.

**Drug Interaction**
Concomitant ocular medications should be administered at least 5 min apart from the instillations of Lubgel™ 1% Eye Drops to avoid washout effects.

**Use In Pregnancy & Lactation**
Use in Pregnancy: There are no data on the use of Carboxymethylcellulose Sodium 1% Liquigel during pregnancy and lactation in humans. Animal studies did not show harmful effects with the active ingredient Carboxymethylcellulose Sodium.
Use in Lactation: Carboxymethylcellulose Sodium is not absorbed systemically; there is no known potential for excretion in human breast milk.

**Pediatric Use**
The safety and effectiveness in pediatric patients have not been established.

**Geriatric Use**
No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

**Side Effect**
Visual disturbances, ocular discharge and eye pruritus are common adverse drug reactions were reported with Carboxymethylcellulose Sodium. Conjunctival hyperaemia and eyelid edema are reported but the frequency is very less.

**Preparation**
10 ml eye drops



# Lubtear® Eye Drops

**Active Ingredient**
Dextran 70 & Hypromellose.

**Indication**
As a lubricant & artificial tear in dry eye & other ocular irritation syndromes associated with deficient tear or mucous secretion. This combination also prevents cornea to damage in patients with keratoconjunctivitis & for ocular lubrication. It is also used for the temporary relief of burning & irritation due to dryness of the eye & for use as the protectant against further irritation.

**Dosage & Administration**
Adults & children: One or two drops three times daily or as directed by the physician.

**Contraindication & Precaution**
This product contains Benzalkonium Chloride BP & should not be used when soft contact lenses are being worn.

**Side Effect**
There are no known side effects with the use of it, however, if the patient experiences any reaction in eye or other part of the body after using this medication than should be consulted with doctor.

**Use in Pregnancy & Lactation**
There is insufficient evidence as to the safety in pregnancy & lactation. Therefore, this product should only be used in pregnancy & lactation if it is considered essential by the physician.

**Preparation**
Each LDPE container contains 10 ml of Dextran 70 0.1% & Hypromellose 0.3%.

# Lumertam®

**Active Ingredient**
Artemether & Lumefantrine.

**Indication**
Lumertam is indicated in the treatment & standby emergency treatment of acute uncomplicated *Plasmodium falciparum* malaria including mixed *P. falciparum* infection of adults, children & infants weighing from 5 kg & above.

**Dosage & Administration**

| Body Weight | Day 1 | | Day 2 | | Day 3 | |
|---|---|---|---|---|---|---|
| | 0 hour | 8 hours later | Morning | Evening | Morning | Evening |
| 5-15 kg | 1 Tablet | 1 Tablet | 1 Tablet | 1 Tablet | 1 Tablet | 1 Tablet |
| 15-25 kg | 2 Tablet | 2 Tablet | 2 Tablet | 2 Tablet | 2 Tablet | 2 Tablet |
| 20-35 kg | 3 Tablet | 3 Tablet | 3 Tablet | 3 Tablet | 3 Tablet | 3 Tablet |
| 35kg & above | 4 Tablet | 4 Tablet | 4 Tablet | 4 Tablet | 4 Tablet | 4 Tablet |



**Contraindication & Precaution**
Hypersensitivity to any of the ingredients, patients with family history of bradycardia or severe cardiac disease & patients with known electrolyte imbalance.

It is not evaluated for prophylaxis of malaria, cerebral malaria or other severe manifestation of severe malaria including pulmonary oedema or renal failure. Hence, should not be used in those conditions.

**Side Effect**
Generally well tolerated & most side effects are of mild to moderate in severity & duration.

**Use in Pregnancy & Lactation**
Not recommended.

**Preparation**
(Artemether 20 mg + Lumefantrine 120 mg)/Tablet.

# Luraprex™

**Active ingredient**
Lurasidone hydrochloride.

**Indication**
Schizophrenia, Bipolar disorder.

**Dosage & Administration**

| Indication | Starting Dose | Recommended Dose |
|---|---|---|
| Schizophrenia | 40 mg per day | 40 mg to 160 mg per day |
| Bipolar Depression | 20 mg per day | 20 mg to 120 mg per day |

**Side effects**
Somnolence, akathisia, extrapyramidal symptoms, and nausea .

**Drug interaction**
Lurasidone dose should be reduced to half of the original level when used concomitantly with moderate inhibitors of CYP3A4 (e.g., diltiazem, atazanavir, erythromycin, fluconazole, verapamil, etc.). If Lurasidone is used concomitantly with a moderate CYP3A4 inducer, it may be necessary to increase the Lurasidone dose.

**Use in pregnancy and lactation**
Pregnancy Category B. Lurasidone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Patient should be advised not to breast-feed an infant if they are taking Lurasidone.

**Preparation**
20 mg & 40 mg tablet.

# Lysivin™

**Active Ingredient**
Multivitamin with L-Lysine

**Indication**
- Improves appetite
- Promotes growth in height & weight
- Helps in building of muscle protein
- Helps to absorb Calcium
- Ensures energy production

**Dosage & Administration**
- Adult: 03 Tablets daily
- Children (from 01 year of age) : 1-3 Tablets daily depending on the age & physical condition

**Pregnancy & lactation**
- The specific information is not available in this respect.

CONTRAINDICATION
- The product is contraindicated in patients with a known
- Hypersensitivity to any of the active ingredients of the product.

**Side Effect**
The product is usually well tolerated and exerts no untoward effects if taken in the dosage recommended.

**Preparation**
30 tablets.

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# Maganta™ Plus

**Active Ingredient**
Magaldrate & Simethicone.

**Indication**
Hyperacidity, gastric & duodenal ulcer, gastritis, heartburn, dyspepsia, gastroesophageal reflux.

It is also indicated for the relief of flatulence, abdominal distention & windy colic.

**Dosage & Administration**
Chewable tablet: 1-4 chewable tablets, 20 to 60 minutes after meals & at bedtime, or as directed by the physician.
Suspension: 2-4 teaspoonfuls (10-20 ml) of suspension, 20 to 60 minutes after meals & at bedtime, or as directed by the physician.



**Contraindication & Precaution**
intestinal obstruction, renal function impairment, appendicitis, chronic diarrhea, sensitivity to aluminium, magnesium & simethicone.
Should be cautious, if allergic to any ingredient to Magaldrate & Simethicone, with a history of kidney problems or taking citrate salts (found in some calcium supplements, antacids & laxative). Do not take with tetracycline antibiotics. Antacids can interfere with the absorption of iron preparation.

**Side Effect**
Constipation, diarrhea, intestinal pain.

**Use in Pregnancy & Lactation**
Thought to be safe antacid during pregnancy & lactation.

**Preparation**
Chewable tablet: Each chewable tablet contains Magaldrate USP 480 mg & Simethicone USP 20 mg. Suspension: Each 5 ml contains Magaldrate USP 480 mg & Simethicone USP 20 mg.

# Maxbon™

**Active Ingredient**
Ibandronic acid

**Indication**
Maxbon Tablet is indicated for:
• Treatment and prevention of postmenopausal osteoporosis in women
• Treatment and prevention of osteoporosis in men

**Dosage & Administration**
The recommended dose for the treatment and prevention of osteoporosis is 150 mg tablet once in a month on the same month is recommended.
How to Take Maxbon Tablet: The tablet should preferably be taken on the same date of each month. The following instructions are applicable for all patients taking Maxbon tablet:

•Take the tablet exactly as prescribed by your health care provider.
•Take the tablet in the morning before you eat or drink anything except plain water
•Take the tablet while you are sitting up or standing
•Swallow whole tablet. Do not chew the tablet or keep it in your mouth to melt or dissolve.
•After taking the tablet you must wait at least 60 minutes before lying down.
•You may sit, stand or do normal activities.
•Take vitamins, calcium or antacids after 60 minutes of taking
•Keep taking Maxbon tablet for as long as your healthcare provider tells you

**Drug Interaction**
Please tell your doctor if you are taking or have recently taken any other medicines, including medicine obtained without a prescription specially aspirin or other NSAIDs. Antacids, supplements or medicine that contains aluminums, calcium, magnesium or other minerals can interfere with the absorption of Ibandronate sodium. If you use these other medicines, do not take these for at least 60 minutes after taking Ibandronic Acid tablet.

**Pregnancy and Lactation**
Ibandronic Acid is contraindicated during pregnancy and lactation

**Special Dosage Instruction**
No dose adjustment is necessary for patients with mild or moderate renal impairment where creatinine clearance is equal to or greater than 30ml/min. No dose adjustment is required for Patients with hepatic impairment.

**Preparation**
150 mg Tablet

# Maxbon™ Kit

**Active Ingredient**
1 tablet of Ibandronic Acid and 60 tablets of Calcium Orotate

**Indication**
Maxbon Kit is indicated for the treatment and prevention of osteoporosis in women after menopause. It increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.

**Dosage & Administration**
Dose: One tablet of Ibandronic Acid 150 mg once monthly on the same date of each month is recommended. To maximize clinical benefit of Ibandronic acid, two tablets of Calcium Orotate 400 mg per day are usually recommended in divided dosage or as directed by physician.

**Dosing Instructions**
•To maximize absorption and clinical benefit, Ibandronic Acid tablet of Maxbon Kit should be taken at least 60 minutes before the first food or drink (other than water) of the day or before taking any oral medication or supplementation, including calcium, antacids or vitamins.
•To facilitate delivery to the stomach and thus reduce the potential for esophageal irritation, Ibandronic Acid tablet should be swallowed whole with a full glass of plain water (250 ml) while the patient is standing or sitting in an upright position.
•Patients should not lie down for 60 minutes after taking Ibandronic Acid tablet.
•Patients should not eat, drink anything except water, or take other medications for at least 60 minutes after taking Ibandronic Acid tablet.
•Plain water is the only drink that should be taken with Ibandronic Acid tablet. Note that some mineral waters may have a higher concentration of calcium and therefore shoul not be used.
•Patients should not chew, crush or let the tablet dissolve in mouths because of a potential for oropharyngeal ulceration.
•Ibandronic Acid 150 mg tablet of Maxbon Kit shoul be taken on the same date of each month (i.e., the patients Ibandronic Acid day).
•The patient must not take two Ibandronic Acid 150 mg tablets within the same week.
•If the once-monthly dose is missed and the patient's next scheduled Ibandronic acid day is more than 7 days away, the patient should be instructed to take one Ibandronic Acid 150 mg tablet in the morning following the date that it is remembered. The patient should then return to taking one Ibandronic Acid 150 mg tablet every month in the morning in their chosen day, according to their original schedule.
•If the once-monthly dose is missed and the patient's next scheduled Ibandronic Acid day is only 1 to 7 days away, the patient must wait until the subsequent month's scheduled Ibandronic Acid day to take their tablet. The patient should then return to taking one Ibandronic Acid 150 mg tablet every month in the morning of their chosen day, according to their original schedule.
•Start taking Calcium Orotate tablets from the next day of Ibandronic Acid day (from 'Day 2' and onwards).

**Contraindications**
Ibandronic Acid is contraindicated in conditions like:
•Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia.
•Inability to stand or sit upright for at least 60 minutes.
•Hypocalcemia.
•Known hypersensitivity to Ibandronic Acid.
Calcium Orotateis contraindicated in conditions like:
•Incomplete or infrequent bowel movements.
•Kidney stone, kidney disease.
•Sarcoidosis.
•Increased activity of the parathyroid gland.
•Extreme loss of body water.

**Precautions**
Take special care if you have:
• Low blood circular level (hypocalcaemia)
• Cannot sit or stand up for 60 minutes
• Have an allergy to Ibandronate Sodium
• Are pregnant or may become pregnant
• Are breast feeding or plan to breast feed
• Adequate intake of Calcium and Vitamin D is important in all patients
• Patients should follow the dosing instructions to minimize the risk of gastrointestinal side effects.

**Drug Interactions**
Ibandronic Acid: Calcium Supplements/ Antacids: Products containing calcium and other multivalent cations (such as aluminium, magnesium, iron) are likely to interfere with absorption of Ibandronic Acid. Ibandronic Acid should be taken at least 60 minutes before any oral medications, including medications containing multivalent cations (such as antacids, supplements or vitamins). Also, patients should wait at least 60 minutes after dosing before taking any other oral medications.
Calcium Orotate:Calcium can decrease absorption of the following drugs when taken together: Bisphosphonates (e.g., alendronate), Quinolone antibiotics (e.g., ciprofloxacin, levofloxacin) and Tetracycline antibiotics (e.g., doxycycline, and minocycline), levothyroxine, phenytoin (an anticonvulsant) and Tiludronate disodium (to treat Paget's disease). Thiazide-type diuretics can interact with Calcium supplements, increasing the risks of hypercalcemia and hypercalciuria. Both Aluminum and Magnesium containing antacids increase urinary Calcium excretion. Mineral oil and stimulant laxatives decrease Calcium absorption. Glucocorticoids can cause Calcium depletion and eventually osteoporosis when they are used for months. Oral contraceptives as well as estrogen compounds reduce Calcium. Anti-inflammatories such as NSAIDs, Aspirin, Ibuprofen deplete Calcium. Corticosteroids deplete Calcium.

**Side Effects**
Ibandronic Acid: Common side effects include Hypertension, Dyspepsia, Nausea, Diarrhea, Abdominal Pain, Arthralgia, Back Pain, Localized Osteoarthritis, Myalgia, Muscle Cramp, Influenza, Nasopharyngitis, Bronchitis, Urinary Tract Infection, Upper Respiratory Tract Infection, Headache, Dizziness, Skin rash, Insomnia etc.
Calcium Orotate:Bloating and swelling in the abdomen are common side effects of Calcium Orotate. Loss of appetite, upset stomach, constipation, nausea, vomiting, unusual weight loss, mood changes, bone/muscle pain, headache, increased thirst/urination, weakness, unusual tiredness, formation of kidney stones may occur infrequently.

**Use in Specific Population**
Pregnancy: There are no adequate and well-controlled studies in pregnant women for Ibandronic Acid and Calcium Orotatecombination: The combination should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.
Pregnancy Category of Ibandronic Acid: C.

**Nursing Mothers**
It is known whether Ibandronic Acid and Calcium Orotatecombination is excreted in human milk. Caution should be exercised when Ibandronic Acid and Calcium Orotatecombination is administered to a nursing woman.

**Pediatric Use**
Safety and effectiveness in pediatric patients (<18 years) have not been established.

**Preparation**
Maxbon Kit contains 1 film coated tablet of Ibandronic Acid 150 mg and 60 film coated tablets of Calcium Orotate INN 400 mg in one calendar strip.

# Maxcef®

**Active Ingredient**
Cefotaxime.

**Indication**
Acute or chronic bronchitis, bacterial pneumonia, infected bronchiectasis, lung abscess & post-operative chest infections, acute & chronic pyelonephritis, cystitis & asymptomatic bacteriuria, cellulitis, peritonitis & wound infections, osteomyelitis, septic arthritis, pelvic inflammatory disease, gonorrhoea, meningitis & other sensitive infections suitable for parenteral antibiotic therapy.

**Prophylaxis**
The administration of Cefotaxime prophylactically may reduce the incidence of certain post operative infections in patients undergoing surgical procedures.

**Dosage & Administration**
1gm every 12 hourly. In severe infections dosage may be increased up to 12 gm daily given in 3 or 4 divided doses. Children : 100-150 mg/kg/day in 2 to 4 divided doses. In very severe infections doses up to 200 mg/kg/day may be required. Neonates : 50 mg/kg/day in 2-4 divided doses. In severe infections 150-200 mg/kg/day in divided doses.

**Contraindication & Precaution**
Hypersensitivity, in renal insufficiency.

**Side Effect**
Mild & transient candidiasis, rashes, fever, transient rises in liver transaminase and/or alkaline phosphatase & diarrhoea. pseudomembranous colitis, changes in renal function, skin rashes, drug fever & very rarely anaphylaxis. Administration of high doses of cephalosporins particularly in patients with renal insufficiency may result in encephalopathy.

**Drug Interaction**
Increased nephrotoxicity has been reported following concomitant administration of cephalosporins & aminoglycoside antibiotics.

**Pregnancy & lactation**
Pregnancy Category B.
Cefotaxime is excreted in the milk. Caution should be exercised when Cefotaxime is administered to a nursing women.

**Preparation**
250 mg IM/IV Injection.

# Maxpime®

**Active Ingredient**
Cefepime.

**Indication, Dosage & Administration**
The recommended adult & pediatric dosages & routes of administration are outlined in the following table. Cefepime should be administered intravenously over approximately 30 minutes. Before administration ensure that the powder has been fully dissolved in the solution.

| Site & Type of Infection | Dose | Frequency | Duration (Days) |
|---|---|---|---|
| Moderate to severe Pneumonia due to *S. pneumoniae**, *P. aeruginosa, K. pneumoniae,* or Enterobacter species | 1-2 gm IV | Every 12 hours | 10 |
| Mild to moderate Uncomplicated or Complicated Urinary Tract Infections, including pyelonephritis, due to *E. coli, K. pneumoniae*, or *P. mirabilis** | 0.5-1 gm IV/IM | Every 12 hours | 7-10 |
| Severe Uncomplicated or Complicated Urinary Tract infections, including pyelonephritis, due to *E- coli* or *K. pneumoniae** | 2 gm IV | Every 12 hours | 10 |
| Moderate to Severe Uncomplicated Skin & skin structure infections due to *S. aureus* or *S. pyogenes* | 2 gm IV | Every 12 hours | 10 |
| Complicated intra-abdominal infections (used in combination with metronidazole) caused by *E.coli*, viridans group streptococci, *P. aeruginosa, K. pneumoniae,* Enterobacter species, or *B. fragilis* | 2 gm IV | Every 12 hours | 7-10 |



Pediatric patients (2 months up to 16 years)
The maximum dose for pediatric patients should not exceed the recommended adult dose. The usual recommended dosage in pediatric patients up to 40 kg in weight for uncomplicated & complicated urinary tract infections (including pyelonephritis), uncomplicated skin & skin structure infections, & pneumonia is 50 mg/kg/dose, administered every 12 hours (50 mg/kg/dose, every 8 hours for febrile neutropenic patients), for durations as given above.

**Contraindication & Precaution**
Cefepime is contraindicated in patients who have shown immediate hypersensitivity reactions to Cefepime or the cephalosporin class of antibiotics, penicillins or other beta-lactam antibiotics.

**Side Effect**
As with some other drugs in this class, encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor & coma), myoclonus & seizures have been reported.

**Drug Interaction**
Renal function should be monitored carefully if high doses of aminoglycosides are to be administered with Cefepime because of the increased potential of nephrotoxicity & ototoxicity of aminoglycoside antibiotics. Nephrotoxicity has been reported following concomitant administration of other cephalosporins with potent diuretics such as furosemide.

**Use in Pregnancy & Lactation**
Pregnancy Category B.
Nursing Mothers
Cefepime is excreted in human breast milk in very low concentrations (0.5 ug/mL). Caution should be exercised when Cefepime is administered to a nursing woman.

**Preparation**
1 gm IM/IV injection.

**Contraindication & Precaution**
Patient with risk of hypersensitivity, orthostatic hypotension; severe hepatic insufficiency, syncope should be taken with caution. (The treatment of severely renal impaired patients should be approached with caution).

**Side Effect**
Dizziness, abnormal ejaculation, less frequently headache, asthenia, postural hypotension, palpitations, rhinitis, nausea, vomiting, diarrhoea, constipation, Hypersensitivity reactions such as rash, pruritus, urticaria, drowsiness, blurred vision, dry mouth, edema, syncope, angioedema and priapism.

**Drug Interaction**
Atenolol, enalapril, nifedipine or theophylline, cimetidine, frusemide.

**Use in Pregnancy & Children**
Tamsulosin Hydrochloride capsules are not indicated for use in pregnant women and children.

**Preparation**
0.4 mg Capsule.



# Maxrin™

**Active Ingredient**
Tamsulosin Hydrochloride.

**Indication**
Treatment of LUTS in men & women.
Treatment of the signs and symptoms of Benign Prostatic Hyperplasia (BPH)- in men.
Treatment for ureteral stone expulsion.

**Dosage & Administration**
1(one) capsule once daily after meal.

# Maxrin™ D

**Active Ingredient**
Tamsulosin Hydrochloride & Dutasteride

**Indication**
Combination of Tamsulosin Hydrochloride & Dutasteride capsules are indicated for the treatment of moderate to severe symptomatic Benign Prostatic Hyperplasia (BPH) in men with enlarged prostates.
Dosage & Administration

**Dosage & Administration**
Adult males (including geriatric patients): The recommended dose of combination is one capsule daily taken orally approximately 30 minutes after the same meal. Although an improvement in symptoms may be observed after 3 months in some patients, it can take up to 6 months before a response to the treatment can be achieved. Missed Dose: If a dose is missed, it can be taken later in the same day. Extra capsules taken for missed doses are not necessary. Do not take two doses in the same day.

**Contraindication**
Combination of Tamsulosin & Dutasteride is contraindicated for use in women and children. It is contraindicated in patients with known hypersensitivity to Tamsulosin Hydrochloride (including Tamsulosin induced angioedema), Dutasteride (including other 5 alpha-reductase inhibitors) or to any ingredient in the formulation.
Warning
Combination of Tamsulosin & Dutasteride is for use in men only. Women who are pregnant, or who may become pregnant, should not handle combination as it may pass through the skin. Combination may affect the normal development of the external genital organs in a male baby. As with all alpha1-adrenoceptor antagonists, a reduction in blood pressure can occur in individual cases during treatment with Tamsulosin, as a result of which, there is a potential risk of syncope. At the first signs of orthostatic hypotension (dizziness, weakness), the patient should sit or lie down until the symptoms have disappeared. Do not use combination with other alpha adrenergic antagonists, as this may increase the risk of hypotension.

**Drug Interactions**
Ketoconazole, Erythromycin, , Paroxetine, , Terbinafine, Cimetidine, other alpha-adrenergic antagonists, Phosphodiesterase-5 Inhibitors, Warfarin etc.

**Use in Pregnancy & Lactation**
Pregnancy: Combination of Tamsulosin & Dutasteride is contraindicated for use in women. There are no adequate and well-controlled studies in pregnant women of this combination or its individual components. Administration of Tamsulosin to pregnant female rats and rabbits at higher than the human therapeutic dose showed no evidence of fetal harm. The potential risk from the use of Tamsulosin during pregnancy in humans is unknown. Dutasteride has not been studied in women because pre-clinical data suggests that the suppression of circulating levels of Dihydrotestosterone may inhibit the development of the external genital organs in a male fetus carried by a woman exposed to Dutasteride.
Lactating Mother: This combination is contraindicated for use in women. It is not known whether Tamsulosin or Dutasteride are excreted in breast milk.
Pediatric Use
This combination is contraindicated for use in children. BPH is not a disease of childhood. Safety and effectiveness of Tamsulosin or Dutasteride in children have not been established.

**Preparation**
Box contains 20 capsules in blister pack.

# Melano™

**Active Ingredient**
Fluocinolone Acetonide USP 0.1 mg, Tretinoin USP 0.5 mg and Hydroquinone USP 40 mg.

**Indication**
The Cream is indicated for the short-term

treatment of moderate to severe melasma of the face (in the presence of measures for sun avoidance, including the use of sunscreens).

**Dosage & Administration**
Apply a thin film of MelanoTM Cream to the affected area once daily, at least 30 minutes before bedtime. Gently wash the face and neck with a mild cleanser. Rinse and pat the skin dry.

**Contraindication**
This product is contraindicated in individuals with a history of hypersensitivity, allergy or intolerance to this product or any of its components.

**Precaution**
This product contains Hydroquinone and Tretinoin that may cause mild to moderate irritation. Local irritation, such as skin reddening, peeling, mild burning sensation, dryness and pruritus may be expected at the site of application. If a reaction suggests hypersensitivity or chemical irritation, the use of the medication should be discontinued. It also contains the corticosteroid Fluocinolone Acetonide. Systemic absorption of topical corticosteroids can produce reversible Hypothalamic-Pituitary-Adrenal (HPA) axis suppression. If HPA axis suppression is noted, the use of this product should be discontinued.

**Side Effect**
A very few patients may get severe allergic reactions from this product. They may have trouble breathing or severe asthma attacks. While patients use this product, skin may develop mild to moderate redness, peeling, burning, dryness or itching.

**Drug Interaction**
Avoid use of medicated or abrasive soaps, cleansers, soaps, cosmetics with drying effects, products with high concentration of alcohol, astringent & other irritants or keratolytic drugs. Also avoid concomitant use of medications with photosensitizing effects.

**Pregnancy & Lactation**
Pregnancy: Pregnancy Category C. MelanoTM Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Lactation: Caution should be exercised when this product is administered to nursing women.

Pediatric Use: Safety and effectiveness of this Cream have not been established in pediatric patients.

**Preparation**
Each pack has a laminated tube containing 30 gm Cream.



# Methigic™

**Active Ingredient**
Methylprednisolone.

**Indication**
1. Endocrine Disorders: Primary or Secondary Adrenocortical Insufficiency, Congenital Adrenal Hyperplasia, Nonsuppurative Thyroiditis, Hypercalcemia associated with Cancer;
2. Rheumatic Disorders: Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Ankylosing Spondylitis, Acute and Subacute Bursitis, Synovitis of Osteoarthritis, Acute nonspecific Tenosynovitis, Post-traumatic Osteoarthritis, Psoriatic Arthritis, Epicondylitis, Acute Gouty Arthritis;
3. Collagen Diseases: Systemic Lupus Erythematosus, Systemic Dermatomyositis

and Acute Rheumatic Carditis;
4. Dermatologic Diseases: Bullous Dermatitis Herpetiformis, Severe Erythema Multiforme (Stevens-Johnson syndrome), Severe Seborrheic Dermatitis, Exfoliative Dermatitis, Mycosis Fungoides, Pemphigus, Severe Psoriasis;
5. Allergy: Seasonal or Perennial Allergic Rhinitis, Drug hypersensitivity reactions, Serum Sickness, Contact Dermatitis, Bronchial Asthma and Atopic Dermatitis;
6. Ophthalmic Diseases: Allergic Corneal Ulcers, Herpes Zoster Ophthalmicus, Anterior segment inflammation, Sympathetic Ophthalmia, Keratitis, Optic Neuritis, Allergic Conjunctivitis, Chorioretinitis, Iritis and Iridocyclitis;
7. Respiratory Diseases: Symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means,
Berylliosis, Aspiration Pneumonitis;
8. Hematological Disorders: Idiopathic Thrombocytopenic Purpura in adults, Secondary Thrombocytopenia in adults, Acquired (Autoimmune) Hemolytic
Anemia, Erythroblastopenia, Congenital (Erythroid) Hypoplastic Anemia;
9. Neoplastic Diseases: For palliative management of Leukemias and Lymphomas in adults, Acute Leukemia of childhood;
10. Edematous states: To induce a Diuresis or remission of Proteinuria in the Nephrotic Syndrome without
Uremia, of the idiopathic type or that due to Lupus Erythematosus;
11. Gastrointestinal Diseases: To tide the patient over a critical period of the disease in Ulcerative Colitis & Regional Enteritis
12. CNS Diseases: Acute Exacerbations of Multiple Sclerosis.

**Dosage & Administration**
The initial dosage of Methylprednisolone tablets may vary from 2 mg to 48 mg per day depending on the specific disease entity being treated. As anti-inflammatory/ immunosuppressive, the initial dosage of Methylprednisolone tablets may vary from 4- 48 mg per day depending on the specific disease entity being treated. In situations of less severity lower doses will generally suffice while in selected patients higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, Methylprednisolone should be discontinued and the patient transferred to other appropriate therapy. It should be emphasized that dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient. After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. It should be kept in mind that constant monitoring is needed in regard to drug dosage. Included in the situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual drug responsiveness and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment; in this latter situation it may be necessary to increase the dosage of Methylprednisolone for a period of time consistent with the patient's condition. If after long-term therapy the drug is to be stopped, it is recommended that it should be withdrawn gradually rather than abruptly. Multiple Sclerosis: In treatment of acute exacerbations of multiple sclerosis daily doses of 200 mg of prednisolone for a week followed by 80 mg every other day for 1 month have been shown to be effective (4 mg of methylprednisolone is equivalent to 5 mg of prednisolone).

**Contraindication**
Systemic fungal infections and known hypersensitivity to components.
*Precaution*
Adrenocortical Insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted.

Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently. There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis. Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

**Use in pregnancy & lactation**
*Pregnancy*
Category C. Drug should be given only if the potential benefit justifies the potential risk to the foetus
*Lactation*
Methylprednisolone has not been adequately evaluated in nursing mothers.

**Drug Interaction**
Erythromycin, Clarithromycin, Phenobarbital, Phenytoin, Rifampin and Ketoconazole inhibit the metabolism of Methylprednisolone. Estrogens, including birth control pills can increase the effect of corticosteroids by 50%. Cyclosporin reduces the metabolism of Methylprednisolone while Methylprednisolone reduces the metabolism of Cyclosporin. Methylprednisolone may increase or decrease the effect of blood thinners (e.g. Warfarin). For all these interactions, the dose of Methylprednisolone may be needed to be lowered.

**Adverse effects**
Short courses of Methylprednisolone are usually well-tolerated with few, mild side effects. Long term, high doses of Methylprednisolone may produce predictable and potentially serious side effects. Whenever possible, the lowest effective doses of Methylprednisolone should be used for the shortest length of time to minimize side effects. Alternate day dosing also can help to reduce side effects. Side effects of Methylprednisolone and other corticosteroids range from mild annoyances to serious irreversible bodily damage. Side effects include fluid retention, weight gain, high blood pressure, potassium loss, headache, muscle weakness, hair growth on the face, glaucoma, cataracts, peptic ulceration, growth retardation in children, convulsions and psychic disturbances including depression, euphoria, insomnia etc. Prolonged use of Methylprednisolone can depress the ability of the body's adrenal glands to produce corticosteroids. Abruptly stopping Methylprednisolone in these individuals can cause symptoms of corticosteroid insufficiency with accompanying nausea, vomiting, and even shock. Therefore, withdrawal of Methylprednisolone usually is accomplished by gradually lowering the dose. Gradually tapering Methylprednisolone not only minimizes the symptoms of corticosteroid insufficiency, it also reduces the risk of an abrupt flare of the disease being treated.

**Preparation**
2, 4, 8 & 16 mg Tablet.



# Melixol®

**Active Ingredient**
Flupenthixol & Melitracen.

**Indication**
Anxiety along with depression.

**Dosage & Administration**
2 tablets in a day, 1 in morning & another at mid day.

**Contraindication**
Hypersensitivity to Melitracen & Flupenthixol, depression of the CNS (e.g. at the time of acute intoxications to alcohol, barbiturates or opiates), state of coma, pheochromocytoma, blood dyscrasy, immediately consecutive recovery to a myocardial infarction, at the time of a cardiac block of any rank, disorders of cardiac conduction as well as coronary insufficiency. The concomitant administration of MAOIs are contra-indicated.

**Precaution & Warning**
The administration of this requires prudence among patients presenting an organic cerebral lesion, convulsions, urinary retention, hyperthyroid, parkinson's syndrome, serious myasthenia, advanced hepatic affection as well as cardiovascular disorders. Among depressive patients, the risk of suicide remains during the treatment. As for all nerve sedatives, a syndrome nerve sedative (potentially fatal) can seldom occur. Extrapyramidal disorders can occur in very rare cases.

**Side Effect**
Side effects are rare. These could be transient restlessness & insomnia.

**Preparation**
Flupenthixol 10 mg & Melitracen 0.5 mg in each tablet.

# Menoral®

**Active Ingredient**
Norethisterone.

**Indication**
- Dysfunctional Uterine Bleeding(DUB)
- PMS (Premenstrual Syndrome)
- Endometriosis
- Dysmenorrhea
- Postponement of menstruation

**Dosage & Administration**
DUB: 1 tablet 3 times a day for 3-4 cycles from day 5 to day 24 of cycle
PMS: 1 tablet 2 to 3 times a day from day 19 to day 26 of several cycle
Endometriosis: 2-3 tablets daily for 4-6 months
Dysmenorrhea: 1 tablet 3 times a day for 3-4 cycles from day 5 to day 24 of cycle
Postponement of menstruation : 1 tablet 3 times a day, to be started before expected onset (Menstruation occurs 2-3 days after stopping)

**Contraindication & Precaution**
- Active thromboembolic processes
- Diabetes mellitus with vascular involvement
- Presence or history of severe hepatic disease
- Presence or history of liver tumors
- Known or suspected sex hormone-dependent malignancies
- Hypersensitivity to the active substance or to any of the excipients

**Side Effect**
Visual disturbance, nausea, headache, migraine, edema, dyspnea, hypersensitivity reactions (urticaria, rash).

**Drug Interaction**
Phenytoin, barbiturates, primidone, carbamazepine, rifampicin may decrease therapeutic efficacy. The requirement of Oral anti-diabetics or Insulin may be changed.

**Use in Pregnancy & Lactation**
The use of Menoral during pregnancy is contra-indicated. Menoral should not be used during lactation.

**Preparation**
5 mg Tablet.

# Merison™

**Active Ingredient**
Betahistine Mesilate

**Indication**
Vertigo and dizziness associated with the following diseases: Meniere's disease, Meniere's syndrome and Peripheral vertigo. Dosage and Administration: Adults: 1 to 2 tablets three times per day after meals.

**Precaution**
Careful administration: History of digestive ulcer, bronchial asthma and pheochromocytoma.

**Adverse Reactions**
Nausea or vomiting, Hypersensitivity reactions, such as skin rash.

**Use In Pregnancy**
Safety of Betahistine Mesilate during pregnancy has not been established. This drug should be administered to pregnant patients or women suspected of being pregnant, only if the expected therapeutic benefit is thought to outweigh any possible risk.

**Preparation**
6 mg Tablet.

# Metaspray® Nasal Spray

**Active Ingredient**
Mometasone Furoate.

**Indication**
Metaspray Nasal Spray is indicated for the treatment of the nasal symptoms of seasonal & perennial allergic rhinitis, in adults & pediatric patients 2 years of age & older. It is indicated for the prophylaxis of the nasal symptoms of seasonal allergic rhinitis in adult & adolescent patients 12 years & older. It is also indicated for the treatment of nasal polyps in patients 18 years & older.

**Dosage & Administration**
Adults & Children 12 Years of Age & Older:
The recommended dose for prophylaxis & treatment of the nasal symptoms of seasonal allergic rhinitis & treatment of the nasal symptoms of perennial allergic rhinitis is two sprays (50 mcg of Mometasone Furoate in each spray) in each nostril once daily (total daily dose of 100 mcg). In patients with a known seasonal allergen that precipitates nasal symptoms of seasonal allergic rhinitis, prophylaxis with Metaspray® Nasal Spray, 50 mcg (200 mcg/day) is recommended 2 to 4 weeks prior to the anticipated start of the pollen season.
Children 2 to 11 Years of Age: The recommended dose for treatment of the nasal symptoms of seasonal & perennial allergic rhinitis is one spray (50 mcg of Mometasone Furoate in each spray) in each nostril once daily (total daily dose of 100 mcg).
Nasal Polyps: Adults 18 years of Age & Older: The recommended dose for nasal polyps is two sprays (50 mcg of Mometasone Furoate in each spray) in each nostril twice daily (total daily dose of 400 mcg). A dose of two sprays (50 mcg of mometasone furoate in each spray) in each nostril once daily (total daily dose of 200 mcg) is also Effective in some patients.

**Contraindication & Precaution**
Hypersensitivity to any of the ingredients of this preparation contraindicates its use. While using nasal corticosteroids, caution is required in patients with active or dormant tuberculous infection, or in untreated fungal, bacterial, systemic viral infections, or ocular herpes simplex.

**Side-Effect**
Side effects are generally mild & included headache, viral infection, sore throat, nosebleeds, & coughing.

**Pregnancy & Lactation**
There are no adequate & well-controlled studies in pregnant women. Mometasone Furoate, like other corticosteroids, should be used during pregnancy only if the potential benefits justify the potential risk to the fetus. It is not known if Mometasone Furoate is excreted

in human milk. Because other corticosteroids are excreted in human milk, caution should be used when Mometasone is administered to nursing women.

**Preparation**
120 Nasal Sprays (50 mcg in each spray)

# Methicol®

**Active Ingredient**
Mecobalamin.

M

**Indication**
For both tablet & injection: Peripheral neuropathies observed in - Diabetic neuropathy, Diabetic retinopathy, Entrapment neuropathy, Amyotrophic lateral sclerosis, Parkinson's disease, Alzheimer's disease, Lumbago, Drug induced neuropathy, Multiple sclerosis, Intercostal neuralgia, Vertebral syndrome, Nerve Compression Syndrome. For injection only: Megaloblastic anemia due to Vitamin B12 deficiency.

**Dosage & Administration**
Methicol Tablet: Adults 3 tablets, equivalent to a total of 1500 mcg of Mecobalamin, administered orally in 3 divided doses.

**Contraindication & Precaution**
Hypersensitivity to Mecobalamin or to any of the excipients used in the preparations. Mecobalamin should not be administered for extensive period (months) to patients who do not show clinical response. Prolonged use of larger doses of Mecobalamin is not recommended for patients whose occupation requires handling mercury or its compounds.

**Side Effect**
Gastrointestinal symptoms (e.g. anorexia, nausea or diarrhea) & skin rash may occur.

**Drug Interaction**
No significant drug interaction reported.

**Use in Pregnancy & Lactation**
Not recommended during pregnancy & lactation.

**Preparation**
500 mcg Tablet.

# Mevin™

**Active Ingredient**
Mebeverine Hydrochloride

**Indication**
- Symptomatic treatment of IBS
- Chronic irritable colon
- Spastic constipation
- Mucous colitis
- Colicky abdominal pain
- Persistent non-specific diarrhoea

**Dosage & Administration**
Adults, elderly & children over 10 years: Mevin™ Tablet: 1 tablet three times daily. Mevin™ is most effective when taken 20 minutes before meals. After several weeks when the desired effect has been obtained, the dosage may be gradually reduced.

**Precaution**
Caution should be exercised in porphyria or allergic reaction to this or any other medicine of this group.

**Side Effect**
Generally Mebeverine is well tolerated. However, few side-effects like skin rash,

urticaria & angioedema may appear.

**Use in Pregnancy & Lactation**
No teratogenicity has been shown in animal experiments. However, the usual precautions concerning the administration of any drug during pregnancy should be exercised. Mebeverine does not excrete in the breast milk after administering the therapeutic dose.

**Use in Children**
Mebeverine is not recommended in children under 10 years.

**Preparation**
135 mg Tablet.



# Mexlo® Eye Drops

**Active Ingredient**
Lomefloxacin.

**Indication**
Conjunctivitis, blepharitis, blepharo-conjunctivitis, Staphylococcus aureus - induced corneal ulcers.

**Dosage & Administration**
At the beginning of therapy on Day 1 instill 5 drops into the conjunctival sac within 20 minutes. There after, until Day 7-9 instill 1 drop 2 times daily into the conjunctival sac.

**Contraindication & Precaution**
Hypersensitivity to lomefloxacin. Long term treatment may enhance development of secondary fungal infections, phototoxicity, exposure to sunlight or UV-radiation should be avoided.

**Side Effect**
Slight & transient burning, allergic reactions, asthma, dyspnoea, urticaria, erythema, pruritus, & hypersensitization.

**Drug Interaction**
Preparations containing heavy metals, such as Zinc, should not be used during 15 minutes preceding & following application of Lomefloxacin.

**Use in Pregnancy & Lactation**
The drug should only be used when the benefit outweighs the potential risk for the foetus or the infant.

**Preparation**
0.3% Eye Drops.

# Migranil®

**Active Ingredient**
Pizotifen.

**Indication**
Prophylactic treatment of recurrent vascular headaches including classical migraine common migraine & cluster headache.

**Dosage & Administration**
1.5 mg daily at bed time as a single dose or in three divided doses.

**Contraindication & Precaution**
Hypersensitivity, narrow-angle glaucoma or prostate hypertrophy. Dosage adjustment may be necessary in patients with kidney insufficiency.

**Side Effect**
Drowsiness, dizziness, dry mouth, nausea & constipation

**Use in Pregnancy**
Clinical data with pizotifen in pregnancy are very limited; it should be administered in pregnancy only if the expected benefits outweigh the potential risks.

**Drug Interaction**
Alcohol, tranquilizers, hypnotics, antidepressants & MAO inhibitors.

**Preparation**
0.5 mg & 1.5 mg Tablet.

**Use in Pregnancy & Lactation**
Butamirate Citrate should not be used during the first trimester of pregnancy. During the remainder of pregnancy, it can be used if indicated by a physician but with caution. The benefits of Butamirate Citrate administration during breast feeding should be carefully weighed against the risks.

**Preparation**
50 mg Sustained Release Tablet, 7.5 mg/ml Syrup (100 ml) & 5mg/ml Paediatric drop(15 ml.)

M

# Mirakof®

**Active Ingredient**
Butamirate Citrate.

**Indication**
Dry (non-productive) cough & also used in pre- & post-operative cough sedation.

**Dosage & Administration**
Mirakof Tablet: Adolescents over 12 years old: 1-2 tablets daily
Adults: 2-3 tablets daily at 8 to 12 hours intervals.
Mirakof Syrup: Adults: 15 ml 4 times daily. Adolescents: 15 ml 4 times daily. Children (6-12 years): 10 ml 3 times daily. (3-6 years): 5 ml 3 times daily.
Mirakof Paediatric Drops: Children 2 months – 1 year: 0.50 ml 4 times daily; Children 1 – 3 years: 0.75 ml 4 times daily

**Contraindication & Precaution**
Hypersensitivity to the active ingredient.

**Side Effect**
Rash, nausea, diarrhoea & vertigo have been observed in a few rare cases, resolving after dose reduction or treatment withdrawal.

# Mirapro™

**Active Ingredient**
Mirtazapine USP 7.5 mg.

**Indications**
It indicated for the treatment of major depressive disorder (MDD).

**Dosage & Administration**
The recommended starting dose for Mirapro™ is 15 mg/day, administered in a single dose, preferably in the evening prior to sleep. It is generally agreed that acute episodes of depression require several months or longer of sustained pharmacological therapy beyond response to the acute episode. Systematic evaluation of Mirapro™ has demonstrated that its efficacy in major depressive disorder is maintained for periods of up to 40 weeks following 8 to 12 weeks of initial treatment at a dose of 15 to 45 mg/day.

**Contraindication**
*Hypersensitivity:* Mirtazapine is contraindicated in patients with a known hypersensitivity to mirtazapine or to any of the excipients.

MonoamineOxidaseInhibitorsTheconcomitant use of Mirtazapine and a monoamine oxidase (MAO) inhibitor is contraindicated. Mirtazapine should not be used within 14 days of initiating or discontinuing therapy with a monoamine oxidase inhibitor (MAOI)

**Side Effects**
The most common side effects of Mirtazapine are dizziness, drowsiness, dry mouth, increased appetite, weight gain etc.

**Precaution**
Patients, their families, and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down.
Patients who are to receive Mirtazapine should be warned about the risk of developing agranulocytosis. Mirtazapine may impair judgment, thinking, and particularly, motor skills, because of its prominent sedative effect. Clinically significant ALT (SGPT) elevations (≥ 3 times the upper limit of the normal range) may occur.

**Use in Pregnancy & Lactation**
Pregnancy Category-C. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during Mirtazapine therapy. Patients should be advised to notify their physician if they are breastfeeding an infant.

**Drug interaction**
Mirtazapine has clinically significant drug-drug interactions with Monoamine Oxidase Inhibitors (MAOI) & other serotonergic drugs such as tryptophan, triptans, linezolid, serotonin reuptake inhibitors, venlafaxine, lithium, tramadol, or St. John's wort. Mirtazapine may interrupt the metabolism or activity of Carbamazepine, Phenytoin or Cimetidine. Patient should avoid Alcohol & Diazepam while taking Mirtazapine.

**Preparation**
7.5 mg Tablet.

# Montene®

**Active Ingredient**
Montelukast.

**Indication**
For the prophylaxis & chronic treatment of asthma in adults & pediatric patients 2 years of age & older. For the relief of symptoms of allergic rhynitis

**Dosage & Administration**
Adolescents & adults 15 years of age & older: One 10 mg tablet daily to be taken in the evening. Patients 6-14 years of age: 5 mg daily to be taken in the evening. Patients 2-5 years of age: 4 mg daily to be taken in the evening.

**Contraindication & Precaution**
Hypersensitivity to the active ingredient.

**Side Effect**
The common adverse effects are headache, rash, dyspepsia, dizziness & abdominal pain. Pediatric patients have experienced diarrhea, sinusitis, & otitis media during montelukast clinical trials.

**Drug Interaction**
Patients with known aspirin sensitivity should continue avoidance of aspirin or nonsteroidal anti-inflammatory agents while taking montelukast.

**Use in Pregnancy**
There have been no reports of its use in pregnant women. Caution should be used prior to initiating montelukast therapy in nursing mothers.

**Preparation**
10 mg Tablet, 5 mg Chewable Tablet & 4 mg Chewable Tablet.

# Motigut®

**Active Ingredient**
Domperidone.

**Indication**
1. Dyspeptic symptom complex: Often associated with delayed gastric emptying, gastroesophageal reflux and esophagitis. epigastric sense of fullness, feeling of abdominal distension, upper abdominal pain, eructation, early satiety, heartburn with or without regurgitations of gastric contents in the mouth, diabetic gastroparesis, non ulcer dyspepsia.
2. Nausea & vomiting: Acute nausea & vomiting of functional, organic, infectious, dietetic origin or induced by radiotherapy or drug therapy or induced in migraine.
3. Parkinson's disease: In dopamine-agonist induced nausea and vomiting.
4. Radiological studies: Speading barium transit in follow through radiological studies.



**Dosage & Administration**
1-2 tablet or 10-20 ml suspension every 6-8 hours daily before meals. Children: 2 ml-4 ml suspension/10 kg or 0.4 ml-0.8 ml paed. drops/ 10 kg 6-8 hours daily.

**Contraindication & Precaution**
Known hypersensitivity, gastro-intestinal stimulation, gastro-intestinal hemorrhage, mechanical obstruction or perforation, prolactinoma, increased risk of extra-pyramidal reactions, should be used with caution in patient with hepatic impairment.

**Side Effect**
Hyperprolactinemia, galactorrhea, breast enlargement, & soreness & reduced libido. Dry mouth, thirst, headache, nervousness, drowsiness, diarrhea, skin rash & itching.

**Drug Interaction**
Bromocriptine, anti-muscarinics & opioid analgesics. MAO (monoamine oxidase) inhibitors.

**Use in Pregnancy & Lactation**
Not recommended during pregnancy. It is secreted in breast milk but in very small quantities insufficient to be considered harmful.

**Preparation**
10 mg Tablet, 60 ml Suspension, 15 ml Paediatric Drops.

# Moxacil®

**Active Ingredient**
Amoxicillin.

**Indication**
Infections of the ear, nose & throat, genitourinary tract, skin & skin structure, lower respiratory tract; gonorrhea, acute uncomplicated (ano-genital & urethral infections). *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence in combination with clarithromycin plus lansoprazol as triple therapy. Prophylactic cover for patients at risk of developing endocarditis when undergoing dental surgery.

**Dosage & Administration**
Adult : Mild/Moderate-500 mg every 12 hours or 250 mg every 8 hours, Severe-875 mg every 12 hours or 500 mg every 8 hours. Children: Mild/Moderate-25 mg/kg/day in divided doses every 12 hours or 20mg/kg/ day in divided doses every 8 hours, Severe-45 mg/kg/day in divided doses every 12 hours or 40 mg/kg/day in divided doses every 8 hours. Gonorrhea, Acute uncomplicated ano-genital, & urethral infections in male & female 3 g as single oral dose. Prepubertal children 50 mg/ kg Amoxicillin, combined with 25 mg/kg Probenecid as a single dose

**Contraindication & Precaution**
It is contraindicated for patients hypersensitive

to Penicillin. In renal impairment the excretion of antibiotic will be delayed & depending on the degree of impairment it may be necessary to reduce the total daily dose. Caution should also be exercised in case of erythematous rashes, glandular fever, history of allergy etc.

**Adverse Effect**
Mild, rare & infrequent Diarrhoea, indigestion or skin rashes.

**Use in Pregnancy & Lactation**
Can be used safely throughout pregnancy at the normal adult dose. Can be used safely during lactation in most instances.

**Drug Interaction**
Concurrent administration of Probenecid delays the excretion of Amoxicillin.

**Preparation**
250 mg & 500 mg Capsule, 125 mg/5 ml Suspension, 125 mg/1.25 ml Paediatric Drops.

# Moxaclav™

**Active Ingredient**
Co-Amoxiclav (Amoxicillin + Clavulanic Acid)

**Indication**
Upper respiratory tract infections; Lower respiratory tract infections; Genito-urinary tract infections; Skin & soft tissue infections; Bone & joint infections e.g. osteomyelitis; Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis etc.

**Dosage & Administration**
Adults & children over 12 years: One Moxaclav 375 mg tablet three times a day. In severe infection, one Moxaclav 625 mg tablet three times a day or one Moxaclav 1gm tablet two times a day. Children of 6-12 years: 2 teaspoonful of Moxaclav Powder for Suspension every 8 hours. Children of 1-6 years: 1 teaspoonful of Moxaclav Powder for Suspension every 8 hours. Children below 1 year: 25 mg/kg/day in divided doses every 8 hours. Moxaclav Forte Powder for Suspension: Children of 2-12 years: ½ to 2 teaspoonful b.i.d. Children of 2 months to 2 years: 25/3.6 mg/kg/day to 45/6.4 mg/kg/day b.i.d. Moxaclav 1.2 IV Injection: 1.2 g every 6-8 hours, Children up to 3 months: 30 mg/kg every 8 hours (every 12 hours in the perinatal period & in premature infants); Child 3 months-12 years, 30 mg/kg every 6-8 hours.

**Precaution & Warning**
Co-amoxiclav should be used with care in patients on anti-coagulation therapy or with severe hepatic dysfunction. In patients with moderate or severe renal impairment, dose should be adjusted.

**Contraindication**
History of Penicillin hypersensitivity. Patients with previous history of Co-amoxiclav or penicillin associated cholestatic jaundice.

**Side Effect**
Mild & transitory nature. Diarrhoea, pseudomembranous colitis, indigestion, nausea, vomiting & candidiasis.

**Drug Interaction**
Oral contraceptives.

**Use in Pregnancy & Lactation**
Use of Co-amoxiclav in pregnancy is not recommended unless considered essential by the physician. During lactation, trace quantities of Amoxicillin can be detected in breast milk.

**Preparation**
375 Tablet (Amoxicillin 250 mg & Clavulanic Acid 125 mg); 625 Tablet (Amoxicillin 500 mg & Clavulanic Acid 125 mg); 1gm Tablet (Amoxicillin 875 mg & Clavulanic Acid 125 mg); 100 ml Powder for Suspension (Amoxicillin 125 mg & Clavulanic Acid 31.25 mg/ 5 ml); 50 ml Forte Powder for Suspension (Amoxicillin 400 mg & Clavulanic Acid 57.5 mg/ 5 ml);,1.2 gm IV Injection (Amoxicillin 1gm & Clavulanic Acid 0.2 gm).

# Mucospel®

**Active Ingredient**
Bromhexine.

**Indication**
Treatment of respiratory disorders associated with viscid or excessive mucus and/or productive cough.

**Dosage & Administration**
Mucospel Syrup: Adults & Children over 10 years : 2 to 4 teaspoonfuls 3 times daily, Children 5-10 years : 1 teaspoonful 3 times daily, Children 2-5 years : 1/2 teaspoonful 3 times daily, Children below 2 years : 1/4 teaspoonful 3 times daily.

**Contraindication & Precaution**
known hypersensitivity or idiosyncratic reaction to Bromhexine Hydrochloride (or any of the other ingredients in the product). Since mucolytics may disrupt the gastric mucosal barrier, Bromhexine should be used with caution in patients with a history of gastric ulceration.

**Use in Pregnancy & Lactation**
Category B. Bromhexine has been taken by a large number of pregnant women & women of child bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus. It is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

**Side Effect**
Gastrointestinal side effects, transient rise in serum aminotransferase values, headache, vertigo (dizziness), sweating & allergic reactions.

**Preparation**
4 mg/5 ml Syrup (100 ml).

# Multivit® Plus

**Active Ingredient**
Vitamin A, D, B1, B2, B6, C, E, Nicotinamide, Cyanocobalamin, Folic Acid, Calcium Pantothenate, Iron, Copper, Manganese, Iodine, Potassium & Zinc.

**Indication**
Vitamin & mineral deficiencies.

**Dosage & Administration**
Orally one Multivit Plus tablet daily for adult & children over 5 years of age or as directed by the physicians.

**Contraindication & Precaution**
Hypersensitivity, severe specific deficiencies of vitamins or minerals, treatment with levodopa as Pyridoxine decreases the efficacy of Levodopa. During the first trimester of pregnancy, larger doses of Vitamin A (more than 10 tablets per day) may be teratogenic, pernicious anemia or other megaloblastic anemia where vitamin B12 is deficient.

**Side Effect**
Iron has been associated with gastrointestinal intolerance.

**Use in Pregnancy & Lactation**
During the first trimester of pregnancy, recommended daily dose should not be exceeded.

**Preparation**
Tablet.

# Myonil®

**Active Ingredient**
Eperisone.

**Indication**
Improvement of muscular hypertonic symptoms in the following diseases- Cervical syndrome, periarthritis of the shoulder, lumbago. Spastic paralysis in the following disease: Cerebrovascular disease, spastic spinal paralysis, cervical spondylosis, postoperative sequelae (including cerebrospinal tumor), sequelae to trauma (spinal trauma, head injury), amyotrophic lateral sclerosis, cerebral palsy, spinocerebellar degeneration, spinal vascular diseases & other encephalomyelopathies.

**Dosage & Administration**
For adults: Usually 3 tablets per day in three divided doses after each meal.

**Contraindication & Precaution**
In patients with a history of hypersensitivity to Eperisone Hydrochloride.

**Use in Pregnancy & Lactation**
Eperisone Hydrochloride should only be used in pregnant women if the expected therapeutic benefits are evaluated to outweigh the possible risks of treatment. The drug should not be used during lactation.

**Side Effect**
Excessive relaxation, stomachache, nausea, vertigo, anorexia, drowsiness, skin rashes, diarrhea, vomiting, indigestion, GI disturbances, insomnia, headache, constipation, etc.

**Preparation**
50 mg Tablet.

# Nalid®

**Active Ingredient**
Nalidixic Acid.

**Indication**
Urinary tract infection.

**Dosage & Administration**
Infants & children 3 months of age & over. Initial: Oral 13.75 mg per kg body weight every six hours for one or two weeks. Maintenance: Oral 8.25 mg per kg body weight every six hours. Usual adult dose initially is 1 g every 6 hours for 7 days reducing to 500 mg every 6 hours or as prescribed by the physician.

**Contraindication & Precaution**
Risk-benefit must be considered during the first trimester of pregnancy & during breast feeding, impaired renal or hepatic function. Nalidixic acid is contraindicated in the following cases - Infants under 3 months, epilepsy, CNS lesions.



**Side Effect**
Gastro-intestinal disturbances including nausea, vomiting, diarrhoea, allergic reaction including urticaria, rashes, fever, arthralgia, muscle weakness, phototoxicity.

**Drug Interaction**
This drug should not be used with the following medications because very serious interactions may occur: certain cancer chemotherapy (alkylating agents such as melphalan).

**Use in Pregnancy & Lactation**
This drug should be used in pregnancy only if clearly needed. Nalidxic acid excreted into milk in small amounts. It is compatible with breast feeding.

**Preparation**
500 mg Tablet & 300 mg/5 ml Powder for Suspension.

# Naurif®

**Active Ingredient**
Granisetron.

**Indication**
Naurif Injection: Prevention of nausea & vomiting associated with initial & repeat courses of emetogenic cancer chemotherapy, therapy including high dose cisplatin. Prevention & treatment of postoperative nausea & vomiting. Naurif Tablet: Nausea & vomiting associated with initial & repeat courses of emetogenic cancer therapy, including high dose of cisplatin. Nausea & vomiting associated with radiation, including total body irradiation & fractionated abdominal radiation.

**Dosage & Administration**
Naurif Injection: Chemotherapy Induced Nausea & Vomiting: Adults: 10 mcg/kg administered intravenously within 30 minutes before initiation of chemotherapy, & only on the day(s) chemotherapy is given. Paediatric patients 2 to 16 years of age: 10 mcg/kg. Treatment of Postoperative Nausea & Vomiting: Adults: Single dose of 1 mg of Naurif should be diluted to 5 ml & administered as a slow intravenous injection (over 30 seconds). Naurif Tablet: Emetogenic chemotherapy: 2 mg once daily or 1 mg twice daily. Administered only on the days(s) chemotherapy is given. Radiation: 2 mg once daily. Two 1 mg tablets are taken within one hour of irradiation.

**Contraindication**
Known hypersensitivity to granisetron.

**Side Effect**
Headache, constipation, asthenia, diarrhea, abdominal pain, dyspepsia, nausea, vomiting, dizziness, insomnia, anxiety.

**Pregnancy**
Pregnancy category B. This drug may be used in pregnancy only if clearly needed.

**Nursing Mother**
Caution should be exercised when granisetron is administered to a nursing mother.

**Preparation**
1 mg/ml Injection, 1 mg Tablet.

# Nebanol®

**Active Ingredient**
Neomycin Sulphate & Bacitracin Zinc.

**Indication**
Topical bacterial infections, atopic or contact stasis & infections, eczematoid dermatitis, neurodermatitis, eczema, anogenital pruritus etc.

**Dosage & Administration**
A thin film to be applied 2 to 4 times daily.

**Contraindication & Precaution**
Hypersensitivity, nephrotoxicity, overgrowth of non-susceptible organisms including fungi.

**Adverse Reaction**
Allergic reaction.

**Preparation**
(5 mg + 250 I.U.)/gm Powder, (5 mg + 500 I.U.)/gm Ointment.

# Nebanol Plus®

**Active Ingredient**
Neomycin Sulphate, Bacitracin Zinc & Polymyxin B Sulphate.

**Indication**
Infected wounds, burns or skin grafts, chronic varicose or other indolent ulcers, furuncles, carbuncles, pyoderma, sycosis barbae, impetigo & acne, secondary infected skin lesions of scabies, pediculosis, tinea pedis & contact & allergic dermatitis.

**Dosage & Administration**
A thin film to be applied one to three times daily.

**Contraindication & Precaution**
Hypersensitivity reaction, ototoxicity. Not recommended for neonates.

**Use in Pregnancy & Lactation**
Not recommended in pregnancy & lactation.

**Preparation**
(3.5 mg + 400 I.U. + 5000 I.U.)/gm Ointment.

# Nebita™

**Active Ingredient**
Nebivolol HCl

**Indication**
Hypertension, Heart Failure
Dosage & administration: Heat Failure: Initially 1.25 mg once daily, then if tolerated increased at intervals of 1–2 weeks to 2.5 mg once daily, then to 5 mg once daily, then to max. 10 mg once daily. Hypertension: Starting dose is 5 mg once daily. The dose can be increased at 2 weeks interval up to 40 mg once daily.

**Contraindication & Precaution**
Nebivolol is contraindicated in the following conditions: severe bradycardia, heart block greater than first degree, patients with cardiogenic shock, decompensated cardiac failure, sick sinus syndrome, patients with severe hepatic impairment, patients who are hypersensitive to any component of this product.

**Side Effect**
The most common side effects are headache, nausea & bradycardia.

**Drug Interaction**
Use caution when Nebivolol is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.). Do not use Nebivolol with other β-blockers, both digitalis glycosides & β-blockers slow atrioventricular conduction & decrease heart rate. Concomitant use can increase the risk of bradycardia, Nebivolol can exacerbate the effects of myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (verapamil & diltiazem), or antiarrhythmic agents, such as disopyramide.

**Use in Pregnancy & Lactation**
β-blockers may cause intra-uterine growth restriction, neonatal hypoglycaemia, & bradycardia; the risk is greater in severe hypertension. If beta-blockers are used close to delivery, infants should be monitored for signs of β-blockade. Nebivolol is advised to avoid during breast-feeding due to possible risk of toxicity due to β-blockade.

**Use in Children**
Safety & effectiveness of Nebivolol in pediatric patients have not been established.

**Preparation**
2.5 mg/Tablet, 5 mg/ Tablet.



# Nebita Plus 5/12.5

**Active Ingredient**
Nebivolol & Hydrochlorothiazide combination.

**Indications**
Essential hypertension.

**Dosage & Administration**
Once daily, preferably at the same time every day.

**Contraindication & Precautions**
Hypersensitivity to the active substances, Liver

function impairment, severe renal insufficiency (Creatinine clearance < 30 ml/min.), Bradycardia, Hypotension. Nebivolol: Beta-blockers should not be used in patients with untreated congestive heart failure (CHF) & bradycardia. In patients with chronic obstructive pulmonary disorders (COPD), beta-blockers should be used with caution as airway constriction may be aggravated. Hydrochlorothiazide: In patients with renal disease, thiazides may increase azotaemia. If progressive renal impairment becomes evident, careful reappraisal of therapy is necessary. Thiazides can cause fluid or electrolyte imbalance. Thiazides may decrease urinary calcium excretion and may cause an intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism.

**Use in Pregnancy & Lactation**
This combination is not recommended during pregnancy. It is not recommended for mothers who are breast-feeding.



**Side Effects**
Nebivolol Headache, Dizziness, Tiredness, Diarrhoea, Constipation, Nausea. Hydrochlorothiazide: Vertigo (spinning sensation), Convulsions, Itchiness, Rash, Increased sensitivity of your skin to sunlight.

**Preparation**
5/12.5 Tablet

# Neuro-B®

**Active Ingredient**
Thiamine (Vit-B1), Pyridoxine (Vit-B6), Cyanocobalamin (Vit-B12).

**Indication**
Indicated in low back pain & in the deficiency of the relevant vitamins including Polyneuropathy of any origin such as- Diabetic, Alcoholic or Toxic neuropathies, Neuritis, Neuralgia, Cervical Syndrome, Shoulder-arm syndrome, Lumbago, Sciatica, Mayalgia, Intercostal neuralgia, Herpes Zoster, Trigeminal Neuralgia Supportive treatment in facial paresis.

**Dosage & Administration**
Tablet : 1 to 3 tablets daily or as directed by the physician. Injection : Preferably injected intramuscularly (deep intragluteal). In severe cases 1 ampoule daily until the acute symptoms subside. For milder cases & follow-up therapy, 2 or 3 ampoules per week.

**Contraindication & Precaution**
Patients on Levodopa therapy & hypersensitivity to any of the active ingredients. Cyanocobalamin should not be given before a diagnosis has been fully established because of the possibility of masking symptoms of subacute degeneration of the spinal cord. Cyanocobalamin is not a suitable form of Vitamin B12 for the treatment of optic neuropathies associated with raised plasma concentrations of cyanocobalamin.

**Side Effect**
Well tolerated. Few allergic responses may be seen in rare cases.

**Use in Pregnancy & Lactation**
Sufficient data yet not availalble in this respect.

**Drug Interaction**
No drug interactions have yet been reported.

**Preparation**
(Thiamine Mononitrate 100 mg, Pyridoxine Hydrochloride 200 mg, Cyanocobalamin 200 mcg)/ Tablet, (Thiamine Mononitrate 100 mg, Pyridoxine Hydrochloride 100 mg, Cyanocobalamin 1000 mcg)/ 3 ml Injection.

# Neurolep®

**Active Ingredient**
Piracetam.

**Indication**
Cerebral vascular accidents & cerebral insufficiencies, mental retardation in children, behaviour & psychotic problems in old age, memory deficits.

**Dosage & Administration**
Adults: One tablet (800 mg) 3 times a day. Children: 50 mg/kg of body weight in 3 divided doses.

**Contraindication & Precaution**
Severe renal insufficiency (creatinine clearance < 20 ml/min), hepatic impairment & those under 16 years of age.

**Side Effect**
Nervousness, agitation, irritability, anxiety & sleep disturbances. Nausea, vomiting, diarrhea & stomachache, vertigo, headache, trembling & sexual stimulation have occasionally been reported.

**Drug Interaction**
Thyroid extract, clonazepam, carbamazepine, phenyton, phenobarbitone & sodium valporate.

**Preparation**
800 mg Tablet & 500 mg/5ml Solution.





# Neurolin®

**Active Ingredient**
Pregabalin.

**Indication**
Neurolin is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy & management of post herpetic neuralgia. It is also indicated for the adjunctive therapy for adult patients with partial onset seizures. It can be used for the management of fibromyalgia & Neuropathic pain associated with spinal cord injury.

**Dosage & Administration**

*Neuropathic pain associated with diabetic peripheral neuropathy:* The maximum recommended dose of Pregabalin (Neurolin) is 100 mg three times a day (300 mg/day) in patients with creatinine clearance of at least 60 mL/min. Dosing should begin at 50 mg three times a day (150 mg/day) & may be increased to 300 mg/day within 1 week based on efficacy & tolerability.

*Post herpetic neuralgia:* The recommended dose of Pregabalin (Neurolin) is 75 to 150 mg two times a day, or 50 to 100 mg three times a day (150 to 300 mg/day) in patients with creatinine clearance of at least 60 mL/min. Dosing should begin at 75 mg two times a day, or 50 mg three times a day (150 mg/day) & may be increased to 300 mg/day within 1 week based on efficacy & tolerability.

*Adjunctive therapy for adult patients with partial onset seizures:* Pregabalin (Neurolin) at doses of 150 to 600 mg/day has been shown to be Effective as adjunctive therapy in the treatment of partial onset seizures in adults. The total daily dose should be divided & given either two or three times daily.

In general, it is recommended that patients be started on a total daily dose no greater than 150 mg/day (75 mg two times a day, or 50 mg three times a day). Based on individual patient response & tolerability, the dose may be increased to a maximum dose of 600 mg/day.

*Management of Fibromyalgia:* The recommended dose of Pregabalin for fibromyalgia is 300 to 450 mg/day. Dosing should begin at 75 mg two times a day (150 mg/day) & may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy & tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day).

*Neuropathic pain associated with spinal cord injury:* The recommended dose range is 150 to 600 mg/day. The recommended starting dose is 75 mg two times a day (150 mg/day). The dose may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy & tolerability. Patients who do not experience sufficient pain relief after treatment with 300 mg/day & who tolerate Pregabalin may be treated with up to 300 mg two times a day.

**Contraindication & Precaution**

Pregabalin (Neurolin) is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components. Discontinuation of Pregabalin without tapering may produce insomnia, nausea, headache & diarrhea. So it should be tapered gradually over a minimum of 1 week rather than discontinued abruptly. Creatinine kinase may be elevated if treated with Pregabalin. It should be discontinued rapidly if myopathy is diagnosed or suspected or if creatinine kinase is elevated markedly.

**Side Effect**

The most common side effects include dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, & abnormal thinking.

**Use in Pregnancy & Lactation**

Pregnancy: Pregnancy category C. Nursing mother: It is not known if pregabalin is excreted in human milk; it is, however, present in the milk of rats. So it should be used in nursing mother only if there is a clear benefit over the risk.

**Use in Children**

The safety & efficacy of pregabalin in paediatric patients have not been established.

**Preparation**

25 mg, 50 mg & 75 mg Capsule.

# Nexum®

**Active Ingredient**

Esomeprazole.

**Indication**

It is indicated for the treatment of -

Gastroesophageal Reflux Disease (GERD), Healing of Erosive Esophagitis, Maintenance of healing of Erosive Esophagitis, Symptomatic Gastroesophageal Reflux Disease (GERD), Risk Reduction of NSAID-associated gastric ulcer & *H. pylori* eradication (Triple therapy).

**Dosage & Administration**
Capsule: Recommended adult dosage schedule of Esomeprazole is -

| **Indications** | **Dose** | **Frequency** |
|---|---|---|
| **Gastroesophageal Reflux Disease (GERD)** | | |
| Healing of erosive esophagitis | 20 mg or 40 mg | Once daily for 4 to 8 weeks* |
| Maintenance of healing of erosive esophagitis | 20 mg | Once daily** |
| Symptomatic GERD | 20 mg | Once daily for 4 weeks *** |
| Risk Reduction of NSAID-associated gastric ulcer | 20 mg or 40 mg | Once daily for up to 6 months** |
| *H. pylori* eradication (Triple therapy) | | |
| Esomeprazole | 20 mg | Twice daily for 10 days |
| Amoxicillin | 1000 mg | Twice daily for 10 days |
| Clarithromycin | 500 mg | Twice daily for 10 days |

*Paediatric use (12 years & older)*
Short term treatment of GERD: 20 mg or 40 mg once daily for up to 8 weeks.
- The majority of patients are healed within 4 to 8 weeks. For patients who do not heal after 4-8 weeks, an additional 4-8 weeks treatment may be considered.
- Controlled studies did not extend beyond 6 months.
- If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered.

**Injection**

| | |
|---|---|
| Duodenal ulcer, gastric ulcer, gastrointestinal lesions refractory to $H_2$ blockers, Zollinger-Ellison syndrome | 40 mg per day intravenously |
| Reflux esophagitis | 20-40 mg per day intravenously |

*Direction for use of IV Injection*
Esomeprazole lyophilized powder & 0.9% Sodium Chloride Injection is for intravenous administration only & must not be given by any other route. Esomeprazole injection 40 mg should be given as a slow intravenous injection. The solution for IV injection is obtained by adding 5 ml 0.9% Sodium Chloride Injection to the vial containing powder. After reconstitution the injection should be given slowly over a period of at least 3 minutes. Use only freshly prepared solution. The reconstituted solution may be stored at room temperature (up to 30°c) for a maximum 12 hours. Half of the IV injection should be used when 20 mg to be administered.

*Direction for use of IV Infusion*
Esomeprazole IV 40 mg should be given as an intravenous infusion over a period of 10 to 30 minutes. Esomeprazole IV should be reconstituted with 5 ml of 0.9% Sodium Chloride Injection & further diluted (admixed) with 5% Dextrose Injection or 0.9% Sodium Chloride Injection or Lactated Ringer's Injection to a final volume of 50 ml. The reconstituted solution may be stored at room temperature (up to 30°c) for a maximum 12 hours prior to dilution. The admixed solution may be stored at room temperature (up to 30°c) & must be used within 12 hours when reconstituted with 0.9% Sodium Chloride Injection or Lactated Ringer's Injection & within 6 hours when reconstituted with 5% Dextrose Injection.

**Contraindication & Precaution**
Esomeprazole is contraindicated in those patients who have known hypersensitivity to any other components of the formulation. Exclude the possibility of malignancy when gastric ulcer is suspected & before treatment for dyspepsia.

**Side-Effect**
Side effects reported with Esomeprazole include headache, diarrhea & abdominal pain.

**Use in Pregnancy & Lactation**
This drug should be used during pregnancy only if clearly needed. Because Esomeprazole is likely to be excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Preparation**
20 mg Capsule, 40 mg Capsule & 40 mg IV Injection.

# Nexum® MUPS

**Active Ingredient**
Esomeprazole 20 & 40 mg.

**Composition**
Each MUPS tablet contains 20 & 40 mg Esomeprazole (as Esomeprazole Magnesium Trihydrate USP)

MUPS: MUPS is abbreviation for Multiple-Unit Pellet System. However, from pharmaceutical industry and research perspective, the term in general refers to MUPS compacted into tablets. Thus, the resulting tablets prepared by compaction of modified release coated multiparticulates or pellets are called as MUPS. It is the more recent and challenging technologies that combine the advantages of both tablets and pellet-filled capsules in one dosage form.

**CLINICAL ADVANTAGE OF ESOMEPRAZOLE MUPS TABLET COMPARED TO CONVENTIONAL MODIFIED-RELEASE TABLETS AND PELLET-FILLED CAPSULES**
•Ensures greater bioavailability
•Ensures uniform emptying of micro pellets from stomach into small intestine facilitates rapid dissolution of enteric coating and drug release resulting in early tmax and Cmax (peak time and peak plasma concentration)
•Ensures lesser possibility of dose dumping

•Is a combination of fast acting and sustained action
•Ensures uniform drug release
•Once daily dosing
•Ensures lesser chance of localized irritation
•Ensures better and more uniform drug absorption
•Is better than capsules in reducing the esophageal residence time
•Minimizes fluctuation in plasma concentration of drug

**Pharmacodynamic Advantages**

• MUPS ensure rapid and uniform gastric emptying and subsequently uniform drug dissolution of pellets in the gastrointestinal tract due to their small size and larger surface, uniform drug absorption is facilitated which results in consistent and controlled pharmacological action.
• A further reduction in inter- and intra-subject variability in drug absorption and clinical response is facilitated since the number of pellets per MUPS dosage form is much more than a conventional pellet-filled capsule and possibility of dose dumping(in stomach) and incomplete drug release is further minimized.

**Indication**

• Gastroesophageal Reflux Disease (GERD)
• Risk Reduction of NSAID-associated gastric ulcer
• *H. pylori* eradication (Triple therapy)
• Zollinger-Ellison Syndrome

**Dosage & Administration**

Adult from age of 18:

| Indication | Dose | Frequency |
|---|---|---|
| Gastroesophageal Reflux Disease (GERD) | | |
| Erosive Esophagitis | 40 mg | Once daily for 4 weeks |
| Maintenance therapy of Healing of Erosive Esophagitis | 20 mg | Once daily |
| Stomach ulcer caused by NSAIDs | 20 mg | Once daily for 4 to 8 weeks |
| *H.pylori* eradication (Esomeprazole MUPS tablet with Amoxicillin and Clarithromycin) | 20 mg | Twice daily for 7 days |
| Zollinger-Ellison syndrome | 40 mg to 80 mg | Twice daily |

12 to 17 years old:

| Indication | Dose | Frequency |
|---|---|---|
| Gastroesophageal Reflux Disease (GERD) | | |
| Erosive Esophagitis | 40 mg | Once daily for 4 weeks |
| Maintenance therapy of Healing of Erosive Esophagitis | 20 mg | Once daily |
| *H. pylori* eradication (Esomeprazole MUPS tablet with Amoxicillin and Clarithromycin) | 20 mg | Twice daily for 7 days |

Esomeprazole MUPS Tablet is not recommended for the children under 12 years of age. Swallow the tablet whole or with a glass of water. The tablet must not be chewed or crushed.
If the patients have trouble swallowing the tablets, put the tablet into a glass of water (Do not use other liquids). Stir the preparation until the tablets disintegrate. Then drink the liquid within 30 minutes. Stir the mixture just always before drinking.
If the patient unable to swallow, the tablet can be mixed with some water and put into a syringe. The drug may then be administered via a tube directly into the stomach.

Take the tablet with or without food.

**Contraindication**

Esomeprazole is contraindicated in those patients who have known hypersensitivity to

any other components of the formulation.

**Use In Pregnancy & Lactation**
Manufacturer advices caution. There is no information available.
It is not known whether Esomeprazole MUPS tablet excreted in breast milk.

**Side Effect**
Headache, abdominal pain, nausea or vomiting.

**Storage**
Store in a cool (below $30^0$ C) and dry place, protected from light and moisture.

**Preparation**
20 & 40 mg tablets.

N

# Nidipine® SR

**Active Ingredient**
Nifedipine.

**Indication**
Hypertension, Angina.

**Dosage & Administration**
20 mg twice daily with food.

**Contraindication & Precaution**
Cardiogenic shock, advanced aortic stenosis, nursing mothers, GI obstruction, inflammatory bowel disease, hypotension, should be swallowed whole & should not be bitten, chewed or broken up. It should be used with caution in patient whose cardiac reserve is poor.

**Side Effect**
Headache, flushing, lethargy, gravitational oedema, rash, nausea, increased frequency of micturition, eye pain, gum hyperplasia, depression, tremor, photosensitivity & few cases of jaundice have been reported.

**Drug Interaction**
ACE inhibitors, Anti-arrhythmics, Anti-bacterials, Anti-epileptics, Antipsychotics, Beta-blockers, Cyclosporin, Muscle relaxants, Ulcer healing drugs.

**Use in Pregnancy**
It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Preparation**
20 mg SR Tablet.

# Nimocal®

**Active Ingredient**
Nimodipine.

**Indication**
For the improvement of neurological outcome by reducing the incidence & severity of ischemic deficits in patients with subarachnoid hemorrhage from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition.

**Dosage & Administration**
Initial dose is 60 mg in every four hours interval for 21 consecutive days. Oral therapy should be commence within 96 hours of the subarachnoid hemorrhage.

**Side Effect**
Headache, dizziness, flushing, heartburn, fast heartbeat, slow heartbeat, upset stomach, stomach pain, constipation, depression etc.

**Precaution**
Blood pressure should be carefully monitored during treatment with Nimodipine based on

its known pharmacology & the known effects of calcium channel blockers. The metabolism of Nimodipine is decreased in patients with impaired hepatic function.

**Use in Pregnancy & Lactation**
Large doses of Nimodipine have been shown to cause birth defects in animals. Human studies have not been done. Nimodipine may pass into breast milk but has not been reported to cause problems; caution is advised.

**Preparation**
30 mg Tablet.

# Nomi®

**Active Ingredient**
Zolmitriptan.

**Indication**
Acute treatement of Migraine with or without aura.

**Dosage & Administration**
One tablet as a single dose. Dose may be repeated after 2 hours if symptoms persist.

**Contraindication**
History of coronary artery disease (CAD) or coronary vasospasm. History of stroke, transient ischemic attack, or hemiplegic or basilar migraine.

**Warnings & Precautions**
Should be used cautiously in patients with history of Myocardial Infarction, Prinzmetal Angina, and Arrhythmias etc.

**Drug Interaction**
It is recommended that patients should leave at least 6 hours between taking an ergotamine preparation & starting Zolmitriptan, & vice versa. Concomitant administration of other 5HT1D agonists within 12 hours of Zolmitriptan treatment should be avoided.

**Side effect**
Neck/throat/jaw pain/tightness/pressure, dizziness, paresthesia, asthenia, somnolence, warm/cold sensation, nausea, heaviness sensation, and dry mouth.

**Precaution & Warning**
Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathways.

**Preparation**
2.5 mg Tablet.



# Normo-K™

**Active Ingredient**
Sodium Polystyrene Sulfonate USP

**Indication**
Indicated for the treatment of hyperkalemia. (Hyperkalemia is mainly caused by Acute or Chronic Kidney Disease. Other causes may include Liver failure, Adrenal insufficiency, Use of certain drugs like ARB, ACE inhibitors, Beta blockers or Excessive use of Potassium supplements.).

**Dosage & administration**
Suspension of this drug should be freshly prepared and not to be stored beyond 24 hours.
Adults (including the elderly) Oral Dose: The average daily oral dose for adult is 15 gm to 60 gm (1 Sachet 1-4 times daily).
Children Oral dose: In smaller children and infants correspondingly lower doses should be employed. An appropriate initial dose is 1 gm/kg body weight daily in divided doses in acute hyperkalemia. For maintenance therapy, dosage may be reduced to 0.5 gm/kg body weight daily.

**Contraindicatio**
Sodium Polystyrene Sulfonate is contraindicated in the following conditions: patients with hypokalemia, patients with a history of hypersensitivity to polystyrene sulfonate resins, obstructive bowel disease, neonates with reduced gut motility (postoperatively or drug induced) and oral administration in neonates.

**Use in Pregnancy & Lactation**
Pregnancy Category C. Animal reproduction studies have not been conducted with Sodium Polystyrene Sulfonate. It is also not known whether it can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. It should be given to a pregnant woman only if clearly needed.
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.



**Preparation**
Each box contains 10 Sachets of Normo-KTM. Each Alu-Alu sachet contains Sodium Polystyrene Sulfonate USP 15 gm (Sodium content is approximately 100 mg per gm of the drug).

# Norpill™1

**Active Ingredient**
Levonorgestrel.

**Indication**
Norpill 1 is an emergency contraceptive that can be used to prevent pregnancy following unprotected intercourse or a known or suspected contraceptive failure.

**Dosage & Administration**
One Norpill 1 tablet should be taken orally as soon as possible within 72 hours after unprotected intercourse.

**Contraindication & Precaution**
Levonorgestrel should not be given to pregnant women. Levonorgestrel, like progestin-only contraceptives, does not protect against HIV infection (AIDS) & other sexually transmitted diseases.

**Side Effect**
Nausea/vomiting, abdominal pain, tiredness, dizziness, changes in vaginal bleeding, breast tenderness, diarrhea, or headache may occur. Tell your doctor immediately.

**Drug Interaction**
Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel-containing medication includes: barbiturates, primidone, phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St Johns' Wort), rifampicin, ritonavir, rifabutin & griseofulvin. Levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism.

**Use in Pregnancy & Lactation**
It should not be given to pregnant women & it will not interrupt the pregnancy. Levonorgestrel is secreted into breast milk. The potential exposure of an infant to levonorgestrel can be reduced if the breastfeeding woman takes the tablets immediately after feeding & avoids nursing following each tablet administration.

**Preparation**
1.5 mg Tablet.

**Help Line:** 01708154284

# Norvis®

**Active Ingredient**
Tiemonium Methylsulphate.

**Indication**
Pain in gastrointestinal, biliary, urinary & gynaecological disease such as gastroenteritis, diarrhoea, dysentery, biliary colic, enterocolitis, cholecystytis, colonopathyes, mild cystitis, & spasmodic dysmenorrhoea.

**Dosage & Administration**
Tablet: 2-6 tablets (100-300 mg) daily in divided doses.
Injection: 1 ampoule (5 mg) three times daily, through Intravenous route slowly or Intramuscular route.
Syrup: 3 mg-6mg/body weight/day or 1.5 ml-3 ml, 3 times a day.

**Side Effect**
Very rare.

**Contraindication**
Glucoma or where acute pain of eyeball with vision disturbance, disorder of prostate or urinary bladder.

**Use in Pregnancy & Lactation**
May be used in pregnancy only if it is clearly needed by the assessment of risk benefit ratio. May be used in lactating mother only if it is clearly needed by the assessment of risk benefit ratio.

**Preparation**
50 mg Tablet, 5 mg/2 ml Injection, 10 mg/5 ml syrup.

# Ocubrom™ Eye Drops

**Active Ingredient**
Bromfenac.

**Indication**
Ocubrom™ 0.07% Eye Drops is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

**Dosage & Administration**
Adults: One drop should be applied to the affected eye once daily beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period. Children: Use and dose must be determined by the doctor

**Contraindication & Precaution**
Bromfenac ophthalmic solution is contraindicated in patients with known hypersensitivity to any ingredient in the formulation.

**Side Effect**
The most commonly reported adverse experiences are: abnormal sensation in eye, conjunctival hyperemia, eye irritation (including burning/stinging), eye pain, eye pruritus, eye redness, headache, and iritis.

**Use in Pregnancy & Lactation**
USFDA Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when Bromfenac ophthalmic solution is administered to a nursing woman.

**Use in Pediatric**
Safety and efficacy in pediatric patients below the age of 18 have not been established yet.

**Preparation**
Each LDPE container contains 5 ml of Bromfenac 0.07% sterile solution.

# Oculant™ Eye Drops

**Active Ingredient**
Polyethylene Glycol 400 BP 0.4% & Propylene Glycol BP 0.3%

**Indication**
Oculant Eye Drops is indicated for the temporary relief of burning & irritation due to dryness of the eye.

**Dosage & Administration**
Instill 1 or 2 drops in the affected eye(s) as needed or as directed by the physician.
Children under 6 years of age: ask a doctor.

**Contraindication & Precaution**
Hypersensitivity to any of the components of the medication. This product may temporarily cause blurred vision right after being placed in the eye(s). Never touch tip of container with any surface to avoid contamination & replace cap after each use.

**Side Effect**
Generally well tolerated. It should not be used if allergic condition occurs to any ingredients of the product.

**Use in Pregnancy & Lactation**
Due to the negligible systemic exposure & the lack of pharmacological activity, this medication can be used during pregnancy.
Nursing Mothers: It is not known whether this medication is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is applied to a nursing woman.

**Use in Children**
Safety & efficacy in pediatric patients have not been established.

**Preparation**
Each plastic dropper bottle contains 10 ml of Polyethylene Glycol 400 BP 0.4% & Propylene Glycol BP 0.3% sterile solution.

# Ocof™

**Active Ingredient**
Dextromethorphan, Phenylephrine & Triprolidine.

**Indication**
Symptomatic relief of upper respiratory tract disorders accompanied by non-productive cough
which benefits from the administration of a nasal decongestant, a histamine H1-receptor antagonist and an antitussive combination.

**Dosage & Administration**
Adults & Children over 12 years: 1 teaspoonful 4 times a day.
6-12 years: 1/2 teaspoonful 4 times a day.
A physician's advice should be obtained before administering this combination to children less than 6 years.

**Contraindication**
This combination is contraindicated in patients with a known hypersensitivity to Dextromethorphan, Phenylephrine or Triprolidine as well as in persons under treatment with Monoamine Oxidase Inhibitor within 2 weeks of stopping such treatment.

**Side Effect**
Side effects of Dextromethorphan appears to be rare and may include drowsiness. Prostatic enlargement could have been an important predisposing factor.

**Precaution**
This combination may cause drowsiness. It may impair the patient's ability to drive and also to use machineries. Although there are no objective data, users of this syrup should avoid the concomitant use of alcohol or other centrally acting sedatives. As with other sympathomimetic agents caution should be exercised in patients with hypertension, heart disease, diabetes, hyperthyroidism, elevated intraocular pressure and prostatic enlargement. This combination should not be used for persistent or chronic cough such as occurs with smoking, asthma, or emphysema or where cough is accompanied by excessive secretion unless directed by a physician.

**Use In Pregnancy & Lactation**
There are no specific data on use of this combination during pregnancy & lactation.

**Preparation**
100 ml syrup with a measuring cup.

# Ofran®

**Active Ingredient**
Ondansetron

**Indication**
Ofran is indicated for
- Prevention of nausea & vomiting associated with highly emetogenic cancer chemotherapy
- Prevention of nausea & vomiting associated with radiotherapy
- Prevention of post operative nausea & vomiting

**Dosage & Administration**
*Prevention of chemotherapy induced nausea & vomiting (CINV):*
Adult- The recommended adult oral dosage of Ofran (Ondansetron) is 24 mg given as three 8 mg tablets in highly emetogenic chemotherapy. In case of moderately emetogenic chemotherapy the oral dose is one 8 mg Ofran (Ondansetron) tablet or 10 ml of Ofran (Ondansetron) oral solution given twice daily
Pediatric patients- for pediatric patients 4 through 11 years of age the dosage is one 4mg Ofran tablet or 5ml of Ofran solution should be administered 3 times a day for 1 to 2 days after completion of chemotherapy.
Radiotherapy induced nausea & vomiting:
Adult- the recommended oral dosage is one 8mg Ofran tablet or 10ml of Ofran oral solution

given 3times daily.
Post operative nausea & vomiting (PONV):
Adult- the recommended dosage is 16 mg given as two 8mg Ofran tablets or 20 ml of Ofran oral solution 1hour before induction of anesthesia.
Dosage adjustment for patients with impaired hepatic function-
The total daily dose of 8mg should not be exceeded.

**Contraindication & Precaution**
Ondansetron is contraindicated in patients with known hypersensitivity to the drug. Hypersensitivity reactions have been reported in patients who have exhibited hyper sensitivity to other 5-HT3 receptor antagonists.
Ondansetron is not a drug that stimulates gastric or intestinal peristalsis. It should not be used instead of nasogastric suction. The use of Ondansetron in patients following abdominal surgery or in patients with chemotherapy-induced nausea & vomiting may mask a progressive ileus and/or gastric distension.

**Use in Pregnancy & Lactation**
In pregnancy: Pregnancy category B. So the drug should be used in pregnancy only if clearly needed.
In lactation: Ondansetron excretes in milk of lactating animals. Caution should be exercised when Ondansetron is administered to nursing mother.

**Preparation**
8 mg Tablet, 4 mg/5 ml (50 ml) solution, 8 mg/4ml Injection.



# Olistat™

**Active Ingredient**
Orlistat

**Indication**
Overweight & Obesity management

**Dosage & Administration**
One capsule 3 times daily with each main meal containing fat before, during or within 1 hour of meal.

**Contraindication & Precaution**
Orlistatis contraindicated in: Pregnancy, Patients with chronic malabsorption syndrome, Patients with cholestasis, Patients with known hypersensitivity to Orlistat or to any component of this product. Precautions should be taken during: Concomitant Drug & Vitamin Use: Orlistat & cyclosporine should not be simultaneously coadministered. To reduce the chance of a drug-drug interaction, cyclosporine should be taken at least 3 hours before or after Orlistat in patients taking both drugs. In addition, in those patients whose cyclosporine levels are being measured, more frequent monitoring should be considered. Patients should be strongly encouraged to take a multivitamin supplement that contains fat-soluble vitamins to ensure adequate nutrition because Orlistat has been shown to reduce the absorption of some fat-soluble vitamins & beta-carotene. In addition, the levels of vitamin D & betacarotene may be low in obese patients compared with non-obese subjects. The supplement should be taken once a day at least 2 hours before or after the administration of Orlistat, such as at bedtime. Liver Injury: Patients should be instructed to report any symptoms of hepatic dysfunction (anorexia, pruritus, jaundice, dark urine, light-colored stools, or right upper quadrant pain) while taking Orlistat. When these symptoms occur, Orlistat & other suspect medications should be discontinued immediately & liver function tests & ALT & AST levels obtained. Increases in Urinary Oxalate: Some patients may develop increased levels of urinary oxalate following treatment with Orlistat. Cases of oxalate nephrolithiasis

& oxalate nephropathy with renal failure have been reported. Monitor renal function when prescribing ORLISTAT to patients at risk for renal impairment & use with caution in those with a history of hyperoxaluria or calcium oxalate nephrolithiasis. Cholelithiasis: Substantial weight loss can increase the risk of cholelithiasis. Miscellaneous: Organic causes of obesity (eg, hypothyroidism) should be excluded before prescribing Orlistat. Patients should be advised to adhere to dietary guidelines Gastrointestinal events may increase when Orlistat is taken with a diet high in fat (>30% total daily calories from fat). The daily intake of fat should be distributed over three main meals. If Orlistat is taken with any one meal very high in fat, the possibility of gastrointestinal effects increases.

**Side Effect**
Commonly-observed adverse events associated with the use of Orlistat include oily spotting, flatus with discharge, fecal urgency, fatty/oily stool, oily evacuation, increased defecation, fecal incontinence.

**Drug Interaction**
Cyclosporine: Data from a Orlistat & cyclosporine drug interaction study indicate a reduction in cyclosporine plasma levels when Orlistat was coadministered with cyclosporine. Orlistat & cyclosporine should not be simultaneously coadministered. Cyclosporine should be administered 3 hours after the administration of Orlistat. Fat-soluble Vitamin Supplements & Analogues: Data from a pharmacokinetic interaction study showed that the absorption of beta-carotene supplement is reduced when concomitantly administered with Orlistat. Orlistat inhibited absorption of a vitamin E acetate supplement. The effect of Orlistat on the absorption of supplemental vitamin D, vitamin A, & nutritionally-derived vitamin K is not known at this time. Levothyroxine: Hypothyroidism has been reported in patients treated concomitantly with Orlistat & levothyroxine postmarketing. Patients treated concomitantly with Orlistat & levothyroxine should be monitored for changes in thyroid function. Administer levothyroxine & Orlistat at least 4 hours apart. Warfarin: Vitamin K absorption may be decreased with Orlistat. Patients on chronic stable doses of warfarin who are prescribed Orlistat should be monitored closely for changes in coagulation parameters.

**Use in Pregnancy & Lactation**
Pregnancy Category X. Orlistat is contraindicated during pregnancy, because weight loss offers no potential benefit to a pregnant woman & may result in fetal harm.It is not known if Orlistat is present in human milk. Caution should be exercised when Orlistat is administered to a nursing woman.

**Use in Children**
Safety & effectiveness in pediatric patients below the age of 12 have not been established.

**Preparation**
60 mg & 120 mg Capsule.



# Olmecar™

**Active Ingredient**
Olmesartan Medoxomil.

**Indication**
For the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

**Dosage & Administration**
Dosage must be individualized. The usual recommended starting dose of Olmesartan is 20 mg once daily when used as monotherapy in patients who are not volume-contracted. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of Olmesartan may be increased to 40 mg.
Doses above 40 mg do not appear to have greater effect. Twice-daily dosing offers no advantage over the same total dose given once daily.

**Contraindication & Precaution**
Olmesartan is contraindicated in patients who are hypersensitive to any component of this product.

**Side Effect**
Treatment with Olmesartan was well tolerated, with an incidence of adverse events similar to placebo. The following adverse events occurred in placebo controlled clinical trials at an incidence of more than 1% of patients treated with Olmesartan, but also occurred at about the same or greater incidence in patients receiving placebo: back pain, bronchitis, creatine phosphokinase increased, diarrhea, headache, hematuria, hyperglycemia, hypertriglyceridemia, influenza like symptoms, pharyngitis, rhinitis & sinusitis.

**Use in Pregnancy & Lactation**
Pregnancy Category: D.
*Nursing Mothers:* It is not known whether Olmesartan is excreted in human milk, but Olmesartan is secreted at low concentration in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
Use in Children: Safety & Effectiveness in pediatric patients have not been established.

**Preparation**
20 mg & 40 mg Tablet.



# Olmecar™ Plus

**Active Ingredient**
Olmesartan Medoxomil & Hydrochlorothiazide.

**Indication**
Indicated for the treatment of hypertension. This fixed dose combination is not indicated for initial therapy.

**Dosage & Administration**
The dose of Olmecar Plus tablet is one tablet once daily. Olmecar Plus tablet may be administered with other antihypertensive agents. A patient whose blood pressure is inadequately controlled by Olmesartan or Hydrochlorothiazide alone may be switched to once daily Olmecar Plus tablet. Dosing should be individualized. Depending on the blood pressure response, the dose may be titrated at intervals of 2-4 weeks. If blood pressure is not controlled by Olmesartan alone, Hydrochlorothiazide may be added starting with a dose of 12.5 mg & later titrated to 25 mg once daily.
If a patient is taking Hydrochlorothiazide, Olmesartan may be added starting with a dose of 20 mg once daily & titrated to 40 mg for inadequate blood pressure control. If large doses of Hydrochlorothiazide have been used as monotherapy & volume depletion or hyponatremia is present, caution should be used when adding Olmesartan or switching to Olmecar Plus tablet, as marked decreases in blood pressure may occur. Consideration should be given to reducing the dose of Hydrochlorothiazide to 12.5 mg before adding Olmesartan. The antihypertensive effect of Olmecar Plus tablet is related to the dose of both components over the range of 10 mg/12.5 mg to 40 mg/25 mg.

**Contraindication & Precaution**
This combination tablet is contraindicated in patients who are hypersensitive to any component of this product. Because of the Hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

**Side Effect**
Some common side effects include: headache, urinary tract infection, chest pain, back pain, peripheral edema, vertigo, abdominal pain, dyspepsia, gastroenteritis, diarrhoea, SGOT increased, GGT increased, SGPT increased, hyperlipemia, creatine phosphokinase increased, hyperglycemia, arthritis, arthralgia, myalgia, coughing, rash etc.

**Use in Pregnancy & Lactation**
*Pregnancy:* Pregnancy Category D. This combination drug should not be used during pregnancy.
*Nursing Mothers:* It is not known whether Olmesartan is excreted in human milk, but Olmesartan is secreted at low concentration in the milk of lactating rats. Thiazides appear in human milk. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

**Use in Children**
Safety & Effectiveness in pediatric patients have not been established.

**Preparation**
Olmesartan Medoxomil 20 mg & Hydrochlorothiazide 12.5 mg.

# Oni™

**Active Ingredient**
Betamethasone Dipropionate & Clotrimazole.

**Indication**
Inflammatory dermal infections like tinea pedis, tinea cruris, tinea corporis etc.

**Dosage & Administration**
Twice a day for 2-4 weeks.

**Contraindication & Precaution**
Hypersensitivity, facial rosacea, acne vulgaris, perioral dermatits, perianal & genital pruritus, napkin eruptions & bacterial or viral infections. systemic absorption produces HPA axis suppression, Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their large skin surface to body mass ratios.

**Side Effect**
Paresthesia, rash, edema & secondary infection, burning & dry skin.

**Use in Pregnancy & Lactation**
The cream should only be used in pregnancy, if the benefit justifies the potential risk to the fetus caution should be exercised when treating nursing mothers.

**Use in Children**
Not recommended under 12 years.

**Preparation**
10 gm Cream.



# Orostar™

**Active Ingredient**
Menthol + Thymol + Eucalyptol + Methyl Salicylate

**Indication**
Dental Plaque, Gingivitis & Bad breath

**Dosage & Administration**
Rinse with 20 ml Orostar Antiseptic Mouthwash

for 30 seconds, twice daily (morning & evening). Then rinse with water. Do not swallow.

**Contraindication & Precaution**
If more than used for rinsing is accidentally swallowed, please consult with a doctor.

**Use in Children**
Not indicated below 12 years of age.

**Preparation**
*Orostar Cool Mint:* 120 ml PET container.

**Drug Interaction**
No drug interaction has been reported.

**Use in Pregnancy & Lactation**
It is safe to use during pregnancy.

**Use in Children**
According to the consultancy of dentist or physician.

**Preparation**
Orostar™ Plus 250 ml: Each PET bottle contains 250 ml mouthwash with a measuring cup.
Orostar™ Plus 120 ml: Each PET bottle contains 120 ml mouthwash with a measuring cup.

O

# Orostar™ Plus

**Active Ingredient**
Eucalyptol+Menthol+Methyl Salicylate+Thymol+Sodium Fluoride

**Indication**
Dental cavities/Tooth decay
Bad breath , Dental plaque , Gingivitis

**Dosage & Administration**
Adults & children of 6 years & older should use once a day after brushing teeth with toothpaste by vigorously swishing 10ml ( as indicated inside cap) or rinse between teeth for 1 minute & then spit out. Do not swallow. Children under 6 years of age should use according to the consultancy of dentist or physician.

**Precaution**
Should not eat or drink for 30 minutes after rinsing. Children under 12 years of age should be instructed in good rinsing habits to minimize swallowing. Children have to be supervised in rinsing as necessary until they are capable of using without supervision. If more than amount used for rinsing is accidentally swallowed, physicians help should be taken immediately.

# Osmolax™

**Active Ingredient**
Lactulose.

**Indication**
Constipation, hepatic encephalopathy.

**Dosage & Administration**
*Constipation:* Initially Osmolax solution may be given twice daily. In due course the dose should be adjusted according to the needs of the individual, but the following serves as a guide line:-
Starting dose:
Adults: (including the elderly) - 15 ml twice daily.
Children: 5 to 10 years - 10 ml twice daily.
Children under 5 years - 5 ml twice daily.
Children under 1 year - 2.5 ml twice daily.
Osmolax solution may, if necessary, be taken with water, fruit juice etc.

*Hepatic encephalopathy:* Adults (including the elderly): Initially 30-50 ml three times a day. Subsequently adjust the dose to produce two

or three soft stools each day.
Children: No dosage recommended for this indication.
Because of Lactulose's physiological mode of action it may take up to 48 hours before effects are obtained. However, clinical experience has shown that this medicament does exhibit a 'carry-over' Effect, which may enable the patient to reduce the dose gradually over a period of time. A maintenance dose of 15 ml per day provides only 14 kilocalories & is therefore, unlikely to adversely affect diabetic patients.

**Contraindication & Precaution**
Galactosaemia. gastro-intestinal obstruction, lactose intolerance.

**Side Effect**
Meteorism & increased flatulence, diarrhoea.

**Use in Pregnancy**
If laxative therapy is needed in pregnancy, use of this drug is acceptable.

**Preparation**
3.4 gm/5 ml Solution.

# Ostel™-D

**Active Ingredient**
Sodium Alendronate + Vitamin $D_3$ (Colecalciferol)

**Indication**
1.Treatment of Osteoporosis in Postmenopausal Women: For the treatment of osteoporosis Ostel-D increases bone mass & reduce the incidence of fractures, including those of the hip & spine. 2. Treatment to Increase Bone Mass in Men with Osteoporosis

**Dosage & Administration**
*Treatment of osteoporosis in post-menopausal women:* Ostel-D 70/2800 tablet once weekly or Ostel-D 10/400 tablet once daily.
*Treatment to increase bone mass in men with osteoporosis:* Ostel-D 70/2800 tablet once weekly or Ostel-D 10/400 tablet once daily.
To permit adequate absorption, Ostel-D must be taken at least 30 minutes before the first food, beverage or medication of the day with plain water only. Other beverages (including mineral water), food & some medications are likely to reduce the absorption of Alendronate. To facilitate delivery to the stomach & thus to reduce the potential for esophageal irritation, Ostel-D tablet should only be swallowed upon rising for the day with a full glass of water. Patients should not lie down for at least 30 minutes after taking Alendronate until after their first food of the day. Patients should not chew or suck on the tablet Ostel-D should not be taken at bed time.

**Contraindication & Precaution**
- Abnormalities of the esophagus which delay esophageal emptying, such as stricture or achalasia
- Inability to stand or sit upright for at least 30 minutes
- Hypersensitivity to any component of this product
- Hypocalcaemia

Hypocalcaemia & other disturbances of mineral metabolism should be corrected before initiation of therapy.
Alendronate can cause local irritation of the upper gastro-intestinal mucosa. Caution should be used when Alendronate is given to patients with active upper gastrointestinal problems such as dysphagia, esophageal disease, gastritis, duodenitis or ulcers. Patients should stop taking medicine & consult their physician if they develop esophageal diseases. No dosage adjustment is necessary for the elderly or for patients with mild-to-moderate renal insufficiency (creatinine clearance 35 to 60 ml/min). Ostel-D is not recommended for patients with more severe renal insufficiency (creatinine clearance < 35 ml/min).

**Side Effect**
Usually mild & generally do not require discontinuation of therapy. Side effects include esophageal reactions, abdominal pain & distension, diarrhoea or constipation, flatulence, musculoskeletal pain, headache, rash, erythema & transient decreases in serum calcium & phosphate.

**Use in Pregnancy & Lactation**
Alendronate Sodium is pregnancy category C. Overdoses of vitamin-D have shown teratogenic effects in pregnant animals. Ostel-D should be used during pregnancy only if the potential benefit justifies the potential risk to the mother & fetus. Colecalciferol & some of its active metabolites pass into breast milk. It is not known whether alendronate is excreted in human milk. Caution should be exercised when Ostel-D is administered to lactating women.

**Preparation**
70/2800 Tablet.

O

# Oxapro®

**Active Ingredient**
Escitalopram.

**Indication**
Major Depressive Disorder (MDD) and Generalized Anxiety Disorder (GAD).

**Dosage & Administration**
Adults & Adolescents (12-17 yr.): 10 mg once daily.

**Contraindication**
Known hypersensitivity to Escitalopram or Citalopram. Concomitant use in patients taking Monoamine Oxidase Inhibitors or Pimozide is contraindicated.

**Warnings & Precautions**
Clinical worsening, suicidality and unusual change in behavior should be monitored during the initial few months of therapy or at times of dose changes. Escitalopram should be prescribed with care in patients with a history of mania and seizure disorder.

**Side Effect**
Insomnia, ejaculation disorder (primarily ejaculatory delay), nausea, increased sweating, fatigue & somnolence, decreased libido etc.

**Use in Pregnancy & Lactation**
Pregnancy Category: C. Use only if the potential benefit justifies the potential risk to the fetus. Escitalopram is excreted in human breast milk. So, caution should be exercised when administered to a nursing woman.

**Preparation**
5 mg & 10 mg Tablet.

# Oxat® 20

**Active Ingredient**
Paroxetine.

**Indication**
Major Depressive Disorder, Obsessive Compulsive Disorder, Panic Disorder, Social Anxiety Disorder, Generalized Anxiety Disorder, Post-traumatic Stress Disorder, premature ejaculation.

**Dosage & Administration**
Recommended initial dosage is 20 mg/day.

**Contraindication**
Known hypersensitivity to Paroxetine. Concomitant use with Monoamine Oxidase Inhibitors, Thioridazine, Pimozide is contraindicated.

**Warnings & Precautions**
Clinical worsening, suicidality and unusual change in behavior should be monitored during the initial few months of therapy or at times of dose changes. Paroxetine should be prescribed with care in patients with a history of mania and seizure disorder.

**Drug Interactions**
Serotonergic Drugs, Drugs Metabolized by Cytochrome P450, Tamoxifen, Phenobarbital etc.

**Side Effect**
Asthenia, sweating, nausea, decreased appetite, somnolence, dizziness, insomnia, tremor, nervousness, ejaculatory disturbance & other male genital disorders, nausea, dry mouth, constipation, dizziness, somnolence, impotence, female genital disorders.

**Use in Pregnancy & Lactation**
TPregnancy Category: D. Paroxetine is excreted in human breast milk. So, caution should be exercised when administered to a nursing woman.

**Preparation**
20 mg Tablet.

Epidermophyton floccosum. Oxifun™ Lotion and Cream are also indicated for the topical treatment of Tinea (pityriasis) versicolor due to Malassezia furfur.

**Dosage & Administration**
Oxifun™ Lotion or Cream should be applied to affected and immediate surrounding areas once to twice daily in patients with Tinea pedis, Tinea corporis, or Tinea cruris. Oxifun™ Cream should be applied once daily in the treatment of Tinea (pityriasis) versicolor. Tinea corporis, Tinea cruris & Tinea (pityriasis) versicolor should be treated for 2 weeks and Tinea pedis for 1 month to reduce the possibility of recurrence.

**Contraindication & Precaution**
Oxiconazole Lotion and Cream are contraindicated in individuals who have shown previous hypersensitivity to Oxiconazole.

**Side Effect**
Pruritus, burning, irritation, allergic contact dermatitis, folliculitis, erythema, papules, fissure, maceration, rash, stinging and nodules.

**Use in Pregnancy & Lactation**
Pregnancy category B.
As Oxiconazole Nitrate is excreted in human milk so caution should be exercised when the drug is administered to a nursing woman

**Preparation**
30 ml lotion & 10 gm cream.

# Oxifun®

**Active Ingredient**
Oxiconazole 1%

**Indication**
Oxifun™ Lotion and Cream are indicated for the topical treatment of the following topical infections: Tinea pedis, Tinea cruris, Tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes or,

# Oxifyl® CR

**Active Ingredient**
Pentoxifylline.

**Indication**
Treatment of peripheral vascular disease evident as intermittent claudication, venous leg ulcers.

**Dosage & Administration**
One tablet two to three times a day with meals for at least 8 weeks.

**Contraindication & Precaution**
Recent cerebral and/or retinal hemorrhage or in patients who have previously exhibited intolerance to this product or methylxanthines such as caffeine, theophylline, & theobromine. Patients on warfarin should have frequent monitoring of prothrombin times, while patients with other risk factors complicated by hemorrhage (e.g., recent surgery, peptic ulceration, cerebral and/or retinal bleeding) should have periodic examinations for bleeding including, hematocrit and/or hemoglobin.



**Side Effect**
Dyspnea, edema, hypotension, anorexia, cholecystitis, constipation, dry mouth/thirst, anxiety, confusion, depression, seizures, epistaxis, flu-like symptoms, laryngitis, nasal congestion, brittle fingernails, pruritus, rash, urticaria, angioedema, blurred vision, conjunctivitis, earache, scotoma, bad taste, excessive salivation, leukopenia, malaise, sore throat/swollen neck glands, weight change.

**Drug Interaction**
Warfarin, Theophylline.

**Use in Pregnancy & Lactation**
Used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the potential for tumorigenicity shown for Pentoxifylline in rats, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

**Preparation**
400 mg CR (Controlled Release) Tablet.

# Paloset™

**Active Ingredient**
Palonosetron

**Indication**
Chemotherapy Induced Nausea & Vomiting: Moderately emetogenic cancer chemotherapy– prevention of acute & delayed nausea & vomiting associated with initial & repeat courses. Highly emetogenic cancer chemotherapy– prevention of acute nausea & vomiting associated with initial & repeat courses.
Postoperative Nausea & Vomiting: Prevention of postoperative nausea & vomiting (PONV) for up to 24 hours following surgery.

**Dosage & Administration**
Chemotherapy Induced Nausea & Vomiting. *Adults:* A single 0.25 mg I.V. dose administered over 30 seconds approximately 30 minutes before the start of chemotherapy. Children (1 Month – 17 yrs) : A single 20 micrograms/kg I.V. dose administered over 15 minutes approximately 30 minutes before the start of chemotherapy. Postoperative Nausea & Vomiting: *Adults:* A single 0.075 mg I.V. dose administered over 10 seconds immediately before the inductionof anesthesia. *Children (1 Month – 17 yrs):* Not recommended.

**Contraindication & Precaution**
Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components. Precaution: Hypersensitivity reactions, including anaphylaxis, have been reported with or without known. Hypersensitivity to other selective 5-$HT_3$ receptor antagonists.

**Side Effect**
The most common side effects of Palonosetron in chemotherapy-induced nausea & vomiting are headache & constipation. The most common side effects of Palonosetron in postoperative nausea & vomiting are QT prolongation, bradycardia, headache, & constipation.

**Drug Interaction**
No potential or clinically significant drug interaction with Palonosetron was found.

**Use in pregnancy & lactation**
Pregnancy Category-B.
There are no adequate & well-controlled studies in pregnant women. Palonosetron should be used during pregnancy only if clearly needed. It is not known whether Palonosetron is excreted in human milk.

**Use in Children**
Can be used in children from 1 month.

**Preparation**
0.075 mg IV Injection & 0.5 mg Tablet.

# Penrif®

**Active Ingredient**
Methyl salicylate (Oil of Wintergreen) & Menthol.

**Indication**
Joint pain & inflammation, muscle pain, backache, minor arthritis.

**Dosage & Administration**
It is applied to affected areas not more than 3 to 4 times daily.

**Warnings**
For external use only. Do not use with a heating pad. Do not swallow. Do not bandage tightly. Keep away from eyes, mucous membranes, broken or irritated skin. If skin redness or excessive irritation develops, pain lasts for more than 10 days, or with arthritis-like conditions in children under 12, do not use & call a physician.

**Preparation**
Methyl salicylate (Oil of Wintergreen) 30% & Menthol 8% Cream.

# Pentadol™

**Active Ingredient**
Tapentadol, HCl.

**Indication**
Pentadol tablet is indicated for the relief of moderate to severe acute pain in patients 18 years of age or older.

**Dosage & Administration**
The dose is 50 mg, 75 mg, or 100 mg every 4 to 6 hours depending upon pain intensity.
On the first day of dosing, the second dose may be administered as soon as one hour after the first dose, if adequate pain relief is not attained with the first dose. Subsequent dosing is 50 mg, 75 mg, or 100 mg every 4 to 6 hours & should be adjusted to maintain adequate analgesia with acceptable tolerability.
Daily doses greater than 700 mg on the first day of therapy & 600 mg on subsequent days have not been studied & are not recommended.
*Use in renal disease*
In patients with severe renal impairment, the safety & Effectiveness of Tapentadol has not been established.
*Use in hepatic disease*
Tapentadol should be used with caution in patients with moderate hepatic impairment. Tapentadol has not been studied in patients with severe hepatic impairment, therefore, use of Tapentadol is not recommended in this population

**Contraindication & Precaution**
This drug is contraindicated in patients with impaired Pulmonary Function, It is also contraindicated in patients with acute or severe bronchial asthma or hypercapnia in unmonitored settings or the absence of resuscitative equipment. This drug is contraindicated in any patient who has or is suspected of having paralytic ileus.
Tapentadol should be administered with caution to patients with conditions accompanied by hypoxia, hypercapnia or respiratory problems such as: asthma, chronic obstructive pulmonary disease etc. In case of patient with sleep apnea syndrome, myxedema,

kyphoscoliosis, central nervous system (CNS) depression should have to be cautious prior administration of Tapentadol. Alternative non-mu-opioid agonist analgesics should be considered & Tapentadol should be employed only under careful medical supervision at the lowest effective dose in such patients.

**Side Effect**
The following treatment-emergent adverse events may happen:
Increase/decrease heart rate, visual disturbance, abdominal discomfort, impaired gastric emptying, irritability, edema, drug withdrawal syndrome, hypersensitivity, involuntary muscle contractions, sensation of heaviness, hypoesthesia, paresthesia, disturbance in attention, sedation, dysarthria, memory impairment, ataxia, presyncope, syncope, coordination abnormal, seizure, urticaria, decreased blood pressure etc.

P

**Drug Interaction**
Patients receiving other mu-opioid agonist analgesics, general anesthetics, phenothiazines, other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) concomitantly with Tapentadol may exhibit additive CNS depression.

**Use in Pregnancy & Lactation**
Pregnancy Category C. There are no adequate & well-controlled studies in pregnant women. This combination preparation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Neonates whose mothers have been taking Tapentadol should be monitored for respiratory depression.

**Preparation**
50 mg, 75 mg & 100 mg Tablet.

# Penvik®

**Active Ingredient**
Phenoxymethyl Penicillin.

**Indication**
Streptococcal infections, scarlet fever, mild erysipelas, bacterial endocarditis, lobar pneumonia.

**Dosage & Administration**
250 to 500 mg every 6 hourly.

**Contraindication & Precaution**
Known to be hypersensitive, severe acute infections.

**Side Effect**
Diarrhoea, abdominal discomfort, nausea, vomiting, spontaneous petechial hemorrhages, serum sickness.

**Drug Interaction**
Zinc oxide, Magnesium oxide, Magnesium carbonate, Calamine etc. Aspirin, sulphamethoxypyrida- zinc & sulphaethidole, aminoglycosides.

**Use in Pregnancy & Lactation**
There is no contraindication to the use of penicillin in pregnancy.

**Preparation**
250 mg Tablet, 500 mg DS Tablet, 100 ml (250 mg/5 ml) Forte Powder for Suspension.

# Perkidopa™

**Active Ingredient**
Levodopa and Carbidopa

**Indication**
Perkidopa™ is indicated in the treatment of Parkinson's disease, post-encephalitic Parkinsonism, and symptomatic Parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

**Dosage & administration**
Usual Initial Dosage: The optimum daily dosage of Perkidopa™ must be determined by careful titration in each patient. If Perkidopa™110 is used, dosage may be initiated with one tablet three or four times a day. Dosage may be increased by one tablet every day or every other day until a total of eight tablets (2 tablets q.i.d.) is reached.
Maintenance dose: Therapy should be individualized and adjusted according to the desired therapeutic response. When more levodopa is required, Perkidopa™ 275 should be substituted for Perkidopa™110. If necessary, the dosage of Perkidopa™ 275 may be increased by one-half or one tablet every day or every other day to a maximum of eight tablets a day. Experience with total daily dosages of carbidopa greater than 200 mg is limited.

**Contraindication**
Nonselective monoamine oxidase (MAO) inhibitors are contraindicated for use with Levodopa and carbidopa. These inhibitors must be discontinued at least two weeks prior to initiating therapy with Levodopa and carbidopa. Levodopa and carbidopa is contraindicated in patients with known hypersensitivity to any component of this drug, and in patients with narrow-angle glaucoma.

**Precaution**
Levodopa alone, as well as combination, is associated with dyskinesias. The occurrence of dyskinesias may require dosage reduction. It should be administered cautiously to patients with severe cardiovascular or pulmonary disease, bronchial asthma, renal, hepatic or endocrine disease.

**Adverse reaction**
The most common adverse reactions reported with Levodopa and Carbidopa have included dyskinesias, such as choreiform, dystonic, and other involuntary movements, and nausea.

**Use in special population**
Pregnancy: Pregnancy Category: C.
Nursing mother: Levodopa has been detected in human milk. Caution should be exercised when administered to a nursing woman.
Pediatric Use: Safety and effectiveness in pediatric patients have not been established. Use of the drug in patients below the age of 18 is not recommended.

**Preparation**
Perkidopa™ 110 Tablet: Each box contains 30 tablets in blister pack. Perkidopa™ 275 Tablet: Each box contains 30 tablets in blister pack.



# Perkinil®

**Active Ingredient**
Procyclidine, HCL.

**Indication**
• Parkinsonism of arteriosclerotic, idiopathic & post-encephalitic origin,

•Control of neuroleptic drug-induced extrapyramidal symptoms, such as pseudo-parkinsonism, akathisia & acute dystonic reactions.

**Dosage & Administration**
2.5 mg 3 times a day, then 5 mg 3 times a day & occasionally 5 mg at night.

**Contraindication & Precaution**
Caution in children & geriatric patients. It is advisable to be cautious in giving Perkinil to patients with diarrhea & cardiovascular disease, glaucoma, urinary retention, hepatic or renal impairment.

**Side Effect**
Dryness of the mouth , Mydriasis, blurred vision & adverse G.I. effects (nausea, vomiting, epigastric distress, constipation), an allergic reaction (rash) or muscular weakness, vertigo, confusion & hallucination.

**Preparation**
5 mg Tablet & 10 mg/2 ml Injection.



# Perkinor™

**Active Ingredient**
Trihexyphenidyl Hydrochloride.

**Indication & Uses**
PerkinorTM (Trihexyphenidyl Hydrochloride) is indicated as an adjunct in the treatment of all forms of Parkinsonism (post encephalitic, arteriosclerotic and idiopathic). It is often useful as adjuvant therapy when treating these forms of Parkinsonism with Levodopa. Additionally, it is indicated for the control of extrapyramidal disorders caused by some drugs such as Dibenzoxazepines, Phenothiazine, Thioxanthenes and Butyrophenones.
Dosage & Administration:
Dosage should be individualized. The initial dose should be low and then increased gradually. Should be taken with food. Total daily intake of PerkinorTM tablets is tolerated best in divided doses.
Idiopathic Parkinsonism: As initial therapy for Parkinsonism, 1 mg of Trihexyphenidyl hydrochloride in tablet may be administered the first day. The dose may then be increased by 2 mg increments at intervals of three to five days. Until a total of 6 to 10 mg is given daily.
Drug induced Parkinsonism: Initial therapy 1 mg. The total daily dosage usually ranges between 5 and 15mg. Subsequent doses may be progressively increased until satisfactory control is achieved.
Concomitant use with Levodopa: When Trihexyphenidyl is used concomitantly with levodopa; the usual dose of each may need to be reduced. Careful adjustment is necessary, depending on the side effects and degree of symptom control. 3 to 6 mg daily in divided doses is usually adequate.
Concomitant use with other Parasympathetic Inhibitors: The total daily intake of Trihexyphenidyl Hydrochloride tablets is tolerated best if divided into 3 doses and taken at mealtimes. High doses (1O mg daily) may be divided into 4 parts, with 3 doses administered at mealtimes and the fourth at bedtime.
Post encephalitic Parkinsonism: usually 12 to 15 mg.
Contraindication: Trihexyphenidyl Hydrochloride is contraindicated in patients with hypersensitivity to Trihexyphenidyl Hydrochloride or to any of the tablet & syrup ingredients. Trihexyphenidyl Hydrochloride is also contraindicated in patients with narrow angle glaucoma.
Adverse Reaction:
Mild nausea or nervousness, blurred vision, dryness of the mouth dizziness, will be experienced by 30 to 50 percent of all patients. Such reactions tend to become less pronounced, and even to disappear, as treatment continues. Potential side effects are confusion, memory impairment, cognitive dysfunctions, constipation, weakness, vomiting and headache.

**Drug Interactions**
Cannabinoids, Barbiturates, Opiates and Alcohol may have additive effects with Trihexyphenidyl Hydrochloride and thus an abuse potential exists. Concurrent use

of alcohol or other CNS depressants with Trihexyphenidyl Hydrochloride may cause increased sedative effects.

**Pregnancy & Lactation**
Trihexyphenidyl Hydrochloride should be given to a pregnant woman only if clearly needed.
US-FDA pregnancy category: C. Caution should be exercised when administered to a nursing woman.

**Preparation**
2 mg tablet, 5 mg tablet & 5mg/5ml syrup.

# Perkirol™

**Active Ingredient**
Ropinirole.

**Indication**
Parkinson's Disease, Restless Legs Syndrome.

**Dosage & Administration**
Parkinson's Disease: Starting dose is 0.25 mg 3 times daily. After week 4, if necessary, daily dosage may be increased by 1.5 mg/day on a weekly basis up to a dose of 9 mg/day, & then by up to 3 mg/day weekly to a total dose of 24 mg/day. Restless Legs Syndrome: Starting dosage is 0.25 mg once daily, 1 to 3 hours before bedtime. After 2 days, the dosage can be increased to 0.5 mg once daily & to 1 mg once daily at the end of the first week of dosing.

**Contraindication & Precaution**
Hypersensitivity to Ropinirole, patients with severe cardiovascular disease should be treated with caution. As with other dopaminergic drugs, caution should be exercised when these compounds are given concomitantly with Ropinirole because of the unknown potential for the occurrence of hypotension, bradycardias or other arrhythmias. Patients should be informed & advised to exercise caution while driving or operating machines during treatment with Ropinirole.

**Side Effect**
Nausea, somnolence, leg edema, abdominal pain, vomiting, syncope, decreases in systolic blood pressure, symptomatic hypotension, bradycardia, excessive daytime somnolence & sudden sleep onset episodes.

**Drug Interaction**
Neuroleptics & other centrally acting dopamine antagonists, such as sulpiride or metoclopramide, theophylline, ciprofloxacin, fluvoxamine & cimetidine, oestrogens.

**Use in Pregnancy & Lactation**
Ropinirole should not be used during pregnancy & in nursing mothers.

**Preparation**
0.25 mg & 2 mg Tablet.



# Pevitin®

**Active Ingredient**
Econazole Nitrate & Triamcinolone Acetonide.

**Indication**
Inflammatory dermatomycoses & inflammatory skin conditions which can be complicated by or threatened by bacterial or fungal skin infection.

**Dosage & Administration**
Apply by gently rubbing onto the skin twice daily for 14 days.

**Contraindication & Precaution**
Tubercular or luetic skin infections or in viral diseases (e.g. herpes, vaccinia, varicella). Hypersensitivity to imidazoles or

corticosteroids, adrenal suppression. Long term therapy with corticosteroids can cause skin lesions such as atrophy, telangiectasia & striae.

**Side Effect**
Local mild irritation & Hypersensitivity.

**Drug Interaction**
No information is available.

**Preparation**
10 gm cream.

P

# Phylopen™

**Active Ingredient**
Flucloxacillin

**Indication**
Boils, abscesses, carbuncles, furunculosis, cellulitis; infected skin conditions e.g. ulcer, eczema & acne; infected wounds, infected burns, protection for skin grafts, otitis media & externa, impetigo, pneumonia, lung abscess, empyema, sinusitis, pharyngitis, tonsillitis, & quinsy, osteomyelitis, enteritis, endocarditis, urinary tract infections, meningitis, septicaemia, prophylactic agent during major surgical procedures for example, cardiothoracic & orthopaedic surgery.

**Dosage & Administration**
Adult : 500 mg six hourly, 2-10 years : half of the adult dose, Under 2 years : quarter of the adult dose.

**Contraindication**
Penicillin hypersensitivity.

**Side Effect**
Uncommon nausea, diarrhoea, skin rashes.

**Drug Interaction**
Gentamicin sulphate, Streptomycin sulphate, vitamin mixtures, lipids, blood products & protein hydrolysates or other proteinaceous fluids.

**Use in Pregnancy & Lactation**
The use of Flucloxacillin in pregnancy should be reserved for cases considered essential by the clinician.

**Preparation**
250 mg Capsule, 500 mg DS Capsule, 125 mg/5 ml Powder for Suspension, 250 mg/5 ml Forte Powder for Suspension, 500 mg injection.

# Prazolok™

**Active Ingredient**
Prazosin

**Indication**
Hypertension, Raynaud's phenomenon and Raynaud's disease, Congestive heart failure & symptomatic treatment of urinary obstruction due to BPH.

**Dosage & Administration**
Hypertension: 0.5 mg – 20 mg daily. Recommended starting dose is 0.5 mg (in the evening), twice or thrice daily for 3 to 7 days. This dose should be increased to 1 mg twice or three times daily for a further 3 to 7 days.
Maximum dose: 20 mg in divided doses.
Congestive heart failure: The recommended starting dose is 0.5 mg two, three or four times daily, increasing to 4 mg in divided doses.
Usual daily maintenance dosage: 4 mg to 20 mg in divided doses
Raynaud's disease: The recommended starting dose is 0.5 mg twice daily given for a period of 3 to 7 days and should be adjusted according

to the patient's clinical response. Usual maintenance dosage is 1 mg or 2 mg twice daily.
Benign prostatic hyperplasia: The recommended dose is 0.5 mg twice daily for a period of 3 to 7 days, with the initial dose administered in the evening. The usual maintenance dosage is 2 mg twice daily.
Patients with moderate to severe grades of renal impairment: It is recommended that therapy be initiated at 0.5 mg daily and that dosage increases be instituted cautiously.
Patients with hepatic dysfunction: it is recommended that therapy should be initiated at 0.5 mg daily and that dosage should be increased cautiously.
Use in the elderly: Since the elderly may be more susceptible to hypotension, therapy should be initiated with the lowest possible dose.

**Contraindication**
Prazosin is contraindicated in patients with known sensitivity to Prazosin & other quinazolines or any of the excipients.

**Side Effect**
Allergic reaction, depression, nervousness, insomnia, Hallucinations, dizziness, drowsiness, headache, faintness, syncope, paraesthesia, worsening of pre-existing narcolepsy, blurred vision, eye pain, reddened sclera, vertigo, tinnitus, palpitations etc.

**Precaution**
In patients with benign prostatic hyperplasia: Prazosin is not recommended for patients with a history of micturition syncope. It should not normally be administered to patients already receiving another alpha-1-antagonist.
In patients with congestive heart failure: Prazosin is not recommended in the treatment of congestive cardiac failure due to mechanical obstruction such as aortic valve stenosis, mitral valve stenosis, pulmonary embolism and restrictive pericardial disease.
In patients with hypertension: Postural hypotension evidenced by dizziness and weakness, or rarely loss of consciousness, has been reported, particularly with the commencement of therapy.

**Pregnancy & Lactation**
Pregnancy category-C

**Drug Interaction**
•Use with phosphodiesterase-5 inhibitors (PDE-5 Inhibitors): Concomitant use of PDE-5 inhibitors (e.g. Sildenafil, Tadalafil, Vardenafil) and Prazosin may lead to symptomatic hypotension in some patients.
•Adding Prazosin to beta-adrenergic antagonist or calcium antagonist therapy may produce a substantial reduction in blood pressure.

**Preparation**
Prazolok™ 1: Each box contains 30 tablets in blister pack.
Prazolok™ 2: Each box contains 30 tablets in blister pack.



# Prolert®

**Active Ingredient**
Fluoxetine.

**Indication**
Depressive illness, Bulimia nervosa, Obsessive compulsive disorders, Pre-menstrual syndrome.

**Dosage & Administration**

| Indication | Adult | Pediatric |
|---|---|---|
| (7-18 years) | | |
| MDD | 20 mg/day | 10-20 mg/day |
| OCD | 20 mg/day | 10 mg/day |
| Bulimia Nervosa | 60mg/day | |
| Panic Disorder | 10 mg/day | |

**Contraindication**
Concomitant use with Monoamine Oxidase Inhibitors, Thioridazine, Pimozide is

contraindicated.

**Side Effect**
Abnormal dreams, abnormal ejaculation, anorexia, anxiety, asthenia, diarrhea, dry mouth, insomnia, nausea, nervousness, rash, somnolence, sweating etc.

**Drug Interaction**
Serotonergic Drugs, Drugs Metabolized by CYP2D6, Drugs that Interfere with Hemostasis (e.g. NSAIDs, Aspirin, Warfarin), . Antipsychotics, Anticonvulsants, etc.

**Use in Pregnancy & Lactation**
Pregnancy Category: C. Use only if the potential benefit justifies the potential risk to the fetus. Fluoxetine is excreted in human breast milk. So, caution should be exercised when administered to a nursing woman.

**Preparation**
20 mg Capsule.



# Promtil™

**Active Ingredient**
Prochlorperazine.

**Indication**
For control of severe nausea & vomiting caused by radiation therapy, cancer chemotherapy, surgery, & other conditions. Relieving nausea, vomiting & attacks of dizziness or spinning sensations (vertigo) associated with Meniere's disease & other inner ear disorders, for the treatment Psychotic illness such as schizophrenia (hallucinations & hostility), acute mania, for the short-term treatment of generalized non-psychotic anxiety.

**Dosage & Administration**
Children (not recommended in children <10 kg or <2 years): 10-14 kg: 2.5 mg every 12-24 hours as needed; maximum: 7.5 mg/day
15-18 kg: 2.5 mg every 8-12 hours as needed; maximum: 10 mg/day
19-39 kg: 5 mg every 12 hours as needed; maximum: 15 mg/day
Adults: Oral: 5-10 mg 3-4 times/day; usual maximum: 40 mg/day

**Contraindication & Precaution**
Hypersensitivity to prochlorperazine or any component of the formulation, severe CNS depression; coma; should not be used in children <2 years of age or <10 kg. Very high or very low blood pressure, liver or heart disease, Reye's syndrome, alcohol or drug dependencies, nervous system problems, blood disorders, allergies (especially drug allergies). Caution should be taken while performing tasks that require alertness, such as driving or using machinery. Use of alcohol can cause extreme drowsiness. This medication may increase sensitivity to sunlight. Prolonged sun exposure should be avoided & a sunscreen & protective clothing should be taken when anybody is exposed to the sun. This medication can reduce sweating making more susceptible to heat stroke.

**Side-Effect**
Drowsiness, jaw, neck, & back muscle spasms, fine worm-like tongue movements, rhythmic face, mouth, or jaw movements, slow or difficult speech, difficulty swallowing, restlessness & pacing, tremors, shuffling walk, skin rash, yellowing of the skin or eyes.

**Use in Pregnancy & Lactation**
No evidence of adverse effects of this drug has been reported during pregnancy & lactation.

**Preparation**
5 mg Tablet.

# Pronor™

**Active Ingredient**
Finasteride.

**Indication**
Indicated for the treatment & control of Benign Prostatic Hyperplasia (BPH).

**Dosage & Administration**
Pronor one (5 mg) tablet daily with or without food.

**Contraindication & Precaution**
Hypersensitivity to any component of this product; women who are or may become pregnant; children, people with severely diminished urinary flow.

**Side Effect**
Pronor is well tolerated. The most frequently reported side-effects have been related to sexual function. In clinical studies the following effects have been reported in ≥ 1% of patient treated for 12 months with 5mg a day of Pronor : impotence (3.7%), decreased libido (3.3%) decreased volume of ejaculate (2.8%).

**Drug Interaction**
No clinically important drug interactions have been identified. Pronor does not appear to significantly affect the cytochrome P450-link drug metabolizing enzyme system. Compounds which have been tested in man include Propanolol, Digoxin, Glibenclamide, Warfarin, Theophylline & Antipyrine.
Although specific interaction studies were not performed in clinical studies, Pronor can be used concomitantly with ACE inhibitors, Alpha blockers, Beta blocker, Calcium channel blockers, Cardiac Nitrates, Diuretics, H2 Antagonists, NSAIDs, Quinilones & Benzodiazepines without evidence of clinically significant adverse interactions.

**Use in Pregnancy & Lactation**
Pronor is contra-indicated in women who are or may become pregnant. It is not known whether Finasteride is excreted in human milk.

**Preparation**
5 mg Tablet.

# Prosalic™ Lotion

**Active Ingredient**
Betamethasone + Salicylic Acid

**Indication**
Indicated for the treatment of hyperkeratotic & dry corticosteroid-responsive dermatitis where the cornified epithelium may resist penetration of the steroid. The Salicylic Acid constituent of Prosalic Lotion, as a result of its descaling action, allows access of the dermis more rapidly than by applying steroid alone.

**Dosage & Administration**
Apply required quantity of spray of Prosalic Lotion to the affected areas & massage gently & thoroughly. The usual frequency of application is twice daily, in the morning & night.

**Contraindication & Precaution**
Betamethasone & Salicylic Acid lotion is contraindicated in viral diseases including vaccinia, varicella, Herpes simplex & fungal infection; also tuberculosis of the skin. It is contraindicated in those patients with a history of sensitivity reactions to any of its components.
If irritation & sensitization develops with the use of Betamethasone & Salicylic Acid lotion, treatment should be discontinued. Systemic absorption of topical corticosteroids or Salicylic Acid may be increased if extensive body surface areas are treated. Application of Salicylic Acid to open wounds or damaged skin should be avoided.

**Side Effect**
Side effects that have been reported with the application of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, hypopigmentation, perioral dermatitis, & allergic contact dermatitis.

**Drug Interaction**
Drug interaction may be observed with other potential corticosteroid containing preparation.

**Use in Pregnancy & Lactation**
Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during

pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.
Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Use in Children**
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid- induced HPA axis suppression & to exogenous corticosteroid effects than mature patients because of a greater absorption due to a larger skin surface area to body weight ratio. Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with growth & development of children.

**Preparation**
Each container contains 25 ml Lotion.



# Proxivir™

**Active Ingredient**
Tenofovir Disoproxil Fumarate.

**Indication**
- Chronic hepatitis B virus infection in adults
- HIV infected adults in combination with other anti retroviral agents.

**Dosage & Administration**
The recommended dose of Tenofovir in chronic hepatitis B virus infection in adults 18 years of age & older with adequate renal function is 300 mg once daily with or without food.
Dose adjustment in renal impairment: Tenofovir is eliminated by renal excretion, so the exposure to Tenofovir increases in patients with renal dysfunction. Dosing interval should be adjusted in all patients with creatinine clearance <50 ml/min, as detailed below -

| Dosing interval adjustment of Tenofovir in patients with renal impairment | | | | |
|---|---|---|---|---|
| Creatinine Clearance (ml/min) | ≥50 | 30 to 49 | 10 t0 29 | Haemodialysis patients |
| Recommended (300mg) dosing Interval | Every 24 hours | Every 48 hours | Every 72 to 96 hours | Every 7 days or after approximately 12 hours of dialysis |

Dose adjustment in hepatic impairment: No dose adjustment is required in patients with hepatic impairment.

**Contraindication & Precaution**
Tenofovir is contraindicated in patients with known hypersensitivity to Tenofovir or any component of the product.
Co-administration with other drugs: Tenofovir should not be administered concurrently with Emtricitabine & Tenofovir combination or Adefovir Dipivoxil.
*Lactic Acidosis & Severe Hepatomegaly with Steatosis*: Though the risk of occurrence of lactic acidosis is low for Tenofovir, treatment should be suspended in any patient who develops lactic acidosis or hepatotoxicity.
*Exacerbation of hepatitis after discontinuation of treatment*: Discontinuation of Tenofovir therapy may be associated with severe acute exacerbation of hepatitis.

**Side Effect**
The most common side effects are nausea, vomiting, diarrhea & flatulence.

**Drug Interaction**
Co-administration of Tenofovir with anti-retroviral, Entecavir, Lamivudine, Methadone, oral contraceptives, Ribavirin & Tacrolimus did not result in significant drug interactions. The Effects of co-administration of Tenofovir with other drugs that are renally eliminated or are known to affect renal function have not been evaluated.

**Use in Pregnancy & Lactation**
Pregnancy category B. It should be used during pregnancy only if clearly needed. It is not known whether it is excreted in human milk. Mothers should be instructed not to breast feed if they are taking Tenofovir.

**Use in Children**
Safety & Effectiveness of Tenofovir in pediatric patients below the age of 18 years have not been established.

**Preparation**
300 mg Tablet.

# Pylotrip®

**Active Ingredient**
Lansoprazole Capsule, Amoxicillin Capsule & Clarithromycin Tablet.

**Indication**
Eradication of *H. pylori* in active chronic gastric, duodenal & gastric ulcers.

**Dosage & Administration**
One strip twice daily for 7-14 days or as per the physician's advice.

**Contraindication & Precaution**
Hypersensitivity.

**Side Effect**
Nausea, vomiting, diarrhoea, dark stools, dry mouth, glossitis, oral moniliasis, stomatitis, tongue discoloration, myalgia, confusion, headache, dizziness, skin reactions, vaginitis, vaginal moniliasis.

**Use in Pregnancy & Lactation**
Use only if the potential benefit justifies the potential risk of the mother.

**Preparation**
(30 mg + 1 gm + 500 mg)/Strip.

# Pylotrip® R

**Active Ingredient**
Rabeprazole+ Amoxycillin + Clarithromycin

**Composition**
Each Pylotrip R contains One Rabeprazole INN 20 mg tablet, Two Amoxycillin BP 500 mg capsules and One Clarithromycin USP 500 mg tablet.

**Indication**
It is indicated for the eradication of *H. pylori* in active chronic gastric, duodenal and gastric ulcers.

**Dosage & Administration**
Each Pylotrip R strip twice daily for 7-14 days or as per the physician's advice.

**Contraindication**
Pylotrip R is contraindicated in patients with known hypersensitivity to any of its component.

**Use In Pregnancy & Lactating Mother**
It should be used during pregnancy only if the potential benefit justifies the potential risk of the mother. Amoxycillin is excreted in human milk in very small amounts. Because of the potential for serious adverse reactions in nursing infants from Pylotrip R a decision should be made whether to discontinue nursing or to discontinue the drug therapy, taking into account the importance of the therapy to the mother.



**Geriatric Use**
Elderly patients may suffer from asymptomatic renal and hepatic dysfunction. Care should be taken when administering Pylotrip® R to these patients.

**Adverse Reaction**
Adverse reactions which were reported as possibly or probably related to treatment (>3%) in clinical trials when all three components of this therapy were given concomitantly are listed below and devided by body systems.
Digestive system: Nausea, vomitng, diarrhoea, dark stools, dry mouth, glossitis, oral moniliasis, stomatitis, tongue discoloration ; Musculoskeletal System - myalgia; Nervous System - confusion, headache, dizziness; Skin - skin reactions; Urogenital System - vaginitis, vaginal moniliasis.

**Preparation**
Box containing 7 Pylotrip R blister strips.

# Quinivir®

**Active Ingredient**
Hydroxychloroquine Sulfate USP

**Indication**
i) Acute and chronic rheumatoid arthritis, ii) Systemic Lupus Erythematosus (SLE), iii) Malaria

**Dosage & Administration**
Hydroxychloroquine Sulfate tablets are for oral administration and are taken with food to avoid stomach upset. i) Acute and chronic rheumatoid arthritis: 400 to 600 mg daily. When good response is obtained (usually 4 to 8 weeks), dose can be reduced to 50%. ii) Systemic Lupus Erythematosus (SLE): 400 mg once or twice daily for several weeks or months depending on response of the patients. Maintenance dose is 200 to 400 mg daily. iii) Malaria: In adults, an initial dose of 800 mg followed by 400 mg in 6-8 hours and 400 mg on each of two consecutive days. For children a total dose representing 25 mg/kg is administered in 3 days as follows. First dose: 10 mg base/kg (but not exceeding a single dose of 620 mg base). Second dose: 5 mg base/kg (but not exceeding a single dose of 310 mg base) 6 hours after first dose. Third dose: 5 mg base/kg 18 hours after second dose. Fourth dose: 5 mg base/kg 24 hours after third dose. * Hydroxychloroquine Sulfate BP 200 mg equivalent to 155 mg of base.

**Side Effects**
Generally Hydroxychloroquine Sulfate is well tolerated. However, few side effects like nausea, vomiting, stomach upset, loss of appetite, diarrhea, tiredness, weakness or headache and visual problem may occur the first several days.

**Precaution**
Children are especially sensitive to the 4-aminoquinoline compounds. Patients should be strongly warned to keep these drugs out of the reach of children. Ophthalmologic examination requires in every 12 months.

**Contraindications**
The presence of retinal and visual field changes attributable to any 4-aminoquinoline compound, patients with known hypersensitivity to 4-aminoquinoline compounds, long term therapy in children.

**Use In Pregnancy & Lactation**
During pregnancy, this drug should be used only if clearly needed. Since small amounts of this medication are found in breast milk consult your doctor before medication.

**Preparation**
200 mg Tablet

# Rabeca™

**Active Ingredient**
Rabeprazole Sodium.

**Indication**
Short-term treatment in healing & symptomatic relief of duodenal ulcers & erosive or ulcerative Gastroesophageal Reflux Disease (GERD). Maintaining healing & reducing relapse rates of heartburn symptoms in patients with GERD. Treatment of daytime & nighttime heartburn & other symptoms associated with GERD. Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome. In combination with Amoxicillin & Clarithromycin to eradicate *Helicobacter pylori*.

**Dosage & Administration**
Can be taken with or without food. Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD): 20 mg to be taken once daily for 4 to 8 weeks. For those patients who have not healed after 8 weeks of treatment, an additional 8 week course may be considered.
Maintenance of Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD Maintenance): The recommended adult oral dose is 20 mg once daily.
Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD): The recommended adult oral dose is 20 mg once daily for 4 weeks. If symptoms do not resolve completely after 4 weeks, an additional course of treatment may be considered.
Healing of Duodenal Ulcers: The recommended adult oral dose is 20 mg once daily after the morning meal for a period up to four weeks. Most patients with Duodenal Ulcer heal within four weeks. A few patients may require additional therapy to achieve healing.
*Helicobacter pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence: Rabeprazole Sodium 20 mg Twice Daily for 7 Days Amoxicillin 1000 mg Twice Daily for 7 Days Clarithromycin 500 mg Twice Daily for 7 Days. All three medications should be taken twice daily with the morning & evening meals. It is important that patients comply with the full 7-day regimen.
Treatment of Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome: The dosage of Rabeprazole Sodium in patients with pathologic hypersecretory conditions varies with the individual patient. The recommended adult oral starting dose is 60 mg once a day. Doses should be adjusted to individual patient needs & should continue for as long as clinically indicated. Some patients may require divided doses. Doses up to 100 mg QD & 60 mg BID have been administered. Some patients with Zollinger-Ellision syndrome have been treated continuously with Rabeprazole Sodium for up to one year.

**Contraindication**
Rabeprazole Sodium is contraindicated in patient with known hypersensitivity to Rabeprazole or to any component in the product.

**Precaution**
Administration of Rabeprazole Sodium to patients with mild to moderate liver impairment resulted in increased exposure & decreased elimination. Caution should be exercised in patients with severe hepatic impairment.

**Drug Intaraction**
Rabeprazole is metabolized by the non enzymatic pathway. Rabeprazole does not have clinically significant interactions with drugs metabolized by the CYP-450 system, such as Warfarin & Theophylline given as single oral dose, Diazepam as a single intravenous dose, & Phenytoin given as a single intravenous dose. In normal subjects, co-administration of Rabeprazole 20 mg QD resulted in an approximately 30% decrease in the bioavailability of Ketoconazole & increase in the AUC & Cmax for digoxin of 90% & 29% respectively.

**Use in Pregnancy & Lactation**
Rabeprazole is USFDA Pregnancy Category C. No data is available on administration of Rabeprazole to pregnant women. However this drug should be used during pregnancy, only if clearly needed. There are no data on the excretion of Rabeprazole into the breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.



**Use in Children**
The safety & effectiveness of Rabeprazole in pediatric patients have not been established.

**Preparation**
20 mg Tablet.

# Ranolin™ XR

**Active Ingredient**
Ranolazine

**Indication**
Ranolazine is indicated for the treatment of chronic angina. Ranolazine may be used with β-blockers, Nitrates, Calcium channel Blockers, Anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, & angiotensin receptor blockers. It has been shown to decrease angina episodes in patients with coronary artery disease on maximal doses of amlodipine. Because Ranolazine prolongs the QT interval, it should be reserved for patients who have not achieved an adequate response with other antianginal drugs.The effect on angina rate or exercise tolerance appeared to be smaller in women than men.

**Dosage & Administration**
Initiate Ranolazine dosing at 500 mg twice daily & increase to 1 gm twice daily, as needed, based on clinical symptoms. Take Ranolazine with or without meals. Ranolazine tablets whole; do not crush, break or chew.
The maximum recommended daily dose of Ranolazine is 1 gm twice daily. If a dose of Ranolazine is missed, take the prescribed dose at the next scheduled time; do not double the next dose.

**Contraindication & Precaution**
Ranolazine is contraindicated in patients:
•With pre-existing QT prolongation
•With hepatic impairment
•Taking QT prolonging drugs
•Taking potent & moderately potent CYP3A inhibitors such as Ketoconazole, Itraconazole, Clarithromycin, Nefazodone, Nelfinavir, Ritonavir, Indinavir, & Saquinavir, including DiltiazemRanolazine blocks $I_{kr}$ & prolongs the QTc interval in a dose-related manner. Clinical experience in an acute coronary syndrome population did not show an increased risk of proarrhythmia or sudden death.
Co-administration of Ranolazine with Digoxin increases the plasma concentrations of digoxin by approximately 1.5 fold & the dose of digoxin may have to be reduced accordingly. The dose of other P-gp substrates may have to be reduced as well when Ranolazine is co-administered. Caution should be exercised when co-administering Ranolazine with P-gp inhibitors such as Ritonavir or Cyclosporine.

**Side Effect**
Cardiac Disorders – bradycardia, palpitations; Ear & Labyrinth Disorders – tinnitus, vertigo; Gastrointestinal Disorders – abdominal pain, dry mouth, vomiting; General Disorders & Administrative Site Adverse Events – peripheral edema; Respiratory, Thoracic, & Mediastinal Disorders – dyspnea; Vascular Disorders – hypotension, orthostatic hypotension.

**Drug Interaction**
*CYP 3A Inhibitors:* Do not use Ranolazine with strong CYP3A inhibitors. With moderate CYP 3A inhibitors (e.g., Diltiazem, Verapamil, Erythromycin) limit maximum dose of Ranolazine to 500 mg twice daily.
*CYP3A Inducers:* Do not use Ranolazine with inducers.
P-gp Inhibitors (e.g., Cyclosporin): May need to lower the Ranolazine dose based on clinical dose.
Drugs transported by P-gp or metabolized by CYP2D6 (e.g., Digoxin, TCA): May need reduced doses of these drugs when used with Ranolazine.

**Use in Pregnancy & Lactation**
Pregnancy Category C. There are no adequate studies assessing the effect of Ranolazine on the developing fetus. There are no adequate well-controlled studies in pregnant women. Ranolazine should be used during pregnancy only when the potential benefit to the patient justifies the potential risk to the fetus. It is not known whether Ranolazine is excreted in human milk. Because of the potentiality for serious adverse reactions from ranolazine in nursing infants, a decision should be made whether to discontinue nursing or to discontinue Ranolazine, taking into account the importance of the drug to the mother.

**Use in Children**
Safety & effectiveness in pediatric patients have not been established.

**Preparation**
Ranolin XR 500 tablet: Each box containing 20 extended release tablets in PVC blister pack.

# Rapiflo™

**Active Ingredient**
Silodosin INN 8 mg.

**Dosage & Administration**
Silodosin 8 mg once daily with a meal is recommended as the dose for the treatment of the signs and symptoms of BPH.
Renal Impairment: Silodosin is contraindicated in patients with severe renal impairment (CCr < 30 mL/min). In patients with moderate renal impairment (CCr 30-50 mL/min), the dose should be reduced to 4 mg once daily taken with a meal. No dosage adjustment is needed in patients with mild renal impairment (CCr 50-80 mL/min).
Hepatic Impairment: Silodosin has not been studied in patients with severe hepatic impairment (Child-Pugh score ≥ 10) and is therefore contraindicated in these patients. No dosage adjustment is needed in patients with mild or moderate hepatic impairment. Missed Dose: If a dose of Silodosin is missed, the missed dose can be taken later the same day. If a day is missed, the missed dose should be skipped and the regular dosing schedule should be resumed. Doses must not be doubled. Overdose: Silodosin was evaluated at doses of up to 48 mg/day in healthy male subjects. The dose-limiting adverse event was orthostatic hypotension. Special Populations: Pediatrics (< 18 years of age): Silodosin is not indicated for use in children.

**Contraindication**
Silodosin is contraindicated in patients known to have hypersensitivity to Silodosin or any component of the Silodosin formulation. Silodosin should not be administered to patients using concomitant potent CYP3A4 inhibitors. (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir) Intraoperative Floppy Iris Syndrome has been observed during cataract surgery in some patients on α-1 blockers or previously treated with α-1 blockers. Silodosin should not be administered to patients using concomitant α-blockers (e.g., prazosin, terazosin, doxazosin).

**Use In Pregnancy & Lactation**
Women of childbearing potential should be considered for treatment only if using adequate contraception. Nursing Mother – It is not known whether Silodosin is excreted in human milk. Because many drugs are excreted in human milk, Silodosin should not be administered during nursing.
Adverse Reactions Retrograde ejaculation and dizziness are the most frequent adverse events with Silodosin. Retrograde ejaculation is reversible upon discontinuation of the drug.

**Warnings and precautions**
As with all α1-adrenoceptor antagonists, a reduction in blood pressure can occur in individual cases during treatment with Silodosin, as a down until the symptoms have disappeared.

**Drug Interactions**
Silodosin is not an inducer or an inhibitor of any of the principal hepatic enzymes involved in the metabolism of other drugs. CYP3A4 is a principal hepatic enzyme isoform involved in the metabolism of Silodosin. Potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, clarithromycin and ritonavir, increase Silodosin blood levels and exposure (Area under the Curve - AUC). Silodosin should not be co-administered with potent inhibitors of CYP3A4. Moderate CYP3A4 inhibitor diltiazem increased the Silodosin AUC by approximately 30%, but the maximum concentration (Cmax) and CYP3A4 hepatic enzyme isoform (such as α1-blockers), herbal remedies (particularly St. John's Wort, Milk Thistle), and grapefruit juice may.

**Preparation**
8 mg Capsule


# Rasalet™

**Active Ingredient**
Rasagiline

**Indication & Uses**
Rasalet is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease as initial monotherapy, and as adjunct therapy to dopamine agonists or to levodopa.

**Dosage & Administration**
Monotherapy: Rasalet 1 mg once daily
As adjunct without Levodopa: Rasalet 1 mg once daily
As adjunct to Levodopa: Rasalet 0.5 mg once daily

**Contraindication**
Rasagiline is contraindicated for use with meperidine, tramadol, methadone, propoxyphene and MAO inhibitors (MAOIs), including other selective MAO-B inhibitors, because of risk of serotonin syndrome.

**Warnings and precautions**
Exacerbation of hypertension may occur during treatment with Rasagiline. Medication adjustment may be necessary if elevation of blood pressure is sustained. Dose should not exceed 0.5 mg once daily for patients with mild hepatic impairment or taking concomitant Ciprofloxacin or other CYP1A2 inhibitors.

**Side effects**
Common side effects of Rasagiline include: dizziness, spinning sensation, joint pain, headache, heartburn, nausea, muscle pain etc.

**Drug interactions**
Concomitant use of Rasagiline with meperidine, dextromethorphan, antidepressants is not recommended.

**Use in specific populations**
Pregnancy: Pregnancy Category C. Rasagiline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing mother: It is not known whether this drug is excreted in human

milk. So, caution should be exercised when administered to a nursing woman. Pediatric use: The safety and effectiveness in pediatric patients have not been established.

**Preparation**
0.5 mg & 1 mg Tablet.

# Rectocare®

**Active Ingredient**
Nitroglycerin.

**Indication**
For relief of pain associated with chronic anal fissure.

**Dosage & Administration**
Nitroglycerin 0.4% ointment should be inserted into the anal cavity with an applicator. The ointment must be inserted at least 1cm into the anus. The dose is twice daily up to a maximum of 8 weeks.

**Contraindication & Precaution**
Nitroglycerin 0.4% ointment is contraindicated in patients with known hypersensitivity to Nitroglycerin or other ingredients of the formulation. Nitroglycerin 0.4% ointment should be used with caution in patients who have severe hepatic or renal disease. It should not be used if patient suffers from severe anemia, glaucoma, hypotension, increased intracranial pressure.

**Side Effect**
Headache & dizziness is a common side effect experienced with Nitroglycerin 0.4% ointment.

**Use in Pregnancy & Lactation**
This ointment should not be used during pregnancy & lactation.

**Use in Children**
Not recommend below 18 years of age.

**Preparation**
Each pack contains a tube of 15 gm ointment & an applicator.

# Remac™

**Active Ingredient**
Clarithromycin.

**Indication**
Pharyngitis, sinusitis, chronic bronchitis, pneumonia, skin & soft tissue infection, duodenal ulcers for eradication of H. pylori.

**Dosage & Administration**
Adults : Remac 250 - 500 mg for 7-14 days. Children: 7.5 mg/kg twice daily.

**Contraindication & Precaution**
Hypersensitivity, caution should be taken in administering this antibiotic to patients with impaired hepatic & renal function. Prolonged or repeated use of Clarithromycin may result in an overgrowth of non-susceptible bacteria or fungi.

**Drug Interaction**
Theophylline,Terfenadine, Carbamazepine.

**Use in Pregnancy & Lactation**
Clarithromycin is not recommended.

**Preparation**
500 mg Tablet, 125 mg/5 ml granules for suspension.

# Remus®

**Active Ingredient**
Tacrolimus.

**Indication**
Moderate to severe atopic dermatitis.

**Dosage & Administration**
Twice daily for one week until clearing of signs & symptoms of atopic dermatitis.

**Contraindication & Precaution**
Hypersensitivity, Netherton's Syndroms, generalized erythroderma.

**Side Effect**
Skin Burning, pruritus, allergic reaction, anaphylactoid reaction, angioedema, anorexia, anxiety.



**Drug Interaction**
Erythromycin, itraconazole, ketoconazole, fleoconazole, calcium channel blockers & cimetidine.

**Use in Pregnancy & Lactation**
Caution should be taken during pregnancy & lactation.

**Preparation**
0.03% & 0.1% Ointment.

# Remdinil

**Active Ingredient**
Remdesivir INN

**Indication**
For the treatment of suspected or laboratory confirmed Corona Virus Disease 2019 (COVID-19) in adult and children hospitalized with severe disease. Severe disease is defined as patients with an oxygen saturation (SpO2) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO). Specifically, Remdesivir is only authorized for hospitalized adults and pediatric patients for whom use of an intravenous agent is clinically appropriate.

**Dosage & Administration**
The recommended dosing and duration of Remdesivir in adults is 200 mg on the first day followed by 9 days of 100 mg once daily to be administered via IV infusion in a total volume of up to 250 mL of 0.9% saline over 30 minutes. The infusion time may be extended up to 120 minutes.
The recommended RDV dosing duration is a total of 10 days

**Method of Administration**
Concentrate for solution for infusion 100 mg: • Dilute concentrated solution in intravenous fluids up to 250 mL prior to intravenous administration. • Diluents that may be used: 0.9 % (9 mg/ml) sodium chloride in water for injection (saline) • The diluted solutions should be used immediately.

**Side Effect**
Multiple-dose IV administration of Remdesivir 150 mg once-daily for 7 or 14 days was generally well tolerated.

**Contraindication**
• Hypersensitivity to the active substance(s) or to any of the excipients • Evidence of multiorgan failure • The use of more than one pressor for septic shock (the use of 1 pressor at low/medium doses for inotropic support due to the use of sedation and paralytics while on the ventilator is allowed) • ALT > 5 x upper limit of normal (ULN) by local laboratory measure • Renal failure (eGRF < 30 mL/min) or dialysis or continuous veno-venous hemofiltration • Participation in any other clinical trial of an experimental agent treatment for other viruses

**Precaution**
In clinical studies, transient elevations in ALT and AST have been observed with single doses of Remdesivir up to 225 mg and multiple once-daily doses of Remdesivir 150 mg for up to 14 days, with mild, reversible PT prolongation in some subjects but without any clinically relevant change in INR or other evidence of hepatic effects. The mechanism of these elevations is currently unknown.

In nonclinical animal studies, toxicity findings were consistent with dose-dependent and reversible kidney injury and dysfunction. In clinical studies, no evidence of nephrotoxicity has been observed with single doses of Remdesivir up to 225 mg or multiple once-daily doses of Remdesivir 150 mg for up to 14 days.

**Use in Pregnancy & Lactation**
Pregnancy and contraception requirements There are no data from the use of Remdesivir in pregnant women. The use of Remdesivir in pregnant woman is not recommended.
Breast-feeding: It is unknown whether Remdesivir/metabolites are excreted in human milk.
Fertility: No human data on the effect of Remdesivir on fertility are available

**Preparation**
100 mg Conc. Solution

# Renorma®

**Active Ingredient**
Tibolone.

**Indication**
Treatment of symptoms resulting from the natural or surgical menopause in post menopausal women. Prevention of osteoporosis in women who have gone through the menopause & are at high risk of fractures, but cannot take other medicines used to prevent osteoporosis.

**Dosage & Administration**
Treatment of symptoms resulting from the natural or surgical menopause.
Prevention of post-menopausal bone mineral density loss: The recommended dose is 2.5 mg once daily.
Improvement of symptoms generally occurs within a few weeks, but optimal results are obtained when therapy is continued for at least 3 months. Women experiencing a natural menopause should commence treatment with tibolone at least 12 months after their last natural bleed. In case of a surgical menopause, treatment with tibolone may commence immediately.

**Contraindication & Precaution**
Contraindicated in - pregnancy & lactation; known, past or suspected breast cancer; known or suspected estrogen dependent malignant tumors (e.g. endometrial cancer); undiagnosed genital bleeding; untreated endometrial hyperplasia; previous idiopathic or current venous thromboembolism (deep venous thrombosis, pulmonary embolism); arterial thromboembolic disease (e.g. angina, myocardial infarction, stroke or TIA); acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal; porphyria
Precautions should be taken in - uterine fibroids or endometriosis, thromboembolic disorders, estrogen dependent tumors, hypertension, liver disorders (e.g. liver adenoma), diabetes, asthma, epilepsy etc.

**Side-Effect**
Gastrointestinal disorders like abdominal pain, skin & subcutaneous tissue disorders like abnormal hair growth, acne, reproductive system & breast disorders like vaginal discharge, genital pruritus, vaginal candidiasis etc.

**Use in Pregnancy & Lactation**
US-FDA pregnancy category D.
Tibolone is contraindicated in lactating women.

**Preparation**
2.5 mg Tablet.

# Repres® SR

**Active Ingredient**
Indapamide.

**Indication**
Essential hypertension, hypertension in patients with renal function impairment, salt & fluid retention associated with congestive heart failure.

**Dosage & Administration**
One tablet daily, preferably in the morning.

**Contraindication & Precaution**
Known allergy to this drug or to sulphonamides, Renal failure, Serious liver disease, Hypokalemia, Disturbed water/electrolyte balance, diabetes, gout & kidney problems. Monitoring of Potassium & Uric acid serum levels is recommended.

**Side Effect**
Dizziness, headache, anorexia, nausea, vomiting, constipation, diarrhea & postural hypotension. Electrolyte imbalances include hypochloremic alkalosis, hyponatremia, hypokalemia, hyperuricemia; hypersensitivity reactions which include skin rashes, cholestatic jaundice & blood dyscrasias including thrombocytopenia, leucopenia, aplastic anemia.

**Drug Interaction**
Other Antihypertensives, Norepinephrine.

**Use in Pregnancy & Lactation**
In pregnant women Indapamide is not recommended. Mothers taking Indapamide should not breast feed.

**Preparation**
1.5 mg SR (Sustained Release) Tablet.

# ResQ™

**Active Ingredient**
Coenzyme Q10

**Indication**
HMG CoA reductase inhibitors mediated decreased level of Coenzyme Q10, Drug induced Myopathy, Protects body against free radial damage with its antioxidant property, Adjuvant therapy in cardiovascular disease especially in angina & congestive heart failure, Immune system depression, Cognitive decline, Useful in the management of Periodontal Disease.

**Dosage & Administration**
Daily doses of Coenzyme Q10 range from 5 to 300 milligrams. Effectiveness is thought to be obtained with doses of 50 to 200 milligrams daily.

**Side Effect**
This product usually has very few side effects. Nausea, loss of appetite, upset stomach, or diarrhoea may infrequently occur.

**Contraindication & Precaution**
Patients with a known hypersensitivity to any component of this product.
Supplemental Coenzyme Q10 may improve beta-cell function & glycemic control in type II diabetics. Therefore, those diabetics who do use supplemental Coenzyme Q10 should determine by appropriate monitoring if they need to make any adjustments in their diabetic medications.

**Drug Interaction**
Warfarin: Supplemental Coenzyme Q10 may decrease the effectiveness of Warfarin. Statins: The statin drugs are known to decrease Coenzyme Q10 levels in humans. Doxorubicin: Coenzyme Q10 may help to decrease the cardiotoxicity of doxorubicin. Antidiabetic medications: Coenzyme Q10 may improve glycemic control in some type II diabetics. If this were to occur, anti-diabetic medications might need appropriate adjusting.

**Use in Pregnancy & Lactation**
Because of lack of information on long-term safety, pregnant women & nursing mothers should avoid Coenzyme Q10.

**Preparation**
30 mg & 60 mg Licap

# Retabac™ Ointment

**Active Ingredient**
Retapamulin

**Indication**
Retabac is indicated for use in adults and pediatric patients (aged 9 months and older) for the topical treatment of impetigo (up to 100 cm2 in total area in adults or 2% total body surface area in pediatric patients) due to Staphylococcus aureus or Streptococcus pyogenes.
It is also effective to treat secondary bacterial skin infections like-
- Infected dermatitis
- Infected traumatic lesions (e.g. small lacerations, sutured wounds, cuts, abrasions etc.)

**Dosage & Administration**
A thin layer of RetabacTM should be applied to the affected area twice daily for 5 days. The treated area may be covered with a sterile bandage or gauze dressing if desired.

Contraindication & Precaution
• In the event of sensitization or severe local irritation, usage should be discontinued.
• Not intended for ingestion or for oral, intranasal, ophthalmic or intravaginal use.

**Side Effect**
Application site irritation (Not more than 2% patients may experience)

**Use in Pregnancy & Lactation**
Pregnancy category B. It is not known whether Retapamulin is excreted in human milk. Caution should be exercised when administered to a nursing woman.

**Preparation**
10 gm ointment.

# Revira®

**Active Ingredient**
Valaciclovir.

**Indication**
Revira is indicated for cold sore of adult & children, genital herpes, chicken pox & herpes zoster.

**Dosage & Administration**
Revira tablets may be given without regard to meals.
Herpes Zoster: The recommended dosage for the treatment of herpes zoster is 1 gram orally 3 times daily for 7 days. Therapy should be initiated at the earliest sign or symptom of herpes zoster & is most effective when started within 48 hours of the onset of zoster rash.
Genital Herpes: Initial Episodes: The recommended dosage for treatment of initial genital herpes is 1 gram twice daily for 10 days. Recurrent Episodes: The recommended dosage for the treatment of recurrent genital herpes is 500 mg twice daily for 3 days. Suppressive Therapy: The recommended dosage for chronic suppressive therapy of recurrent genital herpes is 1 gram once daily in patients with normal immune function. In patients with a history of 9 or fewer recurrences per year, an alternative dose is 500 mg once daily.

In HIV-infected patients with CD4 cell count 100 cells/mm$^3$, the recommended dosage for chronic suppressive therapy of recurrent genital herpes is 500 mg twice daily. Reduction of Transmission: The recommended dosage for reduction of transmission of genital herpes in patients with a history of 9 or fewer recurrences per year is 500 mg once daily for the source partner.
Cold Sores (Herpes Labialis): The recommended dosage for the treatment of cold sores is 2 grams twice daily for 1 day taken about 12 hours apart.
Patients with Acute or Chronic Renal Impairment: In patients with reduced renal function, reduction in dosage is recommended.

**Contraindication & Precaution**
Valaciclovir is contraindicated in patients with a known hypersensitivity or intolerance to Valaciclovir, Aciclovir or any component of the formulation.

**Side Effect**
Nausea, headache, vomiting, dizziness & abdominal pain may occur. In rare cases following adverse reactions reported:
General: Facial edema, hypertension, tachycardia.
Allergic: Acute hypersensitivity reactions including anaphylaxis, angioedema, dyspnea, pruritus, rash, & urticaria.
CNS Symptoms: Aggressive behavior; agitation; ataxia; coma; confusion; decreased consciousness; dysarthria; encephalopathy; mania; & psychosis, including auditory & visual hallucinations; seizures, tremors.
Eye: Visual abnormalities.
Gastrointestinal: Diarrhea.
Hepatobiliary Tract & Pancreas: Liver enzyme abnormalities, hepatitis.
Renal: Elevated creatinine, renal failure.
Hematologic: Thrombocytopenia, aplastic anemia, leukocytoclastic vasculitis, TTP/HUS.

**Use in Pregnancy & Lactation**
Pregnancy Category B. Valaciclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Valaciclovir should be administered to a nursing mother with caution & only when indicated.

**Use in Children**
Safety & effectiveness of Valaciclovir in pre-pubertal pediatric patients have not been established.

**Preparation**
500 mg & 1 gm Tablet

# Rex®

**Active Ingredient**
Beta Carotene , Vitamin C , & Vitamin E.

**Indication**
Reduces risks of cardiovascular diseases in human, reduces risks of cataract, combat infection & chronic diseases, trend toward decreased age-related degenerative changes, defense against infection.

**Dosage & Administration**
1 tablet daily.

**Contraindication & Precaution**
Hypersensitivity , hyperoxaluria.

**Side Effect**
Loose stools, yellow discoloration of skin, chronic overdosage can lead to peeling & redness of the skin, loss of appetite, diarrhoea & other gastro-intestinal disturbances. It has also been stated abdominal pain, fatigue & weakness.

**Drug Interaction**
Neomycin, bleomycin, aminophylline, nitrofurantoin sodium, conjugated oestrogens, sulphafurazole diethanolamine, chloramphenicol sodium succinate, chlorothiazide sodium & hydrocortisone sodium succinate.

**Use in Pregnancy & Lactation**
High doses should not be given in pregnancy & lactation.

**Preparation**
(6 mg + 200 mg + 50 mg)/Tablet.

# Rice ORS®

**Active Ingredient**
Rice ORS for 500 ml Water: Each sachet contains Sodium Chloride BP 1.30 gm, Potassium Chloride BP 0.75 gm, Tri-Sodium Citrate Dihydrate BP 1.45 gm & Processed Rice Powder Pharma Grade 25 gm.
Rice ORS for 250 ml Water: Each sachet contains Sodium chloride BP 0.650 gm, Potassium chloride BP 0.375 gm, Tri-Sodium Citrate Dihydrate BP 0.725 gm & Processed Rice Powder Pharma Grade 12.500 gm

**Indication**
Rice ORS is indicated in -
- Acute fluid & electrolyte loss conditions such as cholera, acute diarrhea & vomiting
- Dehydration
- Severely low concentrations of salts in the blood (severe electrolyte depletion)

**Dosage & Administration**
Dose of Rice ORS depends on the severity of the dehydrating conditions of the patients. The following is a guideline:

| Age | Recommended Dose after each watery stool |
|---|---|
| 6 months to 2 years | 50 ml to 100 ml (10 to 20 Teaspoonfuls) |
| 2 years to 9 years | 100 ml to 200 ml (20 to 40 teaspoonfuls) |
| 10 years & above | 250 ml to 500 ml (1 to 2 glassfuls) |

**Contraindication & Precaution**
Not to be used in -
- Kidney failure resulting in diminished production of urine
- Kidney failure, preventing production of urine
- Obstruction of the stomach or intestines
- Reduced blood flow to vital internal organs (shock)
- Severe & continuous vomiting (intractable vomiting)
- Severe dehydration
- Severe diarrhea in infants

Precautions should be taken in case of significant overdose, especially for the following patients -
- Children less than 1 year of age
- Patients with imbalance of salt concentrations in the blood (electrolyte imbalance)
- Patients with severely decreased kidney function
- Patients with severely decreased liver function

**Drug Interaction**
There is no known drug interaction reported.

**Use in Pregnancy & Lactation**
Rice ORS® is recommended in pregnancy & lactation, as there is no known harmful Effect when this medicine is used.

**Use in Children**
Safety & effectiveness of Rice ORS in pediatric patients below the age of 6 months have not been established.

**Preparation**
Rice ORS for 250 ml Water: Each box contains 10 sachets. Rice ORS for 500 ml Water: Each box contains 10 sachets.

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# Ripril®

**Active Ingredient**
Ramipril.

**Indication**
Mild to severe hypertension, Congestive heart failure.

**Dosage & Administration**
Initial dose is 1.25-2.5 mg once daily. Maintenance dosage in adult is 2.5-20 mg daily as single or in 2 divided doses.

**Contraindication**
Hypersensitivity, angioedema.

**Side Effect**
Dizziness, headache, fatigue & asthenia, hypotension, cough, nausea, vomiting, diarrhoea, rash, urticaria, oliguria, anxiety, amnesia.

**Use in Pregnancy & Lactation**
Not recommended.

**Preparation**
2.5 mg & 5 mg Tablet.




# RivaXa™

**Active Ingredient**
Rivaroxaban

**Indication**
Rivaroxaban 2.5 mg:
For the prevention of atherothrombotic events in adult patients after an Acute Coronary Syndrome (ACS) with elevated cardiac biomarkers (Troponin or CK-MB). It is co-administered with acetylsalicylic acid

(ASA) alone or with ASA plus Clopidogrel or Ticlopidine.
Rivaroxaban 10-20 mg:
•To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
• Deep vein thrombosis (DVT) & pulmonary embolism (PE) and reduction in the risk of recurrence of DVT and of PE
• For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery

**Dosage & Administration**
Rivaroxaban 2.5 mg:
The recommended dose is 2.5 mg twice daily. Patients should also take a daily dose of 75-100 mg Aspirin or a daily dose of 75-100 mg Aspirin in addition to either a daily dose of 75 mg Clopidogrel or a standard daily dose of Ticlopidine.

Rivaroxaban 10-20 mg:
• Nonvalvular Atrial Fibrillation: For patients with Creatinin Clearance>50 mL/min: 20 mg orally, once daily with the evening meal. For patients with Creatinin Clearance 15-50 ml/min: 15 mg orally, once daily with the evening meal
• Treatment of Deep vein Thrombosis (DVT) & Pulmonary Embolism (PE): 15 mg orally twice daily with food for the first 21 days for the initial treatment of acute DVT or PE. After the initial treatment period, 20 mg orally once daily with food for the remaining treatment
• Prevention in the risk of recurrence of Deep vein Thrombosis (DVT) and of Pulmonary Embolism PE: 20 mg once daily with food
• Prophylaxis of DVT following Hip replacement surgery: 10 mg orally, once daily for 35 days
• Prophylaxis of DVT following kneereplacement surgery: 10 mg orally, once daily for 12 days

**Side Effect**
The most common adverse reaction is bleeding, Increased risk of stroke after discontinuation in nonvalvular atrial fibrillation

**Use In Pregnancy & Lactation**
There are no adequate or well-controlled studies of Rivaroxaban in pregnant women, and dosing for pregnant women has not been established Safety and efficacy of Rivaroxaban have not been established in breast-feeding women.

**Preparation**
2.5 mg & 10 mg tablet.

# Robic®

**Active Ingredient**
Ornidazole.

**Indication**
Amoebiasis (Intestinal & hepatic), Giardiasis, Trichomoniasis, Bacterial vaginosis, Treatment of susceptible anaerobic infections.

**Dosage & Administration**
Amoebiasis : Adults: 500 mg twice a day for 5 days. Children: 10-25 mg/kg body weight in 2 divided doses. Amoebic dysentery : Adults : 1.5 gm once a day for 3 days. Children: 40 mg/kg body weight once a day for 3 days. Giardiasis: Adults : 1.5 gm once daily for 1-2 days. Children: 40 mg/kg body weight for 2 days. Trichomoniasis : 1.5 gm once or 500 mg twice a day for 5 days. Sexual partner should also be treated at the same time. Bacterial vaginosis : 3 tablets of 500 mg each as a single dose or one tablet of 500 mg once daily for 5-7 days.

**Contraindication & Precaution**
Hypersensitivity, epilepsy, peripheral neuropathy. In patient with ataxia, vertigo, & mental confusion, Ornidazole should be prescribed with caution.

**Side Effect**
Nausea, vomiting, epigastric pain, dizziness, headache, lassitude. Unlike other nitroimidazoles, Ornidazole does not interact

with alcohol, Leukopenia has been described occasionally.

**Drug Interaction**
Disulfiram-like reactions. Concomitant administration of oral anticoagulants may increase the risk of haemorrhage due to diminished hepatic metabolism. Ornidazole has been reported to decrease the clearance of 5-fluorouracil.

**Use in Pregnancy & Lactation**
Ornidazole should be prescribed only if the potential benefit justifies the potential risk to foetus/neonate.

**Preparation**
500 mg Tablet.



# Rupatrol®

**Active Ingredient**
Rupatadine.

**Indication**
Rupatadine is indicated for the symptomatic treatment of Seasonal & Perennial Allergic Rhinitis & Urticaria.

**Dosage & Administration**
Adults & adolescents (above 12 years) - The recommended dose is 10 mg once daily, with or without food.

**Contraindication & Precaution**
Hypersensitivity to Rupatadine or to any of the excipients. Rupatadine should be used with caution in elderly patients (65 years & older) due to little clinical data. As there is no clinical experience in patients with impaired kidney or liver function, the use of rupatadine 10 mg tablets is at present not recommended in these patients.

**Side Effect**
Sleepiness, headache, dizziness, dry mouth, fatigue, asthenia etc.

**Drug Interaction**
The concomitant administration of rupatadine 20 mg & ketoconazole or erythromycin increases the systemic exposure. rupatadine should be used with caution when it is administered concomitantly with these drug substances & other inhibitors of the isozyme CYP3A4.

**Use in Pregnancy & Lactation**
No adequate data available. Caution should be exercised when prescribing rupatadine to pregnant or lactating women; it is unknown whether rupatadine is excreted into breast milk.

**Preparation**
10 mg Tablet.

# Rosuva™

**Active Ingredient**
Rosuvastatin.

**Indication**
Hypercholesterolemia.

**Dosage & Administration**
5-40 mg once daily.

**Contraindication**
Hypersensitivity to Rosuvastatin or any of it's components, active liver disease or with unexplained persistent elevations of serum transaminases.

**Side Effect**
Generally well tolerated. Myalgia, constipation, asthenia, abdominal pain, & nausea.

**Use in Pregnancy & Lactation**
Not recommended. Should be administered

to women of childbearing age only when such patients are highly unlikely to conceive.

**Preparation**
5mg, 10 mg & 20 mg Tablet.

# Rutix®

**Active Ingredient**
Ofloxacin.

**Indication**
Chronic bronchitis lung abscess, pneumonia, enteric fever, shigellosis. Multi-drug-resistant tuberculosis, uncomplicated skin & skin structure infections, acute, gonorrhoea. Nongonococcal urethritis & cervicitis. Urinary Tract Infections.

**Dosage & Administration**
200 mg to 800 mg daily from 5-7 days. For children 15 mg/kg/day in two divided doses.
Acute or chronic prostatitis: 200 mg twice daily for 28 days.

**Contraindication & Precaution**
Hypersensitivity, epilepsy, children or growing adolescents & in pregnant or breast feeding women.

**Side Effect**
Nausea, rash, vomiting, abdominal pain, diarrhoea, dizziness & insomnia.

**Drug Interaction**
Antacids containing magnesium, aluminium or calcium may decrease absorption of ofloxacin. Iron or Zinc may decrease oral absorption of ofloxacin.

**Preparation**
200 & 400 mg Tablet.

# Saga®

**Active Ingredient**
Sparfloxacin.

**Indication**
Community acquired pneumonia, Chronic Bronchitis.

**Dosage & Administration**
Two Saga tablets on first day as loading dose, thereafter one tablet of Saga every 24 hours for a total of 10 days therapy.

**Contraindication & Precaution**
Hypersensitivity or photosensitivity reactions. Adjustment of the dosage regimen is necessary for the patients with impaired renal function creatinine clearance (< 50 ml/min).

**Side Effect**
Photosensitivity reaction, diarrhoea, nausea, headache, dyspepsia, dizziness, insomnia, abdominal pain & QTc interval prolongation.

**Drug Interaction**
Antacids & Sucralfate, Zinc/iron salts.

**Use in Pregnancy & Lactation & Children**
Should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Safety & effectiveness have not been established in patients below the age of 18 years.

**Preparation**
200 mg Tablet.

# Salicid™

**Active Ingredient**
Salicylic Acid BP 12%

**Indication**
Salicid™ Cream is indicated for the treatment of

following common scaly conditions:
- Corns and Calluses (hard, thick pads of skin caused by pressure and friction. They usually occur on the feet due to poorly fitting shoes and can occur on the hands).
- Warts (small excessive growths of skin caused by a type of virus. Warts often occur on the fingers or on the back of the hands)
- Verruca (occurs only on the sole of the feet and can be painful. It often looks like a small white ring of skin with a black dot in the Centre)

**Dosage & Administration**
Apply to the affected area once daily (preferably at night). If possible, hydrate area for 5 minutes to soften prior to application. Occlude the area at night. Wash off in morning.

**Contraindication & Precaution**
Should not be used in any patient known to be allergic to Salicylic Acid or any other used ingredients.

**Side Effect**
An allergic reaction (shortness of breath, closing of the throat, swelling of the lips, face or tongue and hives) or severe skin irritation may occasionally occur.

**Use in Pregnancy & Lactation**
Pregnancy Category C. If used by nursing mothers, it should not be used on the chest area.

**Preparation**
30 gm cream



# Scabex®

**Active Ingredient**
Permethrin.

**Indication**
Scabies

**Dosage & Administration**
Adults: One full tube (30 gm), Children: 1/8 (30 gm) of a tube. How to use: Patients >2 months of age can use the dermal cream. It should be applied to the whole body excluding head.

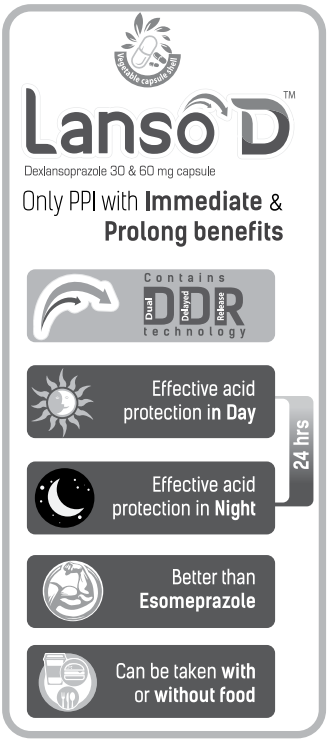
**Contraindication & Precaution**
Hypersensitivity.

**Side Effect**
Skin discomfort, burning, stinging or tingling erythema, edema, eczema, rash & pruritus.

**Drug Interaction**
The treatment of eczematous-like reactions with corticosteroids should be withheld prior to treatment with Permethrin.

**Use in Pregnancy & Lactation**
Permethrin is suggested not to use during pregnancy & lactation.

**Preparation**
30 gm Cream.





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# Seclo®

**Active Ingredient**
Omeprazole.

**Indication**
Seclo capsule & tablet is indicated for gastroesophageal reflux disease including reflux esophagitis, acid reflux disease, duodenal & benign gastric ulcers, *Helicobacter pylori* eradication regimens in peptic ulcer disease, prophylaxis of acid aspiration, Zollinger-Ellison Syndrome & for the treatment of NSAID-associated gastric ulcers, duodenal ulcers or gastroduodenal erosions.
Seclo IV is indicated primarily for the treatment of Zollinger-Ellison syndrome, & may also be used for the treatment of gastric ulcer, duodenal ulcer & reflux esophagitis.

**Dosage & Administration**
Capsule: Omeprazole should be taken 30 minutes before meal.

| Disease | Dosage & Administration |
|---|---|
| Gastroesophageal reflux disease including reflux esophagitis | The usual dosage is 20 mg Omeprazole once daily. The majority of patients are healed after 4 weeks. For those patients not fully healed after the initial course, healing usually occurs during a further 4-8 weeks treatment. Omeprazole has also been used in a dose of 40 mg once daily in patients with reflux esophagitis refractory to other therapy. Healing usually occurred within 8 weeks. Patients can be continued at a dosage of 20 mg once daily. |
| Acid reflux disease | For long-term management Omeprazole 10 mg once daily is recommended, increasing to 20 mg if symptoms return. |
| Duodenal and benign gastric ulcers | The usual dose is 20 mg Omeprazole once daily. The majority of patients with duodenal ulcer are healed after 4 weeks. The majority of patients with benign gastric ulcer are healed after 8 weeks. In severe or recurrent cases the dose may be increased to 40 mg Omeprazole daily. Long-term therapy for patients with a history of recurrent duodenal ulcer is recommended at a dosage of 20 mg Omeprazole once daily. For prevention of relapse in patients with duodenal ulcer the recommended dose is Omeprazole 10 mg once daily, increasing to 20 mg once daily, if symptoms return. |
| *Helicobacter pylori* eradication regimens in peptic ulcer disease | Omeprazole is recommended at a dose of 40 mg once daily or 20 mg twice daily in association with antimicrobial agents Amoxicillin 1 g & Clarithromycin 500 mg both twice a day for 7 to 14 days. |
| Prophylaxis of acid aspiration | For patients considered to be at risk of aspiration of the gastric contents during general anaesthesia, the recommended dosage is Omeprazole 40 mg on the evening before surgery followed by Omeprazole 40 mg 2-6 hours prior to surgery. |
| Zollinger-Ellison syndrome | The recommended initial dosage is 60 mg Omeprazole once daily. The dosage should be adjusted individually & treatment continued as long as clinically indicated. More than 90% of patients with severe disease & inadequate response to other therapies have been effectively controlled on doses of 20-120 mg daily. With doses above 80 mg daily, the dose should be divided & given twice daily. |

<table>
<tr><td>For the treatment of NSAID associated gastric ulcers, duodenal ulcers or gastroduodenal erosions</td><td colspan="3">The recommended dosage of Omeprazole is 20 mg once daily. Symptom resolution is rapid & in most patients healing occurs within 4 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 4 weeks treatment. For the prophylaxis of NSAID-associated gastric ulcers, duodenal ulcers, gastroduodenal erosions & dyspeptic symptoms in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment, the recommended dosage of Omeprazole is 20 mg once daily.</td></tr>
<tr><td colspan="4">Children</td></tr>
<tr><td rowspan="4">GERD or other acid-related disorders</td><td colspan="3">The recommended dose for pediatric patients 1 years of age & older is as follows:</td></tr>
<tr><td>Age</td><td>Body Weight</td><td>Dose</td></tr>
<tr><td>> 1 year</td><td>10 - 20 kg</td><td>10 mg once daily, if needed, 20 mg once daily</td></tr>
<tr><td>> 2 year</td><td>> 20 kg</td><td>20 mg once daily, if needed, 40 mg once daily</td></tr>
<tr><td colspan="4">IV Injection</td></tr>
<tr><td>Duodenal ulcer, gastric ulcer or reflux esophagitis</td><td colspan="3">In patients with duodenal ulcer, gastric ulcer or reflux esophagitis where oral medication is inappropriate, Omeprazole IV 40 mg once daily is recommended.</td></tr>
<tr><td>Zollinger-Ellison Syndrome (ZES)</td><td colspan="3">In patients with Zollinger-Ellison syndrome the recommended initial dose of Omeprazole given intravenously is 60 mg daily. Higher daily doses may be required & the dose should be adjusted individually. When doses exceed 60 mg daily, the dose should be divided & given twice daily.</td></tr>
</table>

*Direction For Use Of IV Injection*

Omeprazole lyophilized powder & water for injection is for intravenous administration only & must not be given by any other route. Omeprazole injection 40 mg should be given as a slow intravenous injection. The solution for IV injection is obtained by adding 10 ml water for injection to the vial containing powder. After reconstitution the injection should be given slowly over a period of at least 2-5 minutes at a maximum rate of 4 ml per minute. Use only freshly prepared solution. The solution should be used within 4 hours of reconstitution.

*Direction For Use Of IV Infusion*

Omeprazole IV infusion 40 mg should be given as an intravenous infusion over a period of 20-30 minutes or more. The contents of one vial must be dissolved in 100 ml saline for infusion or 100 ml 5% dextrose for infusion. The solution should be used within 12 hours when Omeprazole is dissolved in saline & within 6 hours when dissolved in 5% dextrose. The reconstituted solution should not be mixed or co-administered in the same infusion set with any other drug.

**Contraindication & Precaution**

There are no known contraindications to the use of Omeprazole. When gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with Omeprazole is instituted

as treatment may alleviate symptoms & delay diagnosis.

**Side Effect**
Omeprazole is well tolerated. Nausea, diarrhoea, abdominal colic, paresthesia, dizziness & headache have been stated to be generally mild & transient & not requiring a reduction in dosage.

**Use in Pregnancy & Lactation**
US FDA pregnancy category C. Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

**Preparation**
20 mg Capsule, 40 mg Capsule & 40 mg IV Injection.

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# Seclo® MUPS

**Active Ingredient**
Omeprazole

**MUPS**
MUPS is abbreviation for Multiple-Unit Pellet System. However, from pharmaceutical industry and research perspective, the term in general refers to MUPS compacted into tablets. Thus, the resulting tablets prepared by compaction of modified release coated multiparticulates or pellets are called as MUPS. It is the more recent and challenging technology that combines the advantages of both tablets and pellet-filled capsules in one dosage form.
CLINICAL ADVANTAGE OF OMEPRAZOLE MUPS TABLET COMPARED TO CONVENTIONAL MODIFIED-RELEASE OMEPRAZOLE TABLETS AND PELLET-FILLED OMEPRAZOLE CAPSULES
• Ensures greater bioavailability • Ensures uniform emptying of micro pellets from stomach into small intestine facilitates rapid dissolution of enteric coating and drug release resulting in early Tmax and Cmax (peak time and peak plasma concentration) • Ensures lesser possibility of dose dumping • Is a combination of fast acting and sustained action • Ensures uniform drug release • Once daily dosing • Ensures lesser chance of localized irritation • Ensures better and more uniform drug absorption • Better than capsules in reducing the esophageal residence time • Minimizes fluctuation in plasma concentration of drug

**Pharmacodynamic Advantages**
• MUPS ensure rapid and uniform gastric emptying and subsequently uniform drug dissolution of pellets in the gastrointestinal tract due to their small size and larger surface, uniform drug absorption is facilitated which results in consistent and controlled pharmacological action. • A further reduction in inter- and intra-subject variability in drug absorption and clinical response is facilitated since the number of pellets per MUPS dosage form is much more than a conventional

pellet-filled capsule and possibility of dose dumping(in stomach) and incomplete drug release is further minimized

**Indication**

• Duodenal and Gastric ulcers • NSAID-induced gastric and duodenal ulcers• Reflux Oesophagitis • GERD (Gastroesophageal Reflux Disease) • Eradication of *H. pylori* with appropriate antibiotics • Zollinger-Ellison Syndrome

**Dosage & Administration**

Adult :

| Indication | Dose | Frequency |
|---|---|---|
| GERD (Gastroesophageal Reflux Disease) | 20 mg | Once daily for 4 weeks |
| Gastric ulcer | 20 mg | Once daily for 4—8 weeks; in severe cases Twice daily |
| Duodenal ulcer | 20 mg | Once daily for 2—4 weeks; in severe cases Twice daily |
| NSAID-induced ulceration | 20 mg | Once daily for 4—8 weeks |
| Reflux esophagitis | 20 mg | Once daily for 4—8 weeks; in severe cases Twice daily |
| *H. pylori* eradication (Omeprazole MUPS tablet with Amoxicillin and Clarithromycin or Metronidazole) | 20 mg | Twice daily for 1 week |

Children over 2 years old:

| Indication | Dose | Frequency |
|---|---|---|
| Acid regurgitation in GERD (Gastroesophageal Reflux Disease) | 20 mg | Once daily for 2-4 weeks |
| Reflux esophagitis | 20 mg | Once daily for 4-8 weeks |

**Contraindication**

Omeprazole is contraindicated in those patients who have known hypersensitivity to any other components of the formulation.

**Precaution**

Omeprazole tablet should be used carefully if the patient has severe liver dysfunction and severe renal impairment.

**Use In Pregnancy & Lactation**

Not known to be harmful. Omeprazole can be used during pregnancy. Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

**Drug Interaction**

Omeprazole is metabolized through CYP2C19 . When starting or stopping treatment with Omeprazole should be taken into account potential interactions with medicines which are CYP2C19 metabolized.

**Storage**
Store in a cool (below $30^0$ C) and dry place, protect from light and moisture.

**How Supplied**
Seclo® MUPS 20 Tablet: Each box contains 30 tablets in Alu-Alu blister pack

# Secnid®

S

**Active Ingredient**
Secnidazole.

**Indication**
Intestinal Amoebiasis, Hepatic Amoebiasis, Urethritis & Vaginitis due to Trichomonas vaginalis, Giardiasis.

**Dosage & Administration**
DS tablet: (Secnidazole INN) DS tablet should be administered orally. The dosage schedule of is mentioned below:
Acute Intestinal Amoebiasis:
Adults: 2 gm single dose, taken preferably just before meal.
Children: 30 mg/kg single dose, taken preferably just before meal.
Asymptomatic Amoebiasis (minute & cystic form):
Adults: 2 gm once daily for only 3 days, taken preferably just before meal.
Children: 30 mg/kg once daily for only 3 days, taken preferably just before meal.
Hepatic Amoebiasis:
Adults: 1.50 gm/day in a single or divided doses, just before meal, for 5 days. Children: 30 mg/kg/day, in a single or divided dose, just before meal, for 5 days. N. B. Evacuation of pus must be performed simultaneously with Secnid (Secnidazole INN) treatment at the suppurative stage of hepatic amoebiasis.
Giardiasis:
Adults: 2 gm single dose, taken preferably just before meal.
Children: 35-50 mg/kg single dose, taken preferably just before meal.
Trichomoniasis:
Adults: 2 gm single dose, taken preferably just before meal.
The partner should also receive the same treatment concomitantly.
Secnid 500 Suspension: SecnidSuspension should be administered orally. The dosage schedule of Secnid suspension is mentioned below:
Children of 10 to 15 kg body weight: 1 bottle of Secnid 500 Suspension. Children of 16 to 25 kg of body weight: 1 & half bottles of Secnid 500 Suspension. Children of 26 kg or more body weight: 2 bottles of Secnid 500 Suspension.

**Contraindication & Precaution**
Hypersensitivity, Patients should be advised not to take alcohol during treatment with secnidazole, should be avoided to patients with a history of blood dyscrasia.

**Side Effect**
Nausea, epigastric pain, metallic taste, glossitis, & stomatitis, Urticaria, moderate leukopenia (reversible), Rare Side-Effect: Vertigo, ataxia & motor incoordination, paresthesia, & peripheral neuropathy.

**Drug Interaction**
Disulfiram, Warfarin.

**Use in Pregnancy & Lactation**
Secnidazole may be prescribed in pregnancy after the first trimester, should not be used during lactation.

**Preparation**
1 gm DS Tablet.

# Secrin®

**Active Ingredient**
Glimepiride

**Indication**
Type 2 diabetes.

**Dosage & Administration**
1 mg once daily. If necessary, the daily dose can be increased. Any increase can be based on regular blood sugar monitoring, & should be gradual. maximum recommended dose of Secrin is 8 mg daily.

**Contraindication & Precaution**
Type-I diabetes mellitus, diabetic precoma or coma, hypersensitivity to Glimepiride, other sulphonylureas, other sulphonamides. In the initial weeks of treatment, the risk of hypoglycemia may be increased & necessitates careful monitoring.

**Side Effect**
Hypoglycemia, temporary visual impairment, nausea, vomiting, diarrhea, abdominal pain, urticaria, fall in blood pressure.

**Drug Interaction**
Potentiation of the blood-sugar-lowering Effect : Insulin & other oral , antidiabetics, ACE inhibitors, allopurinol, anabolic steroids & male sex hormones, chloramphenicol, coumarin derivatives, fluoxetine, MAO inhibitors, miconazole, para-aminosalicylic acid, pentoxifylline, phenylbutazone, oxyphenbutazone, quinolones, salicylates, sulfonamides, tetracyclines, beta blockers. Weakening of the blood-sugar-lowering Effect: Acetazolamide, barbiturates, corticosteroids, diazoxide, diuretics, epinephrine & other sympathomimetic agents, laxatives, oestrogens & progestogens, phenothiazines, phenytoin, rifampicin, thyroid hormones. H2-receptors antagonists, clonidine & reserpine. Both acute & chronic alcohol intake may potentiate or weaken the blood- sugar-lowering action of glimepiride unpredictably.

**Use in Pregnancy & Lactation**
Glimepiride must not be taken during pregnancy. Glimepiride must not be taken by breast-feeding women.

**Preparation**
1 mg, 2 mg, 3 mg & 4 mg Tablet.

# Secrin® M

**Active Ingredient**
Glimepiride and Metformin Hydrochloride

**Indication**
Secrin® M is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Glimepiride and Metformin is appropriate.

**Dosage & Administration**
The initial recommended dose of Glimepiride & Metformin combination tablet is Glimepiride 1 mg & Metformin Hydrochloride 500 mg one tablet once daily with breakfast or first main meal of the day. Starting dose for patients inadequately controlled on Glimepiride or Metformin monotherapy is Secrin® M 1/500 tablet once daily, and gradually titrated after assessing the therapeutic response. During treatment with Glimepiride & Metformin combination tablet, glucose levels in blood and urine must be measured regularly.
Titration: The daily dose must be titrated in increments of 1 tablet. The maximum recommended
dose per day is 8 mg Glimepiride and 2000 mg Metformin. When switching from combination therapy of Glimepiride & Metformin to separate tablets, Glimepiride & Metformin should be administered separately on the basis of dosage currently being taken. Due to the sustained release

formulation, Secrin® M 1/500 tablet must be swallowed whole and not crushed or chewed. When Glimepiride & Metformin combination tablet is used in combination or with insulin, a lower dose of the Glimepiride or Insulin may be required to reduce the risk of hypoglycemia.

**Contraindication & Precaution**

For Glimepiride:

• In patients hypersensitive to Glimepiride, other sulfonylureas, other sulfonamides, or any of the excipients of Secrin® M tablet.

• In pregnant women, in breast feeding women.

For Metformin:

• Hypersensitivity to metformin or any of the excipients.

• Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.

• Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels >1.5 mg/dL [males], > 1.4 mg/dL [females] or abnormal creatinine clearance)

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**Adverse Effects**

For Glimepiride:

As a result of the blood glucose-lowering action of Glimepiride, hypoglycemia may occur which may also be prolonged. At the start of treatment, there may be temporary visual impairment due to the change in blood glucose levels. Occasionally, gastrointestinal symptoms e.g. nausea, vomiting, sensations of pressure or fullness in the epigastrium, abdominal pain and diarrhoea may occur. Occasionally, allergic or pseudo-allergic reactions may occur e.g. in the form of itching, urticaria or rashes.

For Metformin:

Gastrointestinal symptoms-nausea, vomiting, diarrhoea, abdominal pain and loss of appetite are very common.

**Drug Interaction**

*For Glimepiride:*

The hypoglycemic action of sulfonylureas may be potentiated by certain drugs, including NSAIDs and other drugs that are highly protein bound, such as salicylates, sulfonamides, chloramphenicol, coumarins, probenecid, MAO inhibitors, beta adrenergic blocking agents, and clarithromycin. Certain drugs tend to produce hyperglycemia and may lead to loss of control. These drugs include thiazides, and other diuretics, corticosteriods, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, and isoniazide. A potential interaction between oral miconazole and oral hypoglycemic drugs leading to severe hypoglycemia has been reported.

*For Metformin:*

No information is available about the interaction of Metformin and furosemide when co-administered chronically. Nifedipine appears to enhance the absorption of Metformin. Metformin had minimal effects on nifedipine. Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with Metformin by competing for common renal tubular transport systems. Metformin had no effect on cimetidine pharmacokinetics. Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid.

**Use in Pregnancy & Lactation**

*Pregnancy:* The use of Glimepiride & Metformin combination is not recommended for use in pregnancy. Intake may cause risk/harm to child. It is recommended that such patients change over to insulin.

*Lactation:* The use of Glimepiride & Metformin combination is not recommended for use in lactating mothers, and if the diet alone is inadequate for controlling blood glucose, insulin therapy should be considered.

*Geriatric use:* Metformin is substantially excreted by the kidneys, and because aging is associated with reduced renal function, Glimepiride & Metformin combination should be used with caution in the elderly.

*Pediatric use:* Safety and effectiveness of Glimepiride & Metformin combination in pediatric patients have not been established.

**Preparation**

1 mg & 500 mg Tablet.

# Sedil®

**Active Ingredient**
Diazepam.

**Indication**
Anxiety pain from apprehension & depression, acute & chronic stress of life, skeletal muscle spasm & strychnine poisoning. For surgical measures, Sedil is a useful premedication (I.M. route recommended).

**Dosage & Administration**
Sedil 15 to 30 mg daily in divided doses.

**Contraindication & Precaution**
Sedil is contraindicated in patients with known history of hypersensitivity to it. Porphyria or a family history of porphyria contraindicates the use of Sedil.

**Side Effect**
Infrequent & mild. Drowsiness, headedness, ataxia, vertigo, dry mouth, inattentiveness, hypotension, gastro-intestinal & visual disturbances.

**Drug Interaction**
If diazepam is given concomitantly with centrally acting drugs such as neuroleptics, tranquillizers, antidepressants, hypnotics, analgesics & anaesthetics, the sedative effects are likely to be intensified.

**Use in Pregnancy & Lactation**
· Pregnancy category D
·Breastfeeding is not recommended during treatment

**Preparation**
5 mg Tablet & 10 mg/2 ml Injection.

# Sedno®

**Active Ingredient**
Desloratadine.

**Indication**
Allergic Rhinitis, Chronic Idiopathic Urticaria.

**Dosage & Administration**
Adult & over 12 years: Syrup: 10 ml (2 teaspoonful) once daily. Tablet : One tablet (5 mg) once daily. Children 6-11 years : Syrup: 5 ml (1 teaspoonful) daily. Tablet : 2.5 mg (half of one 5 mg tablet) once daily. Children 1-5 years: Syrup: 2.5 ml (1/2 teaspoonful) daily. Children 6-11 months : Syrup: 2 ml (1.0 mg) once daily or as directed by the physician. Patients with liver or renal Impairment: A starting dose of one Sedno® Tablet (Desloratadine 5 mg) every other day is recommended.

**Contraindication & Precaution**
Hypersensitive to this medication or to any of its ingredients, or to Loratadine. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal or cardiac function, & of concomitant disease or other drug therapy.

**Side Effect**
In general it is well tolerated. Clinical trials suggest a very low rate of adverse effects associated with Desloratadine administration. among the very few adverse effects commonly reported by small percentage of patients are dry mouth, fatigue, myalgia, & somnolence. Less common side effects may include headache, nausea, dizziness, dyspepsia, pharyngitis etc.

**Drug Interaction**
Concomitant administration of Erythromycin, Ketoconazole, Azithromycin, Fluoxetine & Cimetidine with Desloratadine increased the plasma concentration of Desloratadine. But there were no clinically relevant changes in the safety profile of Desloratadine.

**Use in Pregnancy & Lactation**
Category C. Desloratadine should be used during pregnancy only if clearly needed.

A decision should be made whether to discontinue nursing or to discontinue Desloratadine, taking into account the importance of the drug to the mother.

**Preparation**
5 mg Tablet & 2.5 mg/5 ml Syrup.

# Siglimet™

**Active Ingredient**
Sitagliptin Phosphate Monohydrate & Metformin HCl.



**Indication**
**Siglimet**™ is indicated as an adjunct to diet & exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Sitagliptin & Metformin is appropriate

**Dosage & Administration**
Dose of this combination should be individualized on the basis of the patient's current regimen, Effectiveness, & tolerability while not exceeding the maximum recommended daily dose of 100 mg sitagliptin & 2000 mg metformin. Sitagliptin/Metformin combination should generally be given twice daily with meals, with gradual dose escalation, to reduce the gastrointestinal (GI) side effects due to metformin. The recommended starting dose in patients not currently treated with metformin is 50 mg sitagliptin/500 mg metformin hydrochloride twice daily, with gradual dose escalation recommended to reduce gastrointestinal side effects associated with metformin. The starting dose in patients already treated with metformin should provide sitagliptin dosed as 50 mg twice daily (100 mg total daily dose) & the dose of metformin already being taken. For patients taking metformin 850 mg twice daily, the recommended starting dose of this combination is 50 mg sitagliptin/1000 mg metformin hydrochloride twice daily.
Patients treated with an insulin secretagogue or insulin Co-administration of the combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may require lower doses of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.

**Contraindication & Precaution**
Combination (sitagliptin/metformin HCl) is contraindicated in patients with:
- Renal disease or renal dysfunction, e.g., as suggested by serum creatinine levels ≥1.5 mg/dL [males], ≥1.4 mg/dL [females]
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.
- History of a serious hypersensitivity reaction to the combination or sitagliptin, such as anaphylaxis or angioedema.

**Side Effect**
The most common (>5%) adverse reactions due to initiation of metformin therapy are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, & headache

**Drug Interaction**
Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine,triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems.
Co-administration of Digoxin & Sitagliptin may slightly increase the mean peak drug concentration of Digoxin. But no dosage adjustment of digoxin or Sitagliptin is recommended.

**Use in Pregnancy & Lactation**
Pregnancy Category B. There are no adequate & well-controlled studies in pregnant women with the combination of Metformin/Sitagliptin or its individual components; therefore, the safety of the combination in pregnant women is not known. The combination of sitagliptin &

metformin should be used during pregnancy only if clearly needed.

Nursing Mothers:
It is not known whether sitagliptin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SiglimetTM is administered to a nursing woman.

**Use in Children**
Safety & Effectiveness of Sitagliptin/Metformin in pediatric patients under 18 years of age have not been established

**Preparation**
SiglimetTM 50/500 Tablet: SiglimetTM 50/1000 Tablet: SiglimetTM XR 50/500 Tablet: SiglimetTM XR 50/1000 Tablet: SiglimetTM XR 100/1000 Tablet.

# Siglita™

**Active Ingredient**
Sitagliptin Phosphate Monohydrate.

**Indication**
For the Management of Type 2 Diabetes

**Dosage & Administration**
- The recommended dose of SiglitaTM is 100 mg once daily. Siglita™ can be taken with or without food.
- For patients with mild renal insufficiency (creatinine clearance [CrCl] ≥50 mL/min) no dosage adjustment for Siglita™ is required.
- For patients with moderate renal insufficiency (CrCl ≥30 to <50 mL/min), the dose of Siglita is 50 mg once daily.
- For patients with severe renal insufficiency (CrCl <30 mL/min) or with end-stage renal disease (ESRD) requiring hemodialysis or peritoneal dialysis, the dose of Siglita™ is 25 mg once daily. Siglita™ may be administered without regard to the timing of hemodialysis.

**Contraindication & Precaution**
History of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema.

**Side Effect**
The most common adverse reactions are; upper respiratory tract infection, nasopharyngitis & headache. Hypoglycemia may occur in patients treated with the combination of Sitagliptin & sulfonylurea & add-on to insulin.

**Drug Interaction**
Co-administration of Digoxin & Sitagliptin may slightly increase the mean peak drug concentration of Digoxin. But no dosage adjustment of digoxin or Sitagliptin is recommended.

**Use in Pregnancy & Lactation**
Pregnancy Category B
Safety of Sitagliptin in pregnant women has not been established. Sitagliptin should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus.
Nursing Mothers: It is not known whether sitagliptin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sitagliptin is administered to a nursing woman.

**Use in Children**
Safety & Effectiveness of Sitagliptin in pediatric patients under 18 years of age have not been established.

**Preparation**
Siglita 50 mg Tablet.



S

# Solider™

**Active Ingredients**
Solifenacin Succinate INN 5 mg & 10 mg.

**Indications**
Symptomatic treatment of urge incontinence and increased urinary frequency and urgency occur in patient with Overactive Bladder syndrome.

**Dosage & Administration**
The recommended dose of Solifenacin Succinate is 5 mg (One Solider™ 5) once daily. If the 5 mg dose is well tolerated, the dose may be increased to 10 mg (one Solider™ 10) once daily. Solifenacin Succinate should be taken with liquids and swallowed whole. Solifenacin Succinate (Solider™ Tablet) can be administered with or without food, without regard to meals. The maximum effect can be determined after 4 weeks at the earliest.



**Contraindication**
Contraindicated in patients with hypersensitivity to Solifenacin, angioedema, urinary retention, dependent on dialysis, gastroparesis or uncontrolled narrow angle glaucoma and in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the product.

**Adverse Effect**
Side effects of antimuscarinic agents are dry mouth, constipation, blurred vision (accommodation abnormalities), urinary retention and dry eyes.

**Use in Pregnancy and Lactation**
Pregnancy Category C. There are no adequate and well-controlled studies investigating the effects of Solifenacin Succinate in pregnant women. Therefore, Solifenacin Succinate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Women of childbearing potential should be considered for treatment only if using adequate contraception.
Lactating Mother – It is not known whether Solifenacin is excreted in human milk. Because many drugs are excreted in human milk, Solifenacin should not be administered during nursing.
Pediatric Use - Safety and efficacy is not established in children below 18 years of age.

**Dosing considerations**
Dose Adjustment in Renal Impairment: For patients with severe renal impairment (CrCl < 30 mL/min), a daily dose of Solifenacin Succinate greater than 5 mg is not recommended. Solifenacin Succinate is contraindicated in dialysis dependent patients. Dose Adjustment in Hepatic Impairment: For patients with moderate hepatic impairment (Child-Pugh B), a daily dose of Solifenacin Succinate greater than 5 mg is not recommended. Use of Solifenacin Succinate in patients with severe hepatic impairment (Child Pugh C) is not recommended. Dose Adjustment with CYP450, 3A4 Inhibitors: When administered with therapeutic doses of ketoconazole or other potent CYP450, 3A4 inhibitors, e.g. Ritonavir, Nelfinavir, Itraconazole a daily dose of Solifenacin Succinate should be maintained at, or dropped to, 5 mg daily.

**Warning**
Solifenacin Succinate 5 mg should be used with caution in patients with: clinically signi¬ficant bladder outlet obstruction at risk of urinary retention, GI obstructive disorders, risk of decreased GI motility & should not exceed 5 mg. Patient with severe renal impairment (CrCl < 30 mL/min), moderate hepatic impairment (Child-Pugh B), a daily dose of Solifenacin Succinate greater than 5 mg is not recommended. Prolongation of QT Interval: 30-mg daily dosage associated with more pronounced prolongation of QT interval than 10-mg daily dosage. Controlled Angle-closure Glaucoma: Use with caution in patients being treated for angle-closure glaucoma.

**Drug-Drug Interactions**
Drugs metabolized by cytochrome P450: At therapeutic concentrations, Solifenacin does not inhibit CYP1A1/2, 2C9, 2C19, 2D6, or 3A4 derived from human liver microsomes. CYP3A4

inhibitors: In vitro drug metabolism studies have shown that Solifenacin is a substrate of CYP3A4. Inducers or inhibitors of CYP3A4 may alter Solifenacin pharmacokinetics. Following the administration of 10 mg of Solifenacin in the presence of 400 mg of ketoconazole, a potent inhibitor of CYP3A4, the mean C and AUC of Solifenacin increased by 1.5 and 2.7 fold, respectively. Therefore, it is recommended not to exceed a 5 mg daily dose of Solifenacin when administered with therapeutic doses of ketoconazole or other potent CYP3A4 inhibitors. Oral Contraceptives: In the presence of Solifenacin there are no significant changes in the plasma concentrations of combined oral contraceptives (ethinyl estradiol/levonorgestrel). Warfarin & Digoxin: Solifenacin has no signi¬ficant effect on the pharmacokinetics of R-warfarin or S-warfarin & Digoxin.

**Preparation**
5 mg & 10 mg Tablet.

**Dosage & Administration**
Infants, children & adults : 2-6 drops into each nostril as needed daily.

**Contraindication & Precaution**
Tell your doctor about your medical history, especially of heart problems (e.g., congestive heart failure), lung problems (pulmonary edema), kidney problems, low levels of potassium (hypokalemia), high levels of sodium (hypernatremia), & any allergies.

**Side Effect**
No side effects are expected to occur. However stinging, sneezing, increased nasal discharge, or salty taste may occur in some cases.

**Use in Pregnancy & Lactation**
It is unknown if this medication passes into breast milk. Consult with your doctor before breast-feeding.

**Use in Children**
Safe for pediatrics

**Preparation**
10 ml.

S

# Solo™

**Active Ingredient**
Sodium Chloride 0.9%.

**Indication**
Solo Nasal Drops is indicated for dry nasal membranes including dry nose resulting from cold & allergy medications. It moistens dry nasal passages from dry climates or from airplane travel, may help dissolve mucus from stuffy noses & clears the nose after surgery. This sterile saline solution is also used to cleanse various parts of the body (wounds, body cavities) & medical equipment (e.g. bandages, catheters, drainage tubes). It is also used as a mixing solution (diluent) for other medications used to irrigate the body (e.g. bacitracin, polymyxin).

# Solo™ 0.9% IV

**Active Ingredient**
Sodium Chloride BP 0.9% w/v

**Indication**
These intravenous solutions are indicated for use in adults and pediatric patients as sources of electrolytes and water for hydration.
0.9% Sodium Chloride infusion is indicated for extracellular fluid replacement, treatment of metabolic alkalosis in the presence of fluid loss, and mild sodium depletion. 0.9% Sodium Chloride infusion is also indicated for use as a priming solution in hemodialysis procedures.

It is also indicated as pharmaceutical aids and diluents for the infusion of compatible drug additives.

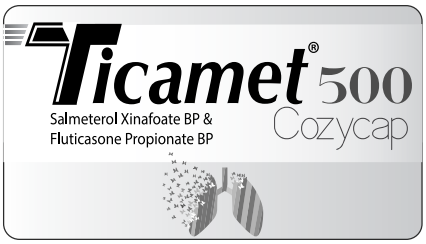
**Dosage & Administration**
The concentration and dosage of Sodium Chloride solution for intravenous use is determined by several factors including age, weight and clinical condition of the patient. Usually the adult dose is about 1000 ml of 0.9% infusion.

**Contraindication & Precaution**
These solutions are contraindicated where the administration of sodium or chloride could be clinically detrimental.
Serum electrolyte concentration should be carefully monitored. Sodium Chloride should be administered with caution to patients with congestive heart failure, peripheral or pulmonary oedema, impaired renal function or pre-eclampsia.



**Use in Pregnancy & Lactation**
Pregnancy Category C. It is also not known whether Sodium Chloride Infusion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Chloride Infusion is administered to a nursing woman.

**Preparation**
500 & 1000 ml intravenous infusion.




# Solodex™ IV

**Active Ingredient**
Sodium Chloride BP 0.9% w/v and Dextrose USP 5% w/v

**Indication**
Solodex solution is indicated when there is combined water and sodium depletion occurs. It provides Dextrose as a nutrient in a suitable medium of Sodium Chloride which is isotonic to body fluid, or it may also be employed as a source of isotonic Sodium Chloride or both. It is usually used in the maintenance and replacement of fluid, electrolyte and carbohydrate in patients who are unable to take fluid and nutrients by mouth e.g. in case of persistent vomiting, during and after surgery, shock or accidents.

**Dosage & Administration**
Dose is variable. It depends on the clinical condition, age and body surface area of the patients.

**Contraindication & Precaution**
0.9 % w/v Sodium Chloride and 5 % w/v Glucose Intravenous Infusion must not be used in cases of hyperhydration states, hypotonic dehydration and hypokalemia.
As the preparation contains Sodium Chloride, it should be administered with caution to patients with congestive heart failure, peripheral or pulmonary oedema, impaired renal function or preeclampsia.

**Use in Pregnancy & Lactation**
Pregnancy Category C. It is also not known whether Dextrose and Sodium Chloride Infusion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose & Sodium Chloride Infusion is administered to a nursing woman.

**Preparation**
Solodex 1000 ml: Each 1000 ml PP bottle

contains solution of Sodium Chloride BP 0.9% w/v and Dextrose 5% USP w/v.
Solodex 500 ml: Each 500 ml PP bottle contains solution of Sodium Chloride BP 0.9% w/v and Dextrose 5% USP w/v.

human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose & Sodium Chloride Infusion is administered to a nursing woman.

**Preparation**
Solodex™ JR IV, 500 ml: Each 500 ml PP bottle contains solution of Sodium Chloride BP 0.45% w/v and Dextrose Anhydrous USP 5% w/v.

# Solodex™ JR IV

**Active Ingredient**
Sodium Chloride BP 0.45% w/v and Dextrose Anhydrous USP 5% w/v

**Indication**
It is indicated in water and sodium depletion. It provides Dextrose as a nutrient in a suitable medium of Sodium Chloride or it may also be employed as a source of Sodium Chloride. It is usually used in the maintenance and replacement of fluid, electrolyte and carbohydrate in patients (especially for children) who are unable to take fluid and nutrients by mouth e.g. in case of persistent vomiting, during and after surgery, shock or accidents.

**Dosage & Administration**
The volume and rate of infusion of the solution depends on the clinical condition, age and body surface area of the patient and judgment of the physicians.

**Contraindication & Precaution**
It is contraindicated in patients with hypernatremia, acidosis, hypokalemia and fluid overload.

**Use in Pregnancy & Lactation**
It is also not known whether Dextrose and Sodium Chloride Infusion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.
It is not known whether this drug is excreted in

# Solodex™ Baby IV

**Active Ingredient**
Sodium Chloride BP 0.225% w/v and Dextrose Anhydrous USP 5% w/v

**Indication**
It is indicated in water and sodium depletion. It provides Dextrose as a nutrient in a suitable medium of Sodium Chloride or it may also be employed as a source of Sodium Chloride. It is usually used in the maintenance and replacement of fluid, electrolyte and carbohydrate in patients (especially for neonates & infants) who are unable to take fluid and nutrients by mouth e.g. in case of persistent vomiting, during and after surgery, shock or accidents.

**Dosage & Administration**
The volume and rate of infusion of the solution depends on the clinical condition, age and body surface area of the patient and judgment of the physicians.

**Contraindication & Precaution**
It is contraindicated in patients with hypernatremia, acidosis, hypokalemia and fluid overload.

**Use in Pregnancy & Lactation**
It is also not known whether Dextrose and Sodium Chloride Infusion can cause fetal harm

when administered to a pregnant woman or can affect reproduction capacity.
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose & Sodium Chloride Infusion is administered to a nursing woman.

**Preparation**
Solodex™ Baby IV, 500 ml: Each 500 ml PP bottle contains solution of Sodium Chloride BP 0.225% w/v and Dextrose Anhydrous USP 5% w/v.

S

# Sonap®

**Active Ingredient**
Naproxen Sodium.

**Indication**
Rheumatoid Arthritis, Degenerative Arthritis, Ankylosing Spondylitis, Juvenile Rheumatoid Arthritis, Tendinitis, Bursitis, acute gout, acute musculoskeletal disorders (such as sprains, direct trauma & fibrositis), migraine & dysmenorrhoea.

**Dosage & Administration**
*Tablet* - Rheumatoid Arthritis, Osteoarthritis, Ankylosing Spondylitis: 250 to 500 mg twice daily. May be increased to 1.50 gm for limiting periods. Mild to moderate pain, primary dysmenorrhoea, acute tendinitis, bursitis, & dysmenorrhoea: 500 mg initially, followed by every 250 mg every 6 to 8 hours as required. Do not exceed a 1.375 gm total daily dose. Acute gout: 750 mg, then 250 mg every6 8 hours until attack subsides. Juvenile arthritis (Children over 5 years): 10 gm/kg daily in two divided doses is recommended.

**Contraindication & Precaution**
Naproxen should be used with caution in patients with cardiac, hepatic & renal impairment, coagulation defect, & previous history of gastro-intestinal ulceration. The drug is contraindicated in patients with a history of hypersensitivity to aspirin or any other NSAID - which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID.

**Side Effect**
Nausea, diarrhoea, occasionally bleeding & ulceration. Hypersensitivity reactions : bronchospasm, rashes & angioedema. CNS side effects : drowsiness, headache, fluid retention, vertigo, tinnitus, & photosensitivity. A few instances of jaundice, impairment of renal function, thrombocytopenia, & agranulocytosis.

**Drug Interaction**
ACE inhibitors, coumarin-type anticoagulants, sulfonylureas, propranolol & other beta-blockers, probenecid, methotrexate.

**Use in Pregnancy & Lactation**
The drug should not be used during pregnancy unless clearly needed. Use in nursing mothers must be avoided.

**Preparation**
250 mg & 500 mg Tablet.

# Specbac®

**Active Ingredient**
Meropenem.

**Indication**
Pneumonias & Nosocomial Pneumonias, Urinary Tract Infections, Intra-abdominal Infections, Gynaecological Infections such as

endometritis, Skin & Skin Structure Infections, Meningitis, Septicaemia, Empiric treatment for presumed infections in adult patients with febrile neutropenia & other polymicrobial infections.

**Dosage & Administration**
Adults : In the treatment of pneumonia, UTI, gynaecological infections such as endometritis, skin & skin structure infections- 500 mg IV every 8 hours. In the treatment of nosocomial pneumonias, peritonitis, presumed infections in neutropenic patients, septicaemia- 1 g IV every 8 hours, In cystic fibrosis- doses up to 2 gm every 8 hours, In meningitis- 2 gm every 8 hours. Children : Over 3 months to 12 years - 10 to 20 mg/kg every 8 hours, Children over 50 kg weight, adult dosage should be used, 4 years to 18 years with cystic fibrosis - 25 to 40 mg/kg every 8 hours, In meningitis - 40 mg/kg every 8 hours

**Contraindication**
Hypersensitivity to this product.

**Adverse Effect**
Inflammation, thrombophlebitis, pain at the site of injection, Skin reactions like rash, pruritus, urticaria etc, abdominal pain, nausea, vomiting, diarrhoea,headache, paraesthesiae.

**Precaution**
As with all beta-lactam antibiotics, rare hypersensitivity reactions have been reported. Before initiating therapy with meropenem, careful inquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics. The co-administration of Specbac with potentially nephrotoxic drugs should be considered with caution.

**Use in Pregnancy & Lactation**
Specbac should not be used in pregnancy unless the potential benefit justifies the potential risk to the foetus. Specbac should not be used in breastfeeding women unless the potential benefit justifies the potential risk to the baby.

**Preparation**
250 mg, 500 mg & 1 gm IV Injection.

# Splendora™

**Active Ingredient**
Minoxidil

**Indication**
For the treatment of alopecia androgenetica (hair loss) in males & females between 18 to 65 years of age.

**Dosage & Administration**
Apply 1 ml (7 sprays) of Splendora™ topical solution twice daily at 12-hour intervals to the scalp, beginning at the centre of the affected area & spreading the solution out to cover the entire affected area. The total daily application dose should not exceed 2 ml. For the best results, Splendora™ topical solution should be allowed to remain on the scalp for about 4 hours before washing. The night-time application should be done 2–4 hours before going to bed to allow the solution to dry out. Splendora™ topical solution should not be massaged into the scalp, but applied lightly. A hair dryer should not be used to speed up the drying of the solution as it may decrease the effectiveness. Splendora™ topical solution should not be mixed with any hair oil. The drug should not be used more than two times a day, or be taken orally or applied to any other part of the body to avoid the risk of adverse effects & unwanted hair growth. More frequent use or longer application time have no effect on hair growth. In case of missing any daily applications of Splendora™ topical solution, the patient should continue with the next application. Hands should be washed immediately if Minoxidil topical solution is applied with the fingertips. Clinical experience with Splendora™ indicates that twice-daily applications for 4 months or more may be required before there is evidence of hair growth. To arrest hair fall, Splendora™ topical solution should be used for not less than 45 days. Depending upon the severity of hair loss or type & extent of baldness, particular strength of Splendora™ topical solution may be selected.

**Contraindication**
- Patients with cardiac abnormalities
- Children below 18 years of age

• Patients using occlusive dressings or other medicines on the scalp
• Patients with red, inflamed infection, or irritated or painful scalp (including psoriasis & sunburn)

**Side Effect**
Dermatitis or hypertrichosis may occur. These incidences may occur in 0.1–5% of patients.

**Drug Interaction**
Minoxidil topical solution should not be used along with other topical agents known to alter the stratum corneum barrier such as tretinoin or dithranol, due to the enhanced absorption of Minoxidil. Although there is no clinical evidence, there exists the theoretical possibility of absorbed Minoxidil potentiating orthostatic hypotension caused by peripheral vasodilators.

**Use In Pregnancy & Lactation**
Minoxidil topical solution should not be used during pregnancy & lactation.

**Preparation**
5% topical solution.



# SQ-Mycetin® Eye/Ear Drops

**Active Ingredient**
Chloramphenicol

**Indication**
Bacterial infection involving conjunctiva or cornea & otitis externa.

**Dosage & Administration**
Eye : 2 drops every 1-4 hours depending upon the severity. Ear : 2-3 drops every 3-4 hours.

**Contraindication & Precaution**
Hypersensitivity or toxic reactions. Blood dyscrasias (granulocytopenia, thrombocytopenia & moderate anaemia) may occur after prolonged ophthalmic use.

**Side Effect**
Bone marrow hypoplasia. Rarely optic atrophy in children, stinging & burning of the eye, vesicular or maculopapular dermatitis, sore throat & angioedema.

**Drug Interaction**
Chymotryptin will be inhibited if given simultaneously with Chloramphenicol.

**Use in Pregnancy & Lactation**
Use only when considered essential by the physicians.

**Preparation**
0.5% Eye/Ear Drops.

# Square Zinc®

**Active Ingredient**
Zinc Sulphate Monohydrate USP

**Indication**
SQUARE Zinc® (Zinc Sulphate Monohydrate) is indicated for the treatment of diarrhea, especially for the children from 2 months to 5 years of age in connection with Oral Rehydration Salts (ORS). SQUARE Zinc® (Zinc Sulphate Monohydrate) is also indicated for the treatment of other zinc deficiency (Loss of appetite, Severe growth retardation, Deformed bone formation, Impaired immunological response, Recurrent Respiratory Tract Infections, Acrodermatits enteropathica, Parakeratatic skin lesions, Defective and

delayed wound healing, Anaemia, Night blindness, Mental disturbances.

**Dosage & Administration**
In the treatment of Diarrhoea: Zinc should be given as soon as diarrhea starts. For infants between 2 to 6 months of age: 10 mg elemental zinc once daily for 10-14 days. For children between 6 months to 5 years of age: 20 mg elemental zinc once daily for 10-14 days. For other indications: The recommended dose for children is 2 to 2.5 mg/kg/day Children under 10 kg: 10 mg elemental zinc 2 times daily. Children within 10 to 30 kg: 20 mg elemental zinc 1-3 times daily. Adults and children over 30 kg body weight: 40 mg elemental zinc 1-3 times daily.

**Contraindication**
It is contraindicated in patients with hypersensitivity to zinc.

**Precaution & Warning**
Concurrent administration of Zinc salt with penicillamine might diminish the effect of Penicillamine. The absorption of Zinc, although poor, may be decreased by various compounds including some foods. Chelation may occur with tetracyclines.

**Drug Interaction**
Zinc may inhibit the absorption of concurrently administered tetracyclines, when both are being given an interval of at least 3 hours should be allowed.

**Overdose**
Zinc sulphate is corrosive in over dose. Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach; ulceration of the stomach followed by perforation may occur. Gastric lavage and emesis should be avoided. Demulcents such as milk should be given. Chelating agents such as sodium edetate may be useful.

**Preparation**
20 mg Tablet

## Sulprex™ HFA Inhaler

**Active Ingredient**
Ipratropium + Salbutamol.

**Indication**
Sulprex HFA Inhaler is indicated for use in patients with chronic obstructive pulmonary disease (COPD) & asthma on a regular aerosol bronchodilator who continue to have evidence of bronchospasm & who require a second bronchodilator.

**Dosage & Administration**
The dose of Sulprex Inhalation Aerosol is two inhalations four times a day. Patients may take additional inhalations as required; however, the total number of Inhalations should not exceed 12 in 24 hours.

**Contraindication & Precaution**
Salbutamol & Ipratropium Bromide combination Inhalation Aerosol is contraindicated in patients with a history of hypersensitivity to soya lecithin or related food products such as soybean & peanut.

**Side Effect**
Adverse reactions, includes edema, fatigue, hypertension, dizziness, nervousness, paresthesia tremor, dysphonia, insomnia, diarrhea, dry mouth, dyspepsia, vomiting, arrhythmia, palpitation, tachycardia, arthralgia, angina, increased sputum, taste perversion, & urinary tract infection/dysuria.

**Preparation**
Sulprex HFA Inhaler : Each puff delivers 20 mcg of Ipratropium bromide & 100 mcg of Salbutamol, 200 puffs.



S

# Sulprex™ Nebuliser Solution

**Active Ingredient**
Ipratropium + Salbutamol.

**Indication**
The management of bronchospasm in patients suffering from chronic obstructive pulmonary disease.

**Dosage & Administration**
Sulprex Nebuliser Solution may be administered from a suitable nebuliser or an intermittent positive pressure ventilator. Adults (including elderly patients & children over 12 years): 1 ampoule three or four times daily.

**Contraindication & Precaution**
It is contraindicated in patients with hypertrophic obstructive cardio- myopathy or tachyarrhythmia & in patients with hypersensitivity to ipratropium bromide, salbutamol sulphate or to atropine or its derivatives.

**Side Effect**
Dry mouth, Nervousness, Dizziness, Tremor, headache, Palpitations, Tachycardia, Cough, Dysphonia, Nausea, Arrhythmia, Atrial fibrillation, Myocardial ischaemia.

**Use in Pregnancy & Lactation**
It should not be used in pregnancy, especially the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus. Similarly, it should not be administered to breast-feeding mothers unless the expected benefit is thought to outweigh any possible risk to the neonate.

**Preparation**
(Ipratropium 500 mcg + Salbutamol 2.5 mg)/2.5 ml, 10 ampoule.

# Sultolin®

**Active Ingredient**
Salbutamol.

**Indication**
Bronchial asthma, Chronic bronchitis, Emphysema.

**Dosage & Administration**
Sultolin SR tablet: 8 mg tablet twice daily Sultolin syrup: 1-2 mg 3 to 4 times daily. Not recommended below 2 years of age. Sultolin 100 HFA Inhaler : 2 puffs 3-4 times daily. Sultolin Cozycap: 1-2 Cozycap may be administered as a single dosage. The usual recommended dosage of Sultolin Cozycap for inhalation for adults for maintenance or prophylactic therapy is the contents of one 200 mg capsule every 4 to 6 hours using a revolizer device.

**Contraindication & Precaution**
Hypersensitivity to the active ingradient.

**Side Effect**
Nervousness, tremor, headache, tachycardia, & palpitation. Less frequent adverse reactions are muscle cramps, insomnia, nausea, weakness, dizziness, & chest discomfort.

**Drug Interaction**
Other oral sympathomimetic agents should not be used concomitantly. Cautions to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants.

**Preparation**
8 mg SR Tablet, 2 mg/5 ml Syrup, HFA Inhaler (100 µg/puff), 200 µg DPI Capsule.

# Sultolin® Respirator Solution

**Active Ingredient**
Salbutamol

**Indication**
Treatment of severe acute asthma (status asthmaticus) & also forms of bronchospasm in adults & children. It is also Effective in children >18 months.

**Dosage & Administration**
By Intermittent Administration : Adult : Sultolin Respirator Solution 0.5-1.0 ml should be diluted to final volume of 2.0-4.0 ml with normal saline for injection. The resulting solution is inhaled from a suitably driven nebulizer until aerosol generation ceases. Should take about 10 minutes. Sultolin Respirator Solution may be used undiluted for intermittent administration. For this 2.0 ml of the solution is placed in the nebulizer & the patient allowed to inhale until bronchodilatation is achieved. This usually takes 3-5 minutes. Children under 12 years age: 0.5 ml of the solution diluted to 2.0-4.0 ml with normal saline. Intermittent treatment may be repeated four times a day. By Continuous Administration : Sultolin Respirator Solution is diluted with normal saline for injection, 1-2 ml solution made upto 100 ml with diluent. The diluted solution is administered as an aerosol by a suitably driven nebulizer. The usual rate of administration is 1-2 mg/hour.

**Contraindication & Precaution**
History of hypersensitivity to any of its components. It should be used with care in patients known to have received large doses of other sympathomimetic drugs & in thyrotoxicosis.

**Side Effect**
Small increase in heart rate, peripheral vasodilation & fine tremor of skeletal muscle.

**Use in Pregnancy**
Unnecessary administration of drugs during the first trimester of pregnancy is undesirable.

**Preparation**
5 mg Salbutamol/ml, 20 ml Respirator Solution.

# Susten™

**Active Ingredient**
Dapoxetine Hydrochloride

**indication**
Indicated for the treatment of premature ejaculation (pe) in men 18 to 64 years of age, who have all of the following:
- persistent or recurrent ejaculation with minimal sexual stimulation before, on or shortly after penetration and before the patient wishes.
- marked personal distress or interpersonal difficulty as a consequence of pe and poor control over ejaculation.

**Dosage & Administration**
Adult men (18 to 64 years of age) : the recommended starting dose for all patients is 30 mg, taken as needed approximately 1 to 3 hours prior to sexual activity. If the effect of 30 mg is insufficient and the side effects are acceptable, the dose may be increased to the maximum recommended dose of 60 mg. The maximum recommended dosing frequency is one dose every 24 hours.

**Over dosage**
There were no unexpected adverse events in a clinical pharmacology study of dapoxetine with daily doses up to 240 mg. In general, symptoms of overdose with ssris include serotonin-mediated adverse reactions such as somnolence, gastrointestinal disturbances such as nausea and vomiting, tachycardia, tremor, agitation and dizziness. In cases of overdose, standard supportive measures should be adopted as required.

**Side Effect**
Dizziness, headache, somnolence, tremor, blurred vision, tinnitus, sinus congestion, nausea, diarrhea, abdominal pain, dry mouth, fatigue, insomnia, hypertension.

**Contraindication**
- patients with known hypersensitivity to dapoxetine hydrochloride.
- patients with significant pathological cardiac

conditions such as heart failure (nyha class ii-iv), conduction abnormalities (second or third degree av block or sick sinus syndrome) not treated with a permanent pacemaker, significant ischemic heart disease of significant valvular disease.
- concomitant treatment with monoamine oxidase inhibitors (maois), thioridazine. Similarly, maois or thioridazine should not be administered within 7 days after dapoxetine has been discontinued.
- concomitant treatment with serotonin reuptake inhibitors (ssris), serotonin-norepinephrine reuptake inhibitors (snris), tricyclic antidepressants (tcas) or other medicinal/herbal products with serotonergic effects or within 14 days of discontinuing treatment with these medicinal/herbal products.

**Drug interaction**
Cns active medicinal products: the use of dapoxetine in combination with cns active medicinal products has not been systematically evaluated in patients with premature ejaculation. Consequently, caution is advised if the concomitant administration of dapoxetine and such medicinal products is required.

Pde5 inhibitors: tadalafil did not affect the pharmacokinetics of dapoxetine. Sildenafil caused slight changes in dapoxetine pharmacokinetics, which are not expected to be clinically significant. However, dapoxetine should be prescribed with caution in patients who use pde5 inhibitors due to possible reduced orthostatic tolerance.

Tamsulosin: concomitant administration of single or multiple doses of 30 mg or 60 mg dapoxetine to patients receiving daily doses of tamsulosin did not result in changes in the pharmacokinetics of tamsulosin. However, dapoxetine should be prescribed with caution in patients who use alpha adrenergic receptor antagonists due to possible reduced orthostatic tolerance.

Warfarin: there are no data evaluating the effect of chronic use of warfarin with dapoxetine; therefore, caution is advised when dapoxetine is used in patients taking warfarin chronically.
Ethanol: concomitant use of alcohol and dapoxetine could increase the chance or severity of adverse reactions such as dizziness, drowsiness, slow reflexes, or altered judgment. Combining alcohol with dapoxetine may increase these alcohol-related effects and may also enhance neurocardiogenic adverse events such as syncope, thereby increasing the risk of accidental injury; therefore, patients should be advised to avoid alcohol while taking dapoxetine.

**Use in Pregnancy & Lactation**
Dapoxetine is not indicated for use by women.

**Preparation**
30 mg tablets.



# Suvotol

**Active Ingredient**
Suvorexant.

**Indication**
Insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

**Dosage & Administration**
Recommended dose is 10 mg, no more than once per night taken before 30 minutes of going to bed, with at least 7 hours remaining before the planned time of awakening.
Time to effect may be delayed if taken with or soon after a meal.

**Contraindications**
Do not use in patients with narcolepsy.

**Special Warning & Precautions**
Daytime somnolence: Risk of impaired

alertness and motor coordination, including impaired driving; risk increases with dose; caution patients taking 20 mg against next-day driving and other activities requiring complete mental alertness.
Need to evaluate for co-morbid diagnoses: Reevaluate if insomnia persists after 7 to 10 days of treatment.

**Side Effects**

- sleepiness during the day
- not thinking clearly
- act strangely, confused, or upset
- sleep-walking

**Use in Pregnancy & Lactation**
Pregnancy Category C.
There is no adequate and well-controlled studies in pregnant women.

**Preparation**
10 mg Tablet

**Dosage & Administration**
1-3 tablets daily with meal or as per direction of the physician.

**Contraindication & Precaution**
A proper balance between fat, protein & starch intake must be maintained to avoid temporary indigestion.

**Side Effect**
Pancreatin may cause buccal & perianal soreness, particularly in infants. Hypersensitivity reactions have been reported; these may be sneezing, lacrimation or skin rashes.

**Drug Interaction**
Alkaline media will rupture the enteric coating. As such to prevent bursting out of the content in the stomach. Pancreatin should not be used concurrently with antacid.

**Use in Pregnancy & Lactation**
Pregnancy category C. Not known whether Pancreatin is distributed into milk. Caution advised if Pancreatin is used.

**Preparation**
325 mg tablet.



# Suzyme®

**Active Ingredient**
Pancreatin

**Indication**
*Children:* - Reduced or absence of pancreatic exocrine secretion
-Cystic fibrosis
*Adults:* In the conditions with deficient pancreatic exocrine function such as
-Following pancreatectomy
-Following total gastrectomy
-Chronic pancreatitis
-Steatorrhea
-Somatostatinoma
-Celiac disease

# Tazid®

**Active Ingredient**
Ceftazidime.

**Indication**
Single infections, Mixed infections, Severe infections in general, Respiratory tract infections, Ear, nose & throat infections, Skin & soft tissue infections, Gastrointestinal, biliary & abdominal infections, Bone & joint infections, Infections associated with hemo & peritoneal

dialysis & with continuous ambulatory peritoneal dialysis (CAPD).

**Dosage & Administration**
1 to 6 gram per day 8 or 12 hourly (IM/IV) in the majority of infections, Infants & Children: The usual dosage range for children aged over two months is 30 to 100 mg/kg/day, given as two or three divided doses. Neonates & children up to 2 months: The usual dosage range is 25 to 60 mg/kg/ day as two divided doses.

**Pregnancy & Lactation**
Pregnancy Category B.
Ceftazidime is excreted in human breast milk & caution should be exercised when administered to a nursing woman.

**Side Effect**
Local: phlebitis or thrombophlebitis with IV administration; pain and/or inflammation after IM injection. Hypersensitivity: Urticarial rash, fever, pruritus, & very rarely angioedema & anaphylaxis (bronchospasm and/or hypotension), diarrhea, nausea, vomiting, abdominal pain, & very rarely oral thrush or colitis, candidiasis, vaginitis, headache, dizziness, paraesthesia & bad taste.

**Contraindication**
Known hypersensitivity to Cephalosporin antibiotics.

**Drug Interaction**
Increased nephrotoxicity has been reported following concomitant administration of cephalosporins & aminoglycoside antibiotics.

**Preparation**
250 mg, 500 mg & 1 gm IM/IV Injection.

## Tazocilin™ 4.5 IV Infusion

**Active Ingredient**
Piperacillin & Tazobactam

**Indication**
Tazocilin 4.5 IV infusion is indicated for the treatment of the following systemic and/or local bacterial infections:
•Nosocomial pneumonia (moderate to severe)
•Community-acquired pneumonia (moderate severity only)
•Uncomplicated & complicated skin & skin structure infections including cellulitis, cutaneous abscesses & ischemic/diabetic foot infections
•Postpartum endometritis or pelvic inflammatory disease
•Appendicitis (complicated by rupture or abscess) & peritonitis
Tazocilin 4.5 IV Infusion may also be used in the management of neutropenic patients (adults, adolescents & children) with fever suspected to be due to bacterial infections.

**Dosage & Administration**
Piperacillin/Tazobactam may be given by slow intravenous infusion (over 20-30 minutes). The usual dosage for adults & children over 12 years is Tazocilin 4.5 IV infusion given every eight hourly. The total daily dose of Piperacillin/ Tazobactam depends on the severity & localization of the infection & can vary from 2.25 gm to 4.50 gm administered in every six or eight hourly. In neutropenia the recommended dose is Piperacillin/Tazobactam 4.5 gm given in every six hours in combination with an aminoglycoside.

**Contraindication & Precaution**
Hypersensitivity to Piperacillin or any of the beta-lactam antibiotics & to Tazobactam or any other beta-lactamase inhibitor.

**Side Effect**
Nausea, vomiting, diarrhoea; less commonly

stomatitis, dyspepsia, constipation, jaundice, hypotension, headache, insomnia & injection-site reactions; rarely abdominal pain, hepatitis, oedema, fatigue, & eosinophilia; very rarely hypoglycemia, hypokalemia, pancytopenia, Stevens-Johnson syndrome & toxic epidermal necrolysis.

**Drug Interaction**
Probenecid, anticoagulants, vecuronium, methotrexate

**Use in Pregnancy & Lactation**
Piperacillin/Tazobactam should only be used during pregnancy if clearly indicated. Piperacillin is excreted in low concentrations in breast milk. Women who are breast-feeding should be treated only if clearly indicated.

**Use in Children**
Children under 2 years: Piperacillin/Tazobactam is not recommended for use in children below 2 years old due to insufficient data on safety.
Hepatic Impairment: No dose adjustment is necessary.

**Preparation**
4.5 gm IV Infusion.

# Tebast™

**Active Ingredient**
Ebastine.

**Indication**
Ebastine is indicated for the symptomatic treatment of:
• Seasonal & perennial allergic rhinitis
• Chronic Idiopathic Urticaria
• Allergic skin disorders

**Dosage & Administration**
Adults (more than 12 years of age): 10 mg (one tablet) once daily, Children (6-12 years of age): 5 mg (half tablet) once daily, Ebastine may be taken with or without food.

**Contraindication**
Patients with a known hypersensitivity to Ebastine or any of its ingredients.

**Side Effect**
The most common side-effects are headache, dry mouth & drowsiness. Less commonly reported side effects include abdominal pain, dyspepsia, nausea & insomnia.

**Drug Interaction**
Concomitant use of Ketoconazole, Itraconazole, Clarithromycin or Erythromycin may increase plasma levels of Ebastine & cause QTc interval prolongation.

**Use in Pregnancy & Lactation**
The safety of ebastine during pregnancy & lactation has not been established

**Preparation**
10 mg tablet

# Terminex™

**Active Ingredients**
Mifepristone & Misoprostol

**Indication**
Termination of early unwanted pregnancy up to 63 days (9 weeks)

**Dosage & Administration**

•Patient will take 1 (one) Mifovent (Mifepristone) Tablet orally
• After 24 hours, patient will take 4 (four) Isovent (Misoprostol) tablets sublingually
• After 10-14th days, patient will confirm her termination of pregnancy by ultrasonography

**Contraindication**

• Confirmed or suspected ectopic pregnancy
• IUD in place
• Chronic adrenal failure
•History of allergy to Mifepristone, Misoprostol or other prostaglandin
•Hemorrhagic disorders or concurrent anticoagulant therapy

**Side Effect**

Commonly reported side effects were nausea, vomiting and diarrhea.

T

**Drug Interaction**

Mifepristone: Although specific drug or food interactions with Mifepristone have not been studied, on the basis of the drug's metabolism by CYP 3A4, it is possible that ketoconazole, itraconazole, erythromycin and grapefruit juice may inhibit its metabolism (increasing serum, levels of Mifepristone).
Misoprostol: Misoprostol has not been shown to interfere with the beneficial effects of aspirin on signs & symptoms of rheumatoid arthritis. Misoprostol does not exert clinically significant effects on the absorption, blood levels and antiplatelet effects of therapeutic doses of aspirin.

**Use in Pregnancy & Lactation**

Terminex is indicated for use in the termination of pregnancy (through 63 days' pregnancy) and has no other approved indication for use during pregnancy.
It is not known whether Mifepristone is excreted in human milk. Many hormones with a similar chemical structure, however, are excreted in breast milk. Since the effects of Mifepristone on infants are unknown, breast-feeding women should consult with their health care provider to decide if they should discard their breast milk for a few days following administration of the medications

**Preparation**

One Mifepristone 200 mg Tablet in one blister & four Misoprostol tablets of 200 mcg each in another blister.

# Tetrax®

**Active Ingredient**

Tetracycline.

**Indication**

Ricketsial infection, *Mycoplasma pneumoniae* infections, Chlamydial Infections, Non-gonococcal or non specific urethritis, Lyme disease, Brucellosis, Miscellaneous infections including granuloma inguinale, cholera, glanders, relapsing fever & *V. vulnifians*, urinary tract infections, bronchitis, PID, STD, travelers diarrhoea, *acne vulgaris*, prostatitis, syphilis, anaerobic infections.

**Dosage & Administration**

1-2 g daily given in 2-4 divided doses, children : 25-50 mg/kg daily.

**Contraindication & Precaution**

Hypersensitivity, systemic lupus erythematosus, renal impairment, in impaired liver function high doses should be avoided. Potentiality hepatotoxic drugs (including erythromycin, chloramphenicol, isoniazide & sulphonamides) should not be given concomitantly.

**Side Effect**

Depression of bone growth, discoloration of the teeth when given during tooth development (i.e. during the later half of pregnancy, during infancy & in childhood) anaphylaxis, urticaria & rashes are uncommon. Photosensitivity reactions, epigastric distress & nausea . Vomiting can occur, appears to aggravate pre-

existing renal failure, candidiasis, Esophageal ulcerations.

**Use in Pregnancy & Lactation & Children**
Tetracycline should not be used during pregnancy, lactation & in children.

**Preparation**
500 mg Capsule.

# Thyrin®

**Active Ingredient**
Levothyroxine Sodium.

**Indication**
Hypothyroidism - Primary (thyroidal), secondary (pituitary), & tertiary (hypothalamic) hypothyroidism & subclinical hypothyroidism.
Pituitary TSH Suppression

**Dosage & Administration**
Dosing must be individualized & adjustments made based on periodic assessment of the patient's clinical response & laboratory parameters.
a) Adult Dosage
Initial starting dose: 25-50 mcg/day, with gradual increments in dose at 6-8 week intervals as needed. The dose is generally adjusted in 12.5-25 mcg increments until the patient with primary hypothyroidism is clinically euthyroid & the serum TSH has normalized.
In patients with severe hypothyroidism: 12.5-25 mcg/day with gradual increment of 25 mcg/day every 2-4 weeks.
In patients with secondary (pituitary) or tertiary (hypothalamic) hypothyroidism: The dose should be titrated until the patient is clinically euthyroid & the serum free- T4 level is restored to the upper half of the normal range.
For patients older than 50 years or for patients under 50 years of age with underlying cardiac disease: 1.7 mcg/kg/day.
b) Pediatric Dosage
Newborns
The recommended starting dose is 10-15 mcg/kg/day. In infants with very low (< 5 mcg/dL) or undetectable serum T4 concentrations, the recommended initial starting dose is 50 mcg/day.
Infants & Children
Initial dose is 25 mcg/day with increments of 25 mcg every 2-4 weeks until the desired effect is achieved.

c) Daily dose per Kg body weight
0-3 months : 10-15 mcg/kg/day
3-6 months : 8-10 mcg/kg/day
6-12 months : 6-8 mcg/kg/day
1-5 years : 5-6 mcg/kg/day
6-12 years : 4-5 mcg/kg/day
>12 years but growth & puberty incomplete: 2-3 mcg/kg/day
Growth & puberty complete: 1.7 mcg/kg/day

**Contraindication & Precaution**
Contraindicated in the following conditions:
• Untreated subclinical or overt thyrotoxicosis of any etiology & acute myocardial infarction,
• Uncorrected adrenal Levothyroxine has a narrow therapeutic index. So, careful dosage titration is necessary to avoid the consequences of over- or under-treatment.

**Side Effect**
Adverse reactions associated with Levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdose. They include the following: fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating, headache, nervousness, anxiety, irritability, tremors, muscle weakness, palpitations etc.

**Use in Pregnancy & Lactation**
US FDA Pregnancy Category A. Pregnancy may increase Levothyroxine requirements. Thyroid hormones are excreted minimally in human milk; caution should be exercised when it is administered to a nursing woman.

**Use in Children**
Can be used.

**Preparation**
25 mcg & 50 mcg Tablet.

# Ticamet® Cozycap

**Active Ingredient**
Salmeterol & Fluticasone Propionate

**Indication**
It is indicated for the long term maintenance treatment of asthma & COPD in patient 12 years of age & older.

**Dosage & Administration**
One dry powder capsule inhalation twice daily approximately 12 hours apart.

**Contraindication & Precaution**
Ticamet 100, 250 & 500 Cozycap is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. The CVS & CNS effects seen with all sympathomimetic drugs (e.g., increased blood pressure, heart rate, excitement) can occur, significant hypokalamia in some patients, systemic eosinophilic conditions, with some patients presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome. Physicians should be alert to eosiniphilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients.

**Side Effect**
Respiratory tract infection, Pharyngitis, Sinusitis, Hoarseness/dysphonia, Oral candidiasis, Bronchitis, Headache, Nausea & vomiting, GI discomfort & pain, Diarrhoea & Musculoskeletal pain, hypersensitivity reactions, including rash, angioedema & bronchospasm.

**Use in Pregnancy & Lactation**
The drug should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Preparation**
100 Cozycap (50 mcg +100 mcg) & 250 Cozycap (50 mcg+250 mcg) & 500 Cozycap (50 mcg+500 mcg).

# Ticamet® HFA Inhaler

**Active Ingredient**
Salmeterol & Fluticasone

**Indication**
Ticamet is indicated in the regular treatment of asthma, where use of a combination (LABA + Steroid) has been found to be appropriate. It is also Effective for COPD patients.

**Dosage & Administration**
Adults & adolescents 12 years & older: 2 puffs twice daily.

**Contraindication & Precaution**
Hypersensitivity to any of the ingredients.

**Precaution**
Ticamet HFA Inhaler should not be used to treat acute asthma symptoms for which a fast & short acting bronchodilator (Salbutamol) is required.

**Side Effect**
The pharmacological side effects of $\beta_2$ agonist treatment are tremor, palpitations & headache. Due to the fluticasone propionate component, hoarseness & candidiasis (thrush) of the mouth & throat can occur in some patients.

**Use in Pregnancy & Lactation**
Administration of Ticamet HFA Inhaler to pregnant women should only considered if the expected benefit to the mother is greater than any possible risk to the foetus.

**Preparation**
125 Inhaler (25 mcg of Salmeterol & 125 mcg of Fluticasone propionate/puff, 120 puffs), & 250 HFA Inhaler (25 mcg of Salmeterol & 250 mcg of Fluticasone propionate/puffs, 120 puffs).

# Ticalog™ 90

**Active Ingredient**
Ticagrelor Antiplatelet

**Indication**
Ticalog™ 90 tablet is indicated for the Prevention of Atherothrombotic events in adult patients with ACS (STEMI, Non-STEMI, Unstable angina) & PCI management.

**Dosage & Administration**
Ticagrelor treatment should be initiated with a single 180 mg loading dose (two tablets of 90 mg) and then continued with 90 mg twice daily. Patients taking Ticagrelor should also take aspirin daily, unless specifically contraindicated. Following an initial dose of aspirin (usually 325 mg), Ticagrelor should be used with a maintenance dose of aspirin of 75-100 mg.

**Contraindication**
Ticagrelor is contraindicated in case of-
- Hypersensitivity to Ticagrelor or to any of the excipients
- Active pathological bleeding (peptic ulcer)
- History of intracranial haemorrhage
- Moderate to severe hepatic impairment
- Co-administration of Ticagrelor with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, nefazodone, ritonavir, and atazanavir)

**Drug Interaction**
CYP3A inhibitors: Avoid use of strong inhibitors of CYP3A (e.g., ketoconazole, itraconazole, voriconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir and telithromycin).
CYP3A inducers: Avoid use with potent inducers of CYP3A (e.g., rifampin, dexamethasone, phenytoin,carbamazepine and phenobarbital).
Aspirin: Use of Ticagrelor with aspirin maintenance doses above 100 mg reduced the effectiveness ofTicagrelor.
Simvastatin, Lovastatin: Ticagrelor will result in higher serum concentrations of simvastatin and lovastatin because these drugs are metabolized by CYP3A4. Avoid simvastatin and lovastatin doses greater than 40 mg.
Digoxin: Because of inhibition of the P-glycoprotein transporter, monitor digoxin levels with initiation of or any change in ticagrelor therapy.
Other Concomitant Therapy: Ticagrelor can be administered with unfractionated or low-molecular-weight heparin, GPIIb/IIIa inhibitors, proton pump inhibitors, beta-blockers, angiotensin converting enzyme inhibitors, and angiotensin receptor blockers.
Over dose:
There is currently no known antidote to reverse the effects ofTicagrelor and it is not expected to be dialysable.Treatment of overdose should follow local standard medical practice.The expected effect of excessive ticagrelor dosing is prolonged duration of bleeding risk associated with platelet inhibition. If bleeding occurs appropriate supportive measures should be taken.

**Side effects**
Dyspnea, bleeding, headache, cough, dizziness, nausea, atrial fibrillation, hypertension, non-cardiac chest pain, diarrhea, back pain, hypotension, fatigue, chest pain.
Use in Pregnancy and Lactation
Pregnancy: Pregnancy category C. There are no or limited amount of data from the use of Ticagrelor in pregnant women.Ticagrelor is not recommended during pregnancy.
Nursing mothers: Available pharmacodynamic/toxicological data in animals have shown excretion ofTicagrelor and its active metabolites in milk. A risk to newborns/infants cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from ticagrelor therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the women.
Use in Children:
The safety and efficacy of ticagrelor in children below the age of 18 in the approved adult indication has not been established.

**Preparation**
10 tablets in Alu-PVDC blister pack.

# Ticas®

**Active Ingredient**
Fluticasone Propionate.

**Indication**
Inflammatory & pruritic manifestations of corticosteroid-responsive eczema/dermatitis.

**Dosage & Administration**
Once or twice daily.

**Contraindication & Precaution**
Rosacea, Acne vulgaris, Peri-oral dermatitis, Primary cutaneous viral infections (e.g., *Herpes Simplex*, chicken pox), Perianal & genital pruritus, etc.The use of Fluticasone Propionate is not indicated in the treatment of primarily infected skin lesions caused by infection with fungi or bacteria & dermatoses in children under one year of age, including dermatitis & napkin eruptions.

**Side Effect**
Local burning & pruritus, hypersensitivity appear, atrophic changes in the skin such as thinning, striae, dilatation of the superficial blood vessels, hypertrichosis & hypopigmentation, secondary infection, hypercorticism.

**Use in Pregnancy & Lactation**
Administration of Fluticasone Propionate during pregnancy & lactation should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus.

**Preparation**
10 gm Cream.


# Tilex® Max

**Active Ingredient**
Glucosamine Sulfate & Diacerein

**Indication**
Osteoarthritis, Rheumatoid arthritis & Joint injuries

**Dosage & Administration**
Adults & children over 12 years and older: 1 tablet twice daily (12 hourly) taken with food for 4-12 weeks.

**Contraindication & Precaution**
There are no known contraindications for Glucosamine. But proven hypersensitivity to Glucosamine is a contraindication. Diabetics are advised to monitor blood glucose levels regularly when taking Glucosamine. No special studies were formed in patients with renal and/or hepatic insufficiency. The toxicological and pharmacoki-netic profile of Glucosamine does not indicate limitations for these patients. However, administration to patients with severe hepatic or renal insufficiency should be under appropriate medical supervision. Children should not be supplemented with Glucosamine. Diacerein or to shellfish (e.g., shrimp, crab); who have diabetes, asthma, alcohol dependence or liver disease. While taking the drug complete blood count, liver function and urinalysis should be monitored regularly. Diacerein is contraindicated in pregnancy, lactation and hypersensitivity to anthraquinone derivatives.

**Side Effect**
No serious adverse effects has been reported diarrhea, constipation, epigastric pain, heartburn, nausea , vomiting, headache, skin rashes, drowsiness, intense yellow coloring of urine.

**Drug Interaction**
There have been no reports of significant drug interactions of glucosamine with antibiotics /

antidepressants / antihypertensive / nitrates / antiarrythmics / anxiolytic / hypoglycemic agents / antisecretives. But decreased absorption of Diacerein with aluminium and /or magnesium hydroxide antacids. Increased risk of diarrhea with laxatives, antibiotics. Avoid co-administration with fibers and phytic acids.

**Use in Pregnancy & Lactation**
Glucosamine and Diacerein are contraindicated during pregnancy and breastfeeding

**Preparation**
750 mg & 50 mg Tablet.

# Timotor™

**Active Ingredient**
Trimebutine Maleate.

**Indication**
Treatment & relief of symptoms associated with irritable bowel syndrome (spastic colon) Postoperative paralytic ileus in order to accelerate the resumption of the intestinal transit following abdominal surgery.

**Dosage & Administration**
For adults: 100mg-200mg, 3 times per day before meals.

**Adverse Reaction**
Trimebutine maleate is generally well tolerated. The infrequently reported adverse effects are as follows: dry mouth, foul taste, diarrhea, dyspepsia, epigastric pain, nausea, constipation, drowsiness, fatigue, dizziness, hot/cold sensations, headache etc.

**Contraindication**
Patients with known hypersensitivity to trimebutine maleate or any excipient.

**Use in Pregnancy & Lactation**
The use of trimebutine maleate in pregnant women is recommended. It is not known if trimebutine maleate passes into breast milk. This medication should be used while breast feeding only if the potential benefits outweigh risks to the nursing infants.

**Drug Interaction**
Trimebutine maleate increases the duration of d-tubocurarine-induced curarization. No other drug interactions have been observed during clinical trials or otherwise reported.

**Preparation**
100 mg Tablet.



# Tofator™

**Active Ingredient**
Tofacitinib Citrate INN

**Indication**
Rheumatoid Arthritis:
Tofacitinib is indicated for the treatment of adult patients with moderately to severely active Rheumatoid Arthritis who have had an inadequate response or intolerance to Methotrexate. It may be used as monotherapy or in combination with Methotrexate or other nonbiologic Disease-Modifying Antirheumatic Drugs (DMARDs).

Psoriatic Arthritis:
Tofacitinib is indicated for the treatment of adult patients with active Psoriatic Arthritis who have had an inadequate response or intolerance to Methotrexate or other Disease-Modifying Antirheumatic Drugs (DMARDs).
Ulcerative Colitis:
Tofacitinib is indicated for the treatment of

adult patients with moderately to severely active Ulcerative Colitis (UC).

**Dosage & Administration**

Administration instructions Do not initiate Tofacitinib if absolute lymphocyte count <500 cells/mm3, an absolute neutrophil count (ANC) <1000 cells/mm3 or hemoglobin <9 g/dL.

Recommended Dosage

Rheumatoid Arthritis: Tofacitinib 5 mg twice daily.

Recommended dosage in patients with moderate and severe renal impairment or moderate hepatic impairment is Tofacitinib 5 mg once daily.

Psoriatic Arthritis (in combination with nonbiologic DMARDs):

Tofacitinib 5 mg twice daily. Recommended dosage in patients with moderate and severe renal impairment or moderate hepatic impairment is Tofacitinib 5 mg once daily.

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Ulcerative Colitis:

Tofacitinib 10 mg twice daily for at least 8 weeks; then 5 or 10 mg twice daily. Discontinue after 16 weeks of 10 mg twice daily, if adequate therapeutic benefit is not achieved. Use the lowest effective dose to maintain response. Use in patients with severe hepatic or renal impairment is not recommended.

Limitations of use:

Use of Tofacitinib in combination with biologic DMARDs or potent immunosuppressants such as Azathioprine and Cyclosporine is not recommended.

**Side Effect**

Most common adverse reactions are:

Rheumatoid and Psoriatic Arthritis:

Reported during the first 3 months in rheumatoid arthritis controlled clinical trials and occurring in >2% of patients treated with Tofacitinib monotherapy or in combination with DMARDs: upper respiratory tract infection, nasopharyngitis, diarrhea, and headache.

Ulcerative Colitis:

Reported in >5% of patients treated with either 5 mg or 10 mg twice daily of Tofacitinib and greater than reported in patients receiving placebo in either the induction or maintenance clinical trials: nasopharyngitis, elevated cholesterol levels, headache, upper respiratory tract infection, increased blood creatine phosphokinase, rash, diarrhea, and herpes zoster.

Precaution Serious Infections:

Use of Tofacitinib should be avoided during an active serious infection, including localized infections.

Gastrointestinal Perforations:

Caution should be used in patients that may be at increased risk. Laboratory Monitoring:

Laboratory Monitoring should be recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids.

Immunizations:

Live vaccines: Use with Tofacitinib should be avoided.

**Contraindication**

None.

Use in specific population Pregnancy & Lactation:

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women.

Pediatric Use:

The safety and effectiveness of Tofacitinib in pediatric patients have not been established.

Geriatric Use:

The frequency of serious infection among Tofacitinib-treated subjects 65 years of age and older was higher than among those under the age of 65. As there is a higher incidence of infections in the elderly population in general, caution should be used when treating the elderly.

**Preparation**

5 mg Table.

# Togent®

**Active Ingredient**
Diphenhydramine HCl & Zinc acetate.

**Indication**
Togent cream is used to temporarily relieve pain & itching associated with: insect bites, minor burns, sunburn, minor skin irritations, minor cuts, scrapes, rashes due to poison ivy, poison oak, & poison sumac, dries the oozing & weeping of poison ivy, poison oak, & poison sumac.

**Dosage & Administration**
Adults & children above 2 years: Apply to the affected area 3 to 4 times daily. Before application of cream, the skin should be clean, cool & dry. Should not have a hot shower or bath before applying. Apply the cream lightly on the skin until the cream disappears. It is important to include all skin surfaces, such as between the fingers & toes, under the nails & on the soles of the feet.

**Contraindication & Precaution**
Use of cream is contraindicated in individuals with a known allergy to its components, other pyrethroids or pyrethrins. Do not use on large areas of the body with any other product containing diphenhydramine, even once taken by mouth. Consult with the physician before use on chicken pox, on measles. When using this product, avoid contact of eyes.

**Side Effect**
Contact dermatitis with mild erythematous vesicular lesions & papules has occasionally been reported.

**Use in Pregnancy & Lactation**
In the absence of specific studies in pregnant women its use in pregnancy should only follow medical advice. However, teratogenic effects would not be anticipated. Although caution should be exercised in administration of diphenhydramine to nursing mothers, levels in breast milk following topical application are likely to be very low.

**Preparation**
10 gm Cream.

# Topicort®

**Active Ingredient**
Hydrocortisone Acetate.
**Indication**
Irritant dermatitis, Allergic dermatitis, Eczema, Seborrheic dermatitis, Lichen simplex & Pruritus ani, Flexural Psoriasis, Itching & rashes, caused by insect bites, minor thermal burns, sunburn, etc.

**Dosage & Administration**
2 or 3 times daily.
**Contraindication & Precaution**
Infections - bacterial; viral; fungal, skin ulcers, hypersensitivity. In infants & children: Long term topical therapy should be avoided, where possible as adrenal suppression can occur.

**Side Effect**
Hypersensitivity.

**Use in Pregnancy & Lactation**
It is recommended that topical corticosteroids should not be used extensively during pregnancy.

**Preparation**
10 gm Cream.



# Torax™

**Active Ingredient**
Ketorolac Tromethamine.

**Indication**
Short-term management of moderate to severe acute post-operative pain & acute pain of other origins.

**Dosage & Administration**
Injecetion: For adults (65 years): Initial dose is 60 mg IM (Single). Maintenance dose is 30 mg IM/IV 6 hourly. Maximum dose is 120 mg/day. For elderly patients (>65 years), Initial dose is 30 mg IM. Maintenance dose is 10-15 mg IM/IV 6 hourly. Maximum dose is 60 mg/day. The maximum duration of treatment should not exceed two days. Tablets: 10 mg every 6 hours as required up to 7 days.

**Contraindication**
Patients having hypersensitivity to this drug or other NSAIDs & those patients in whom aspirin or other prostaglandin synthesis inhibitors induce allergic reactions. It is also contraindicated in a history of peptic ulcer or gastro-intestinal bleeding, moderate or severe renal impairment in a history of asthma. Ketorolac tromethamine can cause gastro-intestinal irritation, ulcers or bleeding in patients with or without a history of previous symptoms. Since ketorolac tromethamine & its metabolites are excreted primarily by the kidney, patients with moderate to severe impairment of renal function (serum creatinine greater than 160 micromol/l) should not receive.



**Drug Interaction**
NSAIDs, aspirin, anti-coagulants, methotrexate, Probenecid.

**Side Effect**
Nausea, vomiting, gastrointestinal bleeding, melaena, peptic ulcer, pancreatitis, anxiety, drowsiness, dizziness, headache, hallucinations, excessive thirst, inability to concentrate, insomnia, malaise, fatigue, pruritus, urticaria, skin photosensitivity, Lyell's syndrome, Stevens-Johnson syndrome, flushing, bradycardia, hypertension, palpitations, chest pain, infertility in female, dyspnoea, asthma, pulmonary oedema, fever, injection site pain.

**Drug Interaction**
Should not be used with other NSAIDs or aspirin. Anti-coagulants may cause an enhanced anti-coagulant Effect.

**Use in Pregnancy & Lactation**
Contraindicated during pregnancy, labour or delivery, or in mothers who are breast feeding.

**Preparation**
10 mg Tablet, 30 mg/1 ml & 60 mg/2 ml Injection.

# Tory®

**Active Ingredient**
Etoricoxib.

**Indication**
Relief of pain & inflammation in - Osteoarthritis, rheumatoid arthritis, other chronic musculoskeletal disorders, acute gout, dysmenorrhoea, & following dental surgery.

**Dosage & Administration**
Adult & adolescent over 16 years: osteoarthritis, chronic musculoskeletal disorders & dysmenorrhoea: 60 mg, once daily, rheumatoid arthritis: 90 mg, once daily, pain following dental surgery & acute gout: 120 mg, once daily.

**Contraindication & Precaution**
Known hypersensitivity to Etoricoxib, patients with active peptic ulceration or gastro-intestinal (GI) bleeding, patients who have developed signs of asthma, acute rhinitis, nasal polyps, angioneurotic oedema or urticaria following the administration of acetylsalicylic acid or other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), patient having inflammatory bowel disease, severe congestive heart failure, to children & adolescents under 16 years of age.

**Side Effect**
Dry mouth, taste disturbance, mouth ulcers, flatulence, constipation, appetite & weight changes, chest pain, fatigue, paraesthesia, influenza-like syndrome & myalgia.

**Drug Interaction**
Oral anticoagulants, diuretics & ACE inhibitors, Acetylsalicylic acid, Cyclosporin & Tacrolimus, Lithium, Methotrexate, oral contraceptives, Prednisone/Prednisolone, Digoxin, drugs metabolized by sulfotransferases (Ethinyl Estradiol), drugs metabolized by CYP isoenzymes, Ketoconazole, Rifampicin, & Antacids.

**Use in Pregnancy & Lactation**
It should be avoided in late pregnancy because it may cause premature closure of the ductus arteriosus. It should be used during the first two trimesters of pregnancy only if the potential benefit justifies the potential risk to the foetus. It is not known whether this drug is excreted in human milk.

**Preparation**
60 mg, 90 mg & 120 mg Tablet.

**Drug Interaction**
Concomitant ocular medications should be administered at least 5 min apart from the instillations to avoid washout effects.

**Side Effect**
Ocular hyperemia, decreased visual acuity, eye discomfort, foreign body sensation, pain and pruritus, redness may be seen in few cases.

**Use in Pregnancy & Lactation**
Use in Pregnancy: Pregnancy Category C. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Use in Lactation**
It is not known whether this drug or its metabolites are excreted in human milk. Caution should be exercised when Travolar is administered to a nursing woman.

**Preparation**
3 ml solution in LDPE container



# Travolar™ Eye Drops

**Active Ingredient**
Travoprost

**Indication**
Travolar Eye Drops is indicated for the reduction of intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension.
Dosage & Administration
The recommended dose is one drop in the affected eye(s) once-daily. Optimal effect is observed with evening dosing.
Contraindication & Precaution
It is contraindicated in patients with known hypersensitivity to any ingredient of this formulation.

# Trevox®

**Active Ingredient**
Levofloxacin.

**Indication**
Acute maxillary sinusitis, Acute bacterial exacerbation of chronic bronchitis, Community-acquired pneumonia, Nosocomial Pneumonia, Complicated urinary tract infections, Uncomplicated UTI, Acute pyelonephritis, Chronic bacterial prostatitis, Uncomplicated & complicated skin & soft tissue infections including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections.
Inhalation anthrax (post-exposure): To prevent the development of inhalational anthrax

following exposure to Bacillus anthracis.

**Dosage & Administration**
Acute sinusitis: 500 mg once daily for 10-14 days, Exacerbation of chronic bronchitis: 250-500 mg once daily for 7 days, Community-acquired pneumonia: 500 mg once daily for 7-14 days, Community-acquired pneumonia: 750 mg once daily for 5 days, Nosocomial Pneumonia: 750 mg once daily for 7-14 days, Complicated urinary-tract infections & acute pyelonephritis: 250 mg daily for 7-10 days, Uncomplicated UTI: 250 mg once daily for 3 days, Acute pyelonephritis: 250 mg once daily for 10 days, Chronic bacterial prostatitis: 500 mg once daily for 28 days, Uncomplicated skin & soft-tissue infections: 500 mg once daily for 7-10 days, Complicated skin & soft-tissue infections: 750 mg once daily for 7-14 days.
Inhalation anthrax (post-exposure): Adult-500 mg once daily for 60 days.



**Contraindication & Precaution**
Hypersensitivity While taking Levofloxacin, adequate amount of water should be taken to avoid concentrated form of urine. Dose adjustment should be exercised during Levofloxacin ingestion in presence of renal insufficiency.

**Side Effect**
Nausea, vomiting, diarrhea, abdominal pain, flatulence, phototoxicity, tremors, depression, confusion etc.

**Drug Interaction**
Antacids, Iron, NSAID, Warfarin.

**Use in Pregnancy & Lactation**
Not recommended for use during pregnancy or nursing, as the effects on the unborn child or infant are unknown.

**Preparation**
500 mg Tablet.

# Trevox® 500 IV

**Active Ingredient**
Levofloxacin 500 mg as Levofloxacin Hemihydrate INN.

**Indication**
Levofloxacin infusion is indicated for the treatment of mild, moderate & severe infections caused by susceptible strains of the designated microorganisms in the conditions listed below-
- Pneumonia: Nosocomial & community acquired
- Acute bacterial sinusitis
- Acute bacterial exacerbation of chronic bronchitis
- Skin & skin structure infections: Complicated & uncomplicated
- Chronic bacterial prostatitis
- Urinary tract infections: Complicated & uncomplicated
- Acute pyelonephritis
- Inhalational anthrax, post-exposure

**Contraindication & Precaution**
Levofloxacin is contraindicated in persons with known hypersensitivity to levofloxacin or other quinolone antibacterials.

**Side Effect**
Headache, nausea, vomiting, diarrhea, constipation, abdominal pain, dyspepsia, edema & injection site reaction. Less common (0.1 to 1%) side Effects include allergic reaction, hyperglycemia, hypoglycemia, anxiety, agitation, tremor, palpitation, abnormal hepatic function, tendonitis etc.

**Drug Interaction**
There are no data concerning an interaction of intravenous fluoroquinolones with oral antacids, sucralfate, multivitamins, didanosine, or metal cations. However, no fluoroquinolone should be co-administered with any solution containing multivalent cations, e.g., magnesium, through the same intravenous line. Levofloxacin may enhance the Effect of warfarin. Elevations of the prothrombin time in the setting of concurrent warfarin & Levofloxacin use have been associated with

episodes of bleeding. Disturbances of blood glucose, including hyperglycemia & hypoglycemia, have been reported in patients treated concomitantly with fluoroquinolones & an anti-diabetic agent. The concomitant administration of a non-steroidal anti-inflammatory drug with a fluoroquinolone, including Levofloxacin, may increase the risk of CNS stimulation & convulsive seizures.

**Use in Pregnancy & Lactation**

There are no adequate & well-controlled studies in pregnant women. Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Based on data on other fluoroquinolones & very limited data on Levofloxacin, it can be presumed that levofloxacin will be excreted in human milk. Because of the potential for serious adverse reactions from Levofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Dosage & Administration**

The usual dose of Levofloxacin infusion is 250 mg or 500 mg adminstered by slow intravenous infusion over 60 minutes every 24 hours or 750 mg administered by slow infusion over 90 minutes every 24 hours.

| **Type of Infection** | **Dosed Every 24 hours** | **Duration (days)** |
|---|---|---|
| Nosocomial Pneumonia | 750 mg | 7-14 |
| Community Acquired Pneumonia | 500 mg<br>or<br>750 mg | 7-14<br>or<br>5 |
| Acute Bacterial Sinusitis | 500 mg<br>or<br>750 mg | 7-14<br>or<br>5 |
| Acute Bacterial Exacerbation of Chronic Bronchitis | 500 mg | 7 |
| Complicated Skin & Skin Structure Infections | 750 mg | 7-14 |
| Uncomplicated SSSI | 500 mg | 7-10 |
| Chronic Bacterial Prostatitis | 500 mg | 28 |
| Complicated Urinary Tract Infection or<br>Acute Pyelonephritis | 250 mg<br>or<br>750 mg | 10<br>or<br>5 |
| Uncomplicated Urinary Tract Infection | 250 mg | 3 |

In each case, sequential therapy (intravenous to oral) may be instituted at the discretion of the

physician.

**Preparation**
500 mg/100 ml solution of Levofloxacin for intravenous infusion.

# Trispray®

**Active Ingredient**
Triamcinolone Acetonide.

**Indication**
Treatment & prophylaxis of the nasal symptoms of seasonal & perennial allergic rhinitis from 6 years of age to adults.

**Dosage & Administration**
Adults & children 12 years & older : The recommended dose is 2 sprays in each nostril once daily. 6-12 years: 1 spray in each nostril once daily. Below 6 years: Not recommended.

**Contraindication**
No contraindication.

**Adverse Reactions**
Rhinitis, headache, pharyngitis, epistaxis, nasal irritation, dry mucous membrane, naso-sinus congestion, sneezing, nasal septal perforation has been reported.

**Drug Interaction**
None is known.

**Precaution**
If there is any reason to suppose that adrenal function is impaired, care must be taken while transferring patients from systemic steroid treatment to Triamcinolone.

**Preparation**
55 mcg/spray, Nasal Spray.

# Trupan®

**Active Ingredient**
Pantoprazole.

**Indication**
Trupan is indicated for the treatment of - Benign gastric ulcer, duodenal ulcer, gastroesophageal reflux disease (GERD), NSAID-induced peptic ulcer, acid hypersecretory conditions including Zollinger-Ellison Syndrome, eradication of *Helicobacter pylori* (in combination with Antibiotics), ulcer resistant to $H_2$ receptor antagonists.

**Contraindication & Precaution**
Pantoprazole is contraindicated in patients with known hypersensitivity to the active drug or any other components of the formulation. Patients should be cautioned that Pantoprazole tablet should not be split, crushed or chewed.

**Side Effect**
Pantoprazole is well tolerated in both short term & long term treatment. Headache & diarrhoea are the most common side effects & rarely included abdominal pain, flatulence, rash, insomnia & hyperglycemia.

**Use in Pregnancy & Lactation**
USFDA Pregnancy category B. Pantoprazole should be used during pregnancy only if clearly needed. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

**Dosage & Administration**

| **Tablet** | |
|---|---|
| **Disease** | **Dosage & administration** |
| Benign gastric ulcer | 40 mg daily in the morning for 4 weeks, continued for further 4 weeks if not fully healed |

| | |
|---|---|
| Duodenal ulcer | 40 mg daily in the morning for 2 weeks, continued for further 2 weeks if not fully healed |
| GERD | 20-40 mg daily in the morning for 4 weeks, continued for further 4 weeks if not fully healed |
| NSAIDs induced peptic ulcer | 20 mg daily |
| Acid hypersecretory conditions including Zollinger-Ellison Syndrome | Initially 80 mg once daily adjusted according to response (Elderly - maximum 40 mg daily), daily doses above 80 mg given in two divided doses |
| Eradication of *Helicobacter pylori* | 40 mg twice daily by triple therapy with Antibiotics |
| Ulcer resistant to $H_2$ receptor antagonists | 40 mg once daily for 8 weeks. 20 mg daily as a maintenance therapy, increased to 40 mg daily if symptoms return. |
| Children: Safety & effectiveness have not been established | |

| **Injection** | |
|---|---|
| Duodenal ulcer & gastric ulcer | 40 mg once daily for 7-10 days |
| Gastroesophageal reflux disease associated with a history of erosive esophagitis | 40 mg once daily for 7-10 days |
| Prevention of rebleeding in peptic ulcer | IV 80 mg, followed by 8 mg/hour infusion for 72 hours |
| Prophylaxis of acid aspiration | 80 mg IV every 12 h for 24 h, followed by 40 mg every 12 h |
| Long-term management of Zollinger-Ellison Syndrome & other pathological hypersecretory conditions | 80 mg IV every 12 hours, may increase to 80 mg every 8 hours if needed, may titrate to higher doses depending on acid output. |

Intravenous Pantoprazole should be replaced with oral therapy as soon as possible.

*Direction For Use Of IV Injection:* Pantoprazole lyophilized powder & 0.9% Sodium Chloride Injection is for intravenous administration only & must not be given by any other route. Pantoprazole injection 40 mg should be given as a slow intravenous injection. The solution for IV injection is obtained by adding 10 ml 0.9% Sodium Chloride Injection to the vial containing powder. After reconstitution the injection should be given slowly over a period of at least 2-5 minutes. Use only freshly prepared solution. The reconstituted solution may be stored at room temperature (up to 30°c) for a maximum 4 hours.

*Direction For Use Of IV Infusion:* Pantoprazole IV 40 mg should be given as an intravenous infusion over a period of approximately 15 minutes. Pantoprazole IV should be reconstituted with 10 ml of 0.9% Sodium Chloride Injection & further diluted (admixed) with 5% Dextrose or 0.9% Sodium Chloride Injection or Lactated Ringer's Injection. The reconstituted solution may be stored at room temperature (up to 30°c) for a maximum 4 hours prior to further dilution. The admixed solution may be stored at room

temperature (up to 30°c) & must be used within 24 hours from the time of initial reconstitution.

**Preparation**
20 mg Tablet, 40 mg Tablet & 40 mg IV Injection.

# Truxil™

**Active Ingredient**
Almitrine & Raubasine

**Indication**
Reduces Neurological damage & accelerates recovery after stroke
Minor age related neurological disorders
Visual disorders related to age
Disorders in the inner ear (hearing loss, dizziness, buzzing etc.)

**Dosage & Administration**
Usually 1-2 tablets daily (with a several hours interval)

**Contraindication & Precaution**
This medicine is contraindicated to those patients having known hypersensitivity to any component of this preparation. Without this if anybody suffers from liver disease, peripheral neuropathy or history of peripheral neuropathy, they should not take this medicine.

**Side Effect**
Some side effects to some people may occur like weight loss, numbness in leg, nausea, heaviness or burning in stomach, vomiting, vertigo, constipation, diarrhea, insomnia, sleepiness, restlessness, anxiety, palpitation etc.

**Drug Interaction**
This drug should not be used with other medicine containing Almitrine. Due to the presence of lactose, this drug should not be used in case galactosemia, glucose or galactose mal-absorption syndrome or in lactose deficiency.

**Use in Pregnancy & Lactation**
Consulting with physicians is required to take this medicine.

**Preparation**
Almitrine 30 mg & Raubasine 10 mg.

# Tryptin®

**Active Ingredient**
Amitriptyline.

**Indication**
Depressive illness, Anxiety, Insomnia, nocturnal enuresis in children.

**Dosage & Administration**
25-50 mg a day in divided dose.

**Contraindication & Precaution**
Myocardial infarction; arrythmias, particularly heartblock of any degree; mania; severe liver disease. Caution in patients with a history of epilepsy, glaucoma, urinary retention, prostatic hypertrophy, constipation, cardiac disease, diabetes, pregnancy, hepatic impairment, thyroid disease, increased intra-occular pressure, psychoses (may aggravate mania).

**Side Effect**
Hypotension, syncope, postural hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrythmias, & heart block stroke. Confusional states, disorientation, delusions, & hallucinations. Dry mouth, blurred vision, mydriasis, increased intraoccular pressure, hyperplasia. Skin rash, urticaria, & photosensitization. Bone-marrow depression, Gastrointestinal: Nausea, epigastric distress,

vomiting anorexia, diarrhoea. Testicular swelling, gynaecomastia; breast enlargement, galactorrhoea. Dizziness, weakness, fatigue, headache, weight loss.

**Drug Interaction**
Monoamine oxidase inhibitors, adrenaline, epinephrine, isoprenaline, noradrenaline, CNS depressant, Alcohol, Cemitidine.

**Use in Pregnancy & Lactation**
The drug should be used during pregnancy & lactation if potential benefit justifies the potential risk to the fetus.

**Preparation**
10 mg & 25 mg Tablet.

12 years of age.
Patients suffering from liver, kidney & prostate problems should avoid this combination. Alcohol must be avoided. If any other medicines like minor Tranquilisers, Barbiturates, Codeine are taken, caution should be exercised. Patients taking this combination need to be careful while driving or operating machinery.

**Side Effect**
Side effects may include swelling of the face, lips and/or tongue, allergic reactions, numbness, drowsiness, dizziness, blurred vision, dry mouth/nose/throat, nausea or vomiting etc.

**Use in Pregnancy & Lactation**
There are no specific data on use of this combination during pregnancy & lactation.

**Preparation**
100 ml Syrup.



# Tusca Plus™

**Active Ingredient**
Guaifenesin, Levomenthol & Diphenhydramine HCl.

**Indication**
Tusca PlusTM is indicated for the symptomatic relief of upper respiratory tract disorders accompanied by productive cough.

**Dosage & Administration**
12 years and above: 10 ml 4 times a day.

**Contraindication & Precaution**
This combination is contraindicated in patients with a known hypersensitivity to Guaifenesin, Levomenthol or Diphenhydramine. If Monoamine Oxidase Inhibitors (MAOIs) have been taken in the last two weeks this combination should not be taken. This combination is not suitable for children under

# Tylace™

**Active Ingredient**
Acetylcysteine

**Indication**
Acetylcysteine is indicated as an adjunctive treatment for patients with abnormal, viscid or inspissated mucus secretions associated with conditions such as-
•Acute and chronic bronchopulmonary disorders (e.g. pneumonia, bronchitis, emphysema, tracheobronchitis, chronic asthmatic bronchitis, tuberculosis, bronchiectasis, primary amyloidosis of the lung)
• Atelectasis caused by mucus obstruction
•Pulmonary complications of cystic fibrosis
•Pulmonary complications of thoracic and

cardiovascular surgery &
•Post-traumatic chest conditions.
It is effective in all respiratory airways disease causing formation of a dense secretion that cannot be or can only partially be expectorated such as acute and chronic bronchitis, laryngitis, sinusitis, tracheitis, in uenza & bronchial asthma. Acetylcysteine is also indicated in the treatment of Paracetamol overdose. Treatment option is optimal if given within 8 hours of Paracetamol ingestion.

**Dosage & Administration**
Adults & children above 6 years of age:
1 tablet daily (Preferably in the evening). The duration of treatment should be 5-10 days in acute treatment.
In Paracetamol overdose:
Initially 140 mg/kg, followed by 70 mg/kg every 4 hours for an additional 17 doses.
Dissolve 1 tablet in a glass of water (200 ml) to drink

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**Contraindication & Precaution**
Known hypersensitivity to active ingredient. Also contraindicated in patients suffering from phenylketonuria and peptic ulcer.

**Side Effect**
Heartburn, nausea, vomiting & diarrhea may occur. Bronchospasm, shortness of breath & upset stomach may occur rarely. Very rarely severe skin reaction or immune reaction may occur.

**Use in Pregnancy & Lactation**
Pregnancy Category B. Caution should be taken in case of pregnancy & lactation while using Acetylcysteine.

**Drug Interaction**
After taking Acetylcysteine orally it increases the bioavailability of Amoxicillin, but shows no effect on Doxycycline and reduces the absorption of Cefalexin. Acetylcysteine seems to increase the effects of Nitroglycerin.

**Preparation**
600 mg Effervescent Tablet

# Ucol™ 2

**Active Ingredient**
Tolterodine Tartrate.

**Indication**
Treatment of Overactive Bladder with symptoms of urinary urgency, frequency and urge incontinence. Also used in treatment of children with bedwetting problem.

**Dosage & Administration**
2 mg b.i.d. Dosage may be reduced from 2mg to 1mg b.i.d.

**Contraindication & Precaution**
contraindicated in patients with Urinary retention, uncontrolled narrow angle glaucoma, known hypersensitivity.
Urinary retention decreased gastrointestinal motility, impaired renal function, impaired hepatic function.

**Side Effect**
Dryness of mouth, dyspepsia and/or reduced lacrimation.

**Drug Interaction**
Ketoconazole, Warfarin, Oral Contraceptives.

**Pregnancy & Lactation**
Should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Use of Tolterodine during lactation should be avoided.

**Preparation**
2 mg film coated Tablet.

# Uriset™

**Active Ingredient**
Potassium Citrate & Citric Acid Monohydrate

**Indication**
- Burning urination (due to decreased pH or acidic urine)
- Preventing kidney stone formation specially caused by uric acid (with or without the presence of calcium stones)
- Gout as an adjuvant with uricosuric agents
- Correcting acidosis caused by kidney disease

**Dosage & Administration**
To relieve from burning urination
Adults and children over 6 years: 10 ml 3 times daily diluted with 1 glass of water
Children 1-6 years: 5 ml 3 times daily, diluted with ½ glass of water
To prevent kidney stones, acidosis caused by kidney disease
Adults and children over 6 years: 10-15 ml 4 times daily, diluted with 1 glass of water
Children 1-6 years: 5-10 ml 4 times daily, diluted with ½ glass of water
In gout therapy (with uricosuric agent)
Adults and children over 6 years: 10-15 ml 4 times daily, diluted with 1 glass of water
Children 1-6 years: 5-10 ml 4 times daily, diluted with ½ glass of water

**Contraindication & Precaution**
Known hypersensitivity to any ingredient. Severe renal impairment with oliguria or azotemia, untreated Addison's disease, adynamia episodica hereditaria, acute dehydration, heat cramps, anuria, severe myocardial damage, and hyperkalemia from any cause. Large doses may cause hyperkalemia & alkalosis, especially in the presence of renal disease. Do not exceed recommended dosage. Discontinue use if adverse reaction occurs. Should be used with caution by patients with low urinary output unless under the supervision of a physician. As with all liquids containing a high concentration of potassium, patients should be directed to dilute adequately with water to minimize the possibility of gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations; and preferable, to take each dose after meals to avoid saline laxative effect.

**Drug Interaction**
Some products that may interact with this drug include: antacids that contain aluminum, aspirin and other salicylates (e.g., salsalate), certain blood pressure medications (e.g., ACE inhibitors such as lisinopril, angiotensin blockers such as losartan), drospirenone, eplerenone, certain heart medications (e.g., quinidine, digoxin), lithium, potassium supplements, certain "water pills" (potassium-sparing diuretics such as amiloride, spironolactone, triamterene).

**Use in Pregnancy & Lactation**
Should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.
It is not known if this drug is found in breast milk or not. Breast-feeding women should consult with their health care provider to confirm about taking this drug.

**Preparation**
Each box contains 200 ml of oral solution in PET bottle and a measuring cup.



# Urocure™

**Active Ingredient**
Nitrofurantoin USP

**Indication**
Treatment of uncomplicated Urinary Tract Infections

**Dosage & Administration**
**Urocure™ 100 SR** Capsule: Adults & children over 12 years: One capsule every 12 hours for seven days. Genito-urinary surgical prophylaxis - One capsule twice daily on the day of the procedure & for next 3 days **Urocure™** Suspension: Adults: 50-100 mg four times a day - the lower dosage level is recommended for uncomplicated urinary tract infections. Pediatric Patients: 5-7 mg/kg of body weight per 24 hours, given in four divided doses (contraindicated less than one month of age).

**Contraindication & Precaution**
Anuria, oliguria or significant impairment of renal

function (creatinine clearance under 60 ml per minute or clinically significant elevated serum creatinine) are contraindications. Nitrofurantoin is contraindicated in patients with a previous history of cholestatic jaundice/hepatic dysfunction associated with Nitrofurantoin. Nitrofurantoin is also contraindicated in those patients with known hypersensitivity to it. Patients should be instructed to complete the full course of therapy; however, they should be advised to contact with their physician if any unusual symptoms occur during therapy. Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Patients should be advised not to use antacid preparations containing Magnesium Trisilicate while taking Nitrofurantoin.

**Side Effect**
The most common side effects are nausea, headache & flatulence. Other side effects are diarrhea, dyspepsia, abdominal pain, constipation, emesis, dizziness, drowsiness etc.



**Drug Interaction**
Co-administration of Nitrofurantoin with antacids containing Magnesium Trisilicate reduce both the rate & extent of absorption. Uricosuric drugs, such as Probenecid & Sulfinpyrazone, can inhibit renal tubular secretion of Nitrofurantoin.

**Use in Pregnancy & Lactation**
Pregnancy: Pregnancy category B. It should be used during pregnancy only if clearly needed.
Lactation:
Nitrofurantoin has been detected in human breast milk in trace amounts. Because of the potential for serious adverse reactions from Nitrofurantoin in nursing infants under one month of age, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Use in Children**
Safety & effectiveness of Nitrofurantoin in neonates below the age of one month have not been established.

**Preparation**
100 SR Capsule.

# Urso™

**Active Ingredient**
Ursodeoxycholic Acid

**Indication**
Urso is indicated for the treatment of different hepatobiliary disorders like, Alcoholic Fatty Liver Disease, Dissolution of gallstones, Primary Billiary Cirrhosis (PBC), Primary Sclerosing Cholangitis (PSC), Non-alcoholic steato hepatitis (NASH), Cholestasis & viral hepatitis.

**Dosage & Administration**
Dissolution of Gall stones: 8 - 12 mg/kg/day either as single night time dose or in divided doses; Primary Billiary Cirrhosis (PBC): 10- 15 mg/kg/day in 2-4 divided doses; Alcoholic Fatty Liver: 300 mg/day; Acute Viral Hepatitis: 600 mg/day; Primary Sclerosing Cholangitis (PSC): 25 - 30 mg/kg/day; Non-alcoholic steato hepatitis (NASH): 13 - 15 mg/kg/day

**Contraindication**
Non-functioning gall-bladder calcified and pigmented gallstones, inflammatory bowel disease.

**Precaution**
It should be used cautiously in those with liver disease.

**Side Effect**
Nausea, vomiting, diarrhea, gallstones calcification and pruritus.

**Use in Pregnancy & Lactation**
Pregnancy category B. No evidence of harm has been reported in pregnancy. It has been effectively used for the treatment of cholestasis of pregnancy during the last trimester without any side effects. Problems have not been documented in humans regarding breast feeding.

**Drug Interaction**
Ursodeoxycholic Acid should not be used with drugs, such as estrogenic hormones that increase bile cholesterol. Concomitant administration with bile-acid binding

drugs including antacids, charcoal and cholestyramine should be avoided since this may reduce the effectiveness of therapy with Ursodeoxycholic Acid.

**Preparation**
150 mg and 300 mg Tablet.

# Utal™

**Active Ingredients**
Ulipristal Acetate 5 mg

**Indication**
Uterine Fibroids

**Dosage & Administration**
• Once daily for 3 months
• The dose can be repeated once with a gap of 8 weeks.

**Contraindication**
Hypersensitivity to the active substance or to any of the excipients. Genital bleeding of unknown aetiology or for reasons other than uterine fibroids
Uterine, cervical, ovarian or breast cancer

**Side Effect**
• Endometrial thickening
• Hot flush
• Headache
• Uterine haemorrhage

**Pregnancy and breastfeeding**
Pregnancy Category X. Not recommended for breast feeding mother.

**Preparation**
5 mg Tablet

# Valoate®

**Active Ingredient**
Sodium Valproate.

**Indication**
Epilepsy, Mania, Chronic Headache

**Dosage & Administration**
Adults: Initial: 600mg/day in 2 divided doses, preferably after food. Dose may be increased by 200mg/day at 3 days interval to a maximum of 2.5g daily in divided doses until control of seizure is achieved.
Maintenance dose: Usually 1-2g daily (20-30 mg/kg daily).
Children (up to 20kg):
Initial: 20mg/ kg daily in divided doses. Dose may be increased in severe cases with proper monitoring of plasma concentration.
Children (over 20kg):
Initial: 400mg/ day (irrespective of weight). Dose may be increased by 20-30 mg/kg if required to achieve control.

**Contraindication & Precaution**
Sodium valproate is contra-indicated in patients with known hypersensitivity of sodium valproate, personal or family history of severe active liver disease hepatic dysfunction, porphyria & known urea cycle disorder.

**Side Effect**
Gastric irritation, nausea, ataxia & tremor; hyperammonaemia, increased appetite & weight gain; transient hair loss, oedema, thrombocytopenia, & inhibition of platelet aggregation, impaired hepatic function leading rarely to fetal hepatic failure; rashes; sedation; rarely lethargy & confusion & also increased alertness; rarely pancreatitis, leucopenia, pancytopenia, red cell hypoplasia, fibrinogen reduction; irregular periods, amenorrhoea, gynaecomastia, toxic epidermal necrolysis, hearing loss, Fancoli's syndrome, dementia, Steven's-Johnson syndrome, & vasculitis have also been reported.

**Drug Interaction**
Sodium valproate is a non specific inhibitor of drug metabolism. Phenobarbital, Phenytoin, Warfarin, Aspirin etc most significantly interacts with sodium valproate

**Use in Pregnancy & Lactation**
Pregnancy category D

**Use in Children**
Can be used for children

**Preparation**
200 mg, 300 mg & 500 mg CR Tablet & 200 mg/5 ml Syrup.

# Vanprox™



**Active Ingredient**
Cefpodoxime.

**Indication**
Lower respiratory tract infections, Upper respiratory tract infections, Urinary tract infections including gonorrhoea, cystitis, Skin & soft tissue infections, Gynecological infections, Acute otitis media, Childhood infections.

**Dosage & Administration**
*Adults (Including age 13 years & older):*
Acute community-acquired pneumonia: 400 mg / 200 mg 12 hourly 14 days.
Acute bacterial exacerbation of chronic bronchitis: 400 mg / 200 mg 12 hourly 10 days.
Uncomplicated gonorrhea (men/women): 200 mg Single dose.
Rectal gonococcal infection in women: 200 mg Single dose.
Skin & soft tissue infections: 200 mg twice days.
Pharyngitis and/or tonsillitis: 200 mg 12 hourly 5-10 days.
Uncomplicated urinary tract infection: 200 mg 12 hourly 7 days
Acute maxillary sinusitis: 400 mg/200 mg 12 hourly 10 days
*Child:* 15 days-6 months : 4 mg/kg every 12 hours, 6 months-2 years : 40 mg every 12 hours, 3-8 years: 80 mg every 12 hours, Over 9 years : 100 mg every 12 hours.

**Contraindication & Precaution**
Known allergy to the cephalosporin class of antibiotics. In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of Cefpodoxime should be reduced because high & prolonged serum antibiotic concentration can occur in such individuals following usual doses. As with other antibiotics, prolonged use of Cefpodoxime may result in overgrowth of nonsusceptible organisms. If superinfection occurs during therapy, appropriate measures should be taken.

**Side Effect**
Gastrointestinal disorders (such as diarrhoea, nausea, vomiting & abdominal pain), rash, urticaria & itching.

**Use in Pregnancy & Lactation**
Pregnancy Category B.
Cefpodoxime is excreted in breast milk & caution should be exercised when administered to a nursing women.

**Drug Interaction**
Antacids, H2-blockers, Probenecid, Nephrotoxic drugs.

**Preparation**
40 mg/5 ml Suspension, 20 mg/ml Paediatric Drops.

# Vertina® D

**Active Ingredient**
Doxylamine Succinate & Pyridoxine Hydrochloride.

**Indication**
Nausea and Vomiting of Pregnancy (NVP).

**Dosage & Administration**
Take two tablets daily at bedtime.

Maximum 4 tablets daily.
Take on an empty stomach with a glass of water.

**Contraindications**
This combination is contraindicated in women with known hypersensitivity to Doxylamine Succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride, monoamine oxidase inhibitors (MAO) or any inactive ingredient in the formulation.

**Special Warning & Precautions**
Vertina-D use is not recommended if a woman is concurrently using central nervous system (CNS) depressants including alcohol. The combination may result in severe drowsiness leading to falls or accidents.

**Side Effects**
Side effects may include somnolence.

**Use in Pregnancy & Lactation**
Pregnancy category A.
Women should not breastfeed while using Vertina -D.

**Preparation**
Tablet

# Vertina® Plus

**Active Ingredient**
Meclizine & Pyridoxine.

**Indication**
For prophylaxis & symptomatic relief of nausea, vomiting, dizziness, motion sickness, radiation sickness & vertigo associated with diseases of vestibular system (e.g. Meniere's syndrome, labyrinthitis & other vestibular disturbances) & morning sickness during pregnancy.

**Dosage & Administration**
Nausea & vomiting (including morning sickness in pregnancy): One tablet 1-2 times daily or as directed by physician.
Motion sickness: The initial dose is one or two tablets daily; it should be taken one hour prior to journey for protection against motion sickness. Therefore, the dose may be repeated every 24 hours as indicated for the duration of journey.
Vertigo: One tablet two times daily or as directed by physician.
Labyrinthine & vestibular disturbances: The optimal dose of Meclizine HCl is usually 25 to 100 mg daily in divided doses, depending on the clinical response.
Radiation sickness: 50 mg (Meclizine HCl) administered 2 to 12 hours prior to radiation treatment. Pyridoxine (vitamin B6) has been shown to be safe & Effective in dosages of 50 to 200 mg per day.

**Contraindication & Precaution**
The fixed-dose combination is contra-indicated in individuals who have shown a previous hypersensitivity to these ingredients. Due to its potential anticholinergic action, patient with asthma, bronchitis, emphysema, enlarged prostate, glaucoma or urinary tract blockade should take Meclizine HCl (like other antiemetics) with caution.

**Side Effect**
Drowsiness, dry mouth, urinary retention or rare occasions, blurred vision have been reported. Sensory neuropathy reported with high dosage of Pyridoxine hydrochloride given for extended periods.

**Use in Pregnancy & Lactation**
Indicated.

**Preparation**
Meclizine HCl 25 mg & Pyridoxine HCl 50 mg film coated Tablet.

# Viglimet™

**Active Ingredient**
Vildagliptin & Metformin HCl

**Indication**
Viglimet is indicated in patients with type 2 diabetes who are unable to achieve sufficient glycemic control at their maximally tolerated dose of oral Metformin alone or who are already treated with the combination of Vildagliptin & Metformin as separate tablets.

**Dosage & Administration**
Adults: Based on the patient's current dose of Metformin, Combination of Vildagliptin & Metformin may be initiated at either 50 mg/500 mg or 50 mg/850 mg twice daily, 1 tab in the morning & the other in the evening. The recommended daily dose is 100 mg Vildagliptin plus 2000 mg Metformin HCl. Patients receiving Vildagliptin & Metformin from separate tablets may be switched to combination of Vildagliptin & Metformin containing the same doses of each component. Doses higher than 100 mg of Vildagliptin are not recommended. There is no clinical experience of Vildagliptin & Metformin in triple combination with other antidiabetic agents. Taking Combination of Vildagliptin & Metformin with or just after food may reduce gastrointestinal symptoms associated with Metformin.

**Contraindication & Precaution**
Combination (Vildagliptin & Metformin HCl) is contraindicated in patients with:
•Hypersensitivity to the active substance or to any of the excipients
•Patients with Renal Impairment: Creatinine clearance <60 mL/min.
•Patients with Hepatic Impairment: patients with pre-treatment alanine aminotransferase (ALT) or aspartate aminotrasferase (AST) >2.5 times the upper limit of normal (ULN).
•patients with type 1 diabetes

**Side Effect**
The majority of adverse reactions were mild & transient, not requiring treatment discontinuations.
Lactic acidosis can occur due to Metformin. Rare cases of hepatic dysfunction. Some common side effects like tremor, headache, dizziness, nausea, hypoglycaemia, fatigue are seen. Clinical trials of up to & more than 2 years' duration did not show any additional safety signals or unforeseen risks when use this combinatin.

**Drug Interaction**
In pharmacokinetic studies, no interactions were seen with pioglitazone, Metformin, glibenclamide, digoxin, warfarin, amlodipine, ramipril, valsartan or simvastatin. As with other oral antidiabetic medicinal products the glucose-lowering effect of Vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products & sympathomimetics. Close monitoring of glycemic control is required, when cationic drugs are co-administered. Glucocorticoids, beta 2-agonists, diuretics & ACE inhibitors may alter blood glucose. The patient should be informed & more frequent blood glucose monitoring performed, especially at the beginning of treatment. If necessary, the dosage of Vildagliptin & Metformin tablets may need to be adjusted during concomitant therapy & on its discontinuation.

**Use in Pregnancy & Lactation**
Pregnancy: There are no adequate data on the use of Vildagliptin & Metformin in pregnant women; hence the potential risk for humans is unknown.
Nursing Mothers: It is not known whether Vildagliptin is excreted in human milk. Due to lack of human data, Vildagliptin & Metformin should not be used during lactation.

**Use in Children**
Combination of Vildagliptin & Metformin is not recommended in patients 18 years of age.

**Preparation**
Viglimet 50/500 Tablet.

# Viglita™

**Active Ingredient**
Vildagliptin

**Indication**
Viglita is indicated as an adjunct to diet & exercise to improve glycemic control in patients with type 2 diabetes mellitus. Or monotherapy in dual combination with Metformin, a sulphonylurea, a thiazolidinedione, or insulin when diet, exercise & a single antidiabetic agent do not result in adequate glycemic control.

**Dosage & Administration**
The recommended dose of Viglita is
50 mg or 100 mg daily for monotherapy. 50 mg twice daily (morning & evening) when used in dual combination with Metformin or a thiazolidinedione; 50mg once daily in the morning when used in dual combination with a sulphonylurea.
Viglita may be taken with or without a meal. No dosage adjustment is required in the elderly, or in patients with mild renal impairment.

**Contraindication & Precaution**
Vildagliptin is contraindicated in patients with: Hypersensitivity to the active substance or to any of the excipients, Patients with moderate to severe renal Impairment, Patients with Hepatic Impairment: patients with pre-treatment alanine aminotransferase (ALT) or aspartate aminotrasferase (AST) >3 times the upper limit of normal (ULN), patients with type 1 diabetes

**Side Effect**
The majority of adverse reactions were mild & transient, not requiring treatment discontinuations. Rare case of hepatic dysfunction is seen. Clinical trials of up to & more than 2 years' duration did not show any additional safety signals or unfore seen risks when use this combination.

**Drug Interaction**
In pharmacokinetic studies, no interactions were seen with pioglitazone, Metformin, glibenclamide, digoxin, warfarin, amlodipine, ramipril, valsartan or simvastatin. As with other oral antidiabetic medicinal products the glucose-lowering effect of Vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products & sympathomimetics.

**Use in Pregnancy & Lactation**
Pregnancy: Vildagliptin should not be used in pregnancy
Nursing Mothers: Vildagliptin should not be used during lactation.

**Use in Children**
Vildagliptin is not recommended in patients 18 years of age.

**Preparation**
Each tablet contains Vildagliptin INN 50 mg.



# Vigorex™

**Active Ingredient**
Sildenafil

**Indication**
Erectile Dysfunction.

**Dosage & Administration**
The usual starting dose of Vigorex is 50 mg once daily. It should be taken before 30-40 minutes of intercourse. Depending on effectiveness & tolerance; the dose may be increased to a maximum recommended dose of 100 mg or decreased to 25 mg. The maximum dosing frequency is once per day. Vigorex may takes longer time to work if you take it with a heavy meal.

**Contraindication**
Sildenafil was shown to potentiate the hypotensive effects of nitrates & its administration to patients who are using organic

nitrates, either regularly & or intermittently, in any form is therefore contraindicated.

**Side Effect**
Sildenafil: Sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat. Common side effect includes headache, facial flushing, indigestion, effects on vision, light sensitivity, blurred vision or reduced, stuffy nose & dizziness. Uncommon side effect includes vomiting, skin rash, bleeding at the back of the eye, red eyes, eye pain, double vision, abnormal sensation in the eye, irregular or rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, chest pain & feeling tired.

**Warnings**
In patients with preexisting cardiovascular disease, there is a potential risk in sexual activity. Sildenafil should not be generally used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status. There is no controlled clinical data on the safety or efficacy of Sildenafil in Patients who have suffered from a myocardial infarction, stroke, or life-threatening arrhythmia within the last 6 months. Caution should be taken in patients with resting hypotension (BP <90/50) or hypertension (BP >170/110), cardiac failure or coronary artery disease causing unstable angina, retinitis pigmentosa. Prolonged erection greater than 4 hours & priapism (painful erections greater than 6 hours in duration) have been reported infrequently since market approval of Sildenafil. In this situation, patient should seek immediate medical assistance.

**Precaution**
Sildenafil tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell the healthcare professional treating your condition that you have taken Sildenafil & if you did, do not take Sildenafil with other medicines unless your doctor tells you can. You should not take Sildenafil if you are taking medicines called nitrates as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or chest pain). You should not take Sildenafil if you are using any of the drugs known as nitric oxide donors such as amyl nitrite as the combination may also lead to potentially dangerous decrease in your blood pressure. If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of Sildenafil. Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking Sildenafil with alpha-blocker. This is most likely to occur within 4 hours after taking Sildenafil. In order to reduce the likelihood of these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil. Your doctor may start you on a lower dose (25 mg) of Sildenafil if you have hypotension (avoid if systolic blood pressure below 90 mmHg), recent stroke, unstable angina & myocardial infarction. Drinking alcohol can temporally impair your ability to get an erection, to get the maximum benefit from your medicine; you are advised not to drink excessive amounts of alcohol before taking Sildenafil.

**Pregnancy, Lactation & Paediatric use**
Sildenafil is not indicated for use in newborns, children & women.

**Preparation**
25 mg, 50 mg & 100 mg Tablet.

# Vigosol™ IV

**Active Ingredient**
Solution of 5% Composite Amino Acid with Electrolytes & D-Sorbitol

**Indication**
VigosolTM IV is indicated as a source of amino acids for protein synthesis in patients needing intravenous nutrition. VigosolTM IV is particularly suitable for patients with basal amino acid requirements. VigosolTM IV is also indicated in faster recovery in surgery, burns, renal insufficiency, hepatic insufficiency and effective management of cancer.

**Dosage & Administration**
The nitrogen requirement for maintenance of body protein mass depends on the patient's condition (nutritional state and degree of metabolic stress). The requirements are 0.10-0.15 g nitrogen/kg/day (no or minor metabolic stress and normal nutritional state), 0.15-0.20 g nitrogen/kg/day (moderate metabolic stress with or without malnutrition) and up to 0.20-0.25 g nitrogen/kg/day (severe catabolism as in burns, sepsis and trauma). The dosage range 0.10- VigosolTM IV/kg/day. In obese patients, the dose should be based on the estimated ideal weight. Depending upon patient's requirements, 1000-2000 ml VigosolTM IV may be infused intravenously per 24 hours. It should be infused slowly, at rates 1.4-2.8 ml (30-60 drops) per minute.

**Contraindication & Precaution**
Contraindicated in patients with inborn errors of amino acids metabolism, irreversible liver damage and severe uremia when dialysis facilities are not available.

**Use in Pregnancy & Lactation**
Successful and safe administration of amino acid solutions during pregnancy in the human has been reported. Animal reproduction studies have not been carried out with Amino acid.

**Preparation**
VigosolTM IV: Each box contains sterile solution of 5% composite Amino Acid with electrolytes & D-Sorbitol for infusion in a glass bottle with Infusion set, Alcohol pad, First Aid Bandage & Plastic hanger.

# VOLINAC™

**Active Ingredient**
Diclofenac Sodium

**Composition**
VOLINAC gel: Each gram gel contains Diclofenac Diethylamine BP equivalent to Diclofenac Sodium BP 10 mg.

**Pharmacology**
Diclofenac Diethylamine is systemically absorbed through the skin; it inhibits the enzyme cyclooxygenase, thus reducing the formation of PGE2. Moreover, it also increases the uptake of Arachidonic acid into the cellullar pool. Menthol is a vasodiator. It dilates the blood vessels, produces a feeling of coolness and produces analgesia. Methyl salicylate is a known anti-inflammatory agent.

**Indication**
Indicated for the quick relief from pain, swelling and inflammation due to musculo-skeletal disorders such as sprains, strains, tendinitis, bursitis, hands, neck & shoulder pain, sciatica, muscle stiffness, joint pain, back ache and lumbago.

**Dosage & Administration**
Approximately one-inch band of gel should be applied to the affected site three to four times daily with rubbing till the film disappears.

**Contraindications**
Known hypersensitivity to any part of the preparation.

**Precautions**
For external use only. Avoid contact with the

eyes. Stop use and ask a doctor if condition worsens or does not improve within 7 days. Keep out of the reach of children. If swallowed, get medical help or contact a poison control center right away.

**Side-effects**
Usually well tolerated. Extremely low frequency of hypersensitivity reactions.

**Use in Pregnancy & Lactation**
The safety of VOLINAC Gel has not been established during pregnancy. There are no well-controlled studies of diclofenac in pregnant women.

**Use in Pediatric patients**
Safety and effectiveness in pediatric patients have not been established.

**Storage**
Store in a cool and dry place, protected from light.



How supplied
50 gm tube.

# Viodin®

**Active Ingredient**
Povidone-Iodine

**Indication**
Viodin solution is used in the treatment of Primary or secondary topical infections, infected surgical incisions, infected decubitus or stasis ulcers, pyodermas, secondarily infected dermatoses, & infected traumatic lesions, burns, incisions & other topical lesions. Viodin ointment can cure abrasions, minor cuts & wounds. Mouth-wash is indicated for acute mucosal infection for mouth & pharynx.

**Dosage & Administration**
Viodin® 5% Ointment: For the treatment of infection: Apply once or twice daily or at dressing changes for a maximum of 14 days. For the prevention of infection: Apply once or twice a week for as long as necessary. The affected skin should be cleaned and dried and can be covered with a dressing or bandage. Viodin® 1% Mouthwash Gargle: Adults and children over 6 years of age: Use undiluted or diluted with an equal volume of warm water. Gargle or rinse with up to 10 ml for up to 30 seconds without swallowing. Repeat up to four times daily for up to 14 consecutive days or as directed. Viodin® 10% Solution: Apply full strength as an antiseptic skin cleanser.

**Contraindication & Precaution**
It is contraindicated in known or suspected iodine hypersensitivity. Regular use is contraindicated in patients or users with thyrod disorders. Povidone iodine is not recommended for regular use in neonates.Special caution is needed when regular applications to broken skin are made to patients with pre-existing renal insufficiency. Regular use should be avoided in patients on concurrent lithium therapy.

Povidone iodine 1% Mouthwash/Gargle is not for use in children under 6 years of age. Do not use for more than 14 days.

**Side Effect**
Local skin reactions, severe burns may produce systemic adverse effects such as metabolic acidosis, hypernatraemia & impairment of renal function.

**Preparation**
1% (50 mg/5 ml) Mouth-wash/Gargle, 10% (500 mg/5 ml) Solution, 5 % (50 mg/gm) Ointment.

# Virux®

**Active Ingredient**
Aciclovir.

**Indication**
For the treatment of viral infections due to *Herpes simplex* virus (type I & II) & *Varicella zoster* virus (herpes zoster & chickenpox).
For the treatment of *Herpes simplex* virus infections of the skin & mucous membranes including initial & recurrent genital herpes.
For the prophylaxis of herpes simplex infections in immunocompromised patients.

**Dosage & Administration**
Treatment of initial *Herpes simplex*: 200 mg 5 times daily usually for 5 days. For immunocompromised patients 400 mg 5 times daily for 5 days (longer if new lesions appear during treatment or if healing incomplete; increase dose to 800 mg 5 times daily for genital herpes in immuno-compromised) or as directed by the registered physician.
Children under 2 years: half of the adults dose.
Children over 2 years: Adult dose.
Prevention of recurrence of *Herpes simplex*: 200 mg 4 times daily or 400 mg twice daily possibly reduced to 200 mg 2 or 3 times daily & interrupted every 6-12 months.
Children under 2 years: Half of the adult dose.
Children over 2 years: Adult dose.
Prophylactic treatment of *Herpes simplex* in the immunocompromised: 200 to 400 mg 4 times daily.
Children under 2 years: Half of the adult dose.
Children over 2 years: Adult dose.
Treatment of varicella (chicken pox): Adult & children over 40 kg - 800 mg 4 times daily for 5 days.
Children below 40 kg: 20 mg / kg (maximum 800 mg) per dose orally 4 times daily (80 mg / kg/day) for 5 days.
Or, Children under 2 years : 200 mg 4 times daily
Children 2-5 years : 400 mg 4 times daily
Children Over 6 years : 800 mg 4 times daily
Treatment of herpes zoster (Shingles): 800 mg 5 times daily for 7 days.
Treatment of initial rectal (Proctitis) herpes infections: An oral Aciclovir dosage of 400 mg 5 times daily for 10 days or until clinical resolution occurs has been recommended.
Cream : Virux cream should be applied to lesions or impending lesions 5 times daily (at 4 hourly intervals omitting the night-time dose). Treatment should continue for 5 days. If healing does not occur, treatment may be extended for up to 10 days.
Children :
HSV infections in children over 2 years should be given adult doses & children below 2 years should be given half of the adult dose.

Dosage & Administration of Virux IV Inj.

| Indication | Immune status | Dosage |
|---|---|---|
| Herpes simplex infection | Normal or immunocompromised | 5 mg/kg every 8 hours |
| Very severe Herpes zoster infection (shingles) | Normal | 5 mg/kg every 8 hours |
| Varicella zoster infection | Immunocompromised | 10 mg/kg every 8 hours |
| Herpes simplex encephalitis | Normal or immunocompromised | 10 mg/kg every 8 hours |

**Contraindication & Precaution**
Known to be hypersensitive to Aciclovir. Virux® cream is not recommended for application to mucous membrane such as eye, mouth, vagina etc.

**Side Effect**
Skin rashes, nausea, vomiting, diarrhea, headache & abdominal pain.

**Drug Interaction**
Probenecid, Amphotericin B, Ketoconazole.

**Use in Pregnancy & Lactation**
The drug should be used during pregnancy only when the potential benefits justify the possible risks to the fetus; the drug's potential for causing chromosomal damage at high concentrations should be considered. Because of the potential for serious adverse reactions to aciclovir in nursing infants, a decision should be made whether to discontinue nursing or the drug.

**Preparation**
200 & 400 mg Tablet, 200 mg/5ml Suspension ,50 mg/gm Cream & 500 mg IV inj.

# Virux® HC

**Active Ingredient**
Aciclovir & Hydrocortisone

**Indication**
Virux® HC Cream is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and children (6 years of age and older).

**Dosage & Administration**
The cream should be topically applied 5 times per day for 5 days. Therapy should be initiated as early as possible after the first signs and symptoms.

**Contraindication**
There is no known contraindication.

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**Precaution**
Aciclovir and Hydrocortisone should not be used in the eye, inside the mouth or nose, or on the genitals. Patients should seek medical advice when a cold sore fails to heal within 2 weeks.

**Side Effect**
The following most common adverse reactions (< 1%) were local skin reactions like drying or flaking of the skin; burning or tingling, erythema; pigmentation changes, application site reactions including signs and symptoms of inflammation.

**Use in Pregnancy & Lactation**
Pregnancy Category B. There are no adequate and well-controlled studies of systemic Aciclovir in pregnant women. No studies have been performed in pregnant women. Systemic exposure of Aciclovir and Hydrocortisone following topical administration of this cream is minimal.

**Drug Interaction**
No drug interaction studies have been performed with Aciclovir and Hydrocortisone.

**Preparation**
(50mg + 10mg)/ gm Cream.

# Xenole®

**Active Ingredient**
Naproxen & Esomeprazole

**Indication**
For the relief of signs & symptoms of Osteoarthritis, Rheumatoid Arthritis & Ankylosing Spondylitis & to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

**Dosage & Administration**
One Xenole 375 or Xenole 500 tablet twice daily, at least 30 minutes before meal.

**Contraindication & Precaution**
Known hypersensitivity, History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs, during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery, Late pregnancy.

**Side Effect**
Most common side effects are erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea etc.

**Drug Interaction**
Concomitant use of NSAIDs may reduce the antihypertensive Effect of ACE inhibitors, diuretics, & beta-blockers.

**Use in Pregnancy & Lactation**
Pregnancy category C.

**Use in Children**
Use in children less than 18 years has not been established yet

**Preparation**
Naproxen 375 mg + Esomeprazole 20 mg Tablet & Naproxen 500 mg + Esomeprazole 20 mg Tablet

# Xfin

**Active Ingredient**
Terbinafine HCL.

**Indication**
Fungal infections of the skin caused by dermatophytes such as Trichophyton rubrum, Trichophyton mentagrophytes, Microsporum canis and Epidermophyton floccosum. Xfin™ Tablet: Onychomycosis of the toenail or fingernail due to dermatophytes, Ringworm (Tinea corporis, Tinea cruris and Tinea pedis) where oral therapy is considered appropriate due to the site, severity or extent of the infection; Xfin™ Cream: Yeast infections of the skin principally caused by the genus Candida (e.g. Candida albicans), Pityriasis (tinea) versicolor due to Pityrosporum orbiculare (also known as Malassezia furfur)

**Dosage & Administration**
Tablet: In each indication, dose of Terbinafine Tablet is 250 mg once daily. Cream: Cream can be applied once or twice daily. Duration of treatment varies according to the indication and the severity of infections.

**Preparation**
250 mg Tablet & 10 gm Cream

# Xflam™

**Active Ingredient**
Dexibuprofen

**Indication**
Management of pain & inflammation associated with Osteoarthritis & other musculoskeletal disorders. Symptomatic treatment of mild to moderate pain & inflammation including dysmenorrhoea & dental pain.

**Dosage & Administration**
The recommended dosage is 600-900 mg Dexibuprofen per day, at 2-3 divided doses. Maximum single dose is 400 mg. The dosage can be raised temporarily up to 1200 mg Dexibuprofen per day in patients with acute disorders or exacerbations. *Elderly patient:* Lowest Effective dose is recommended. The dosage can be raised to adult dosage if well tolerated.

**Contraindication & Precaution**
Dexibuprofen is contraindicated in patients with previous history of hypersensitivity to Dexibuprofen or other NSAIDs. Dexibuprofen is contraindicated in patients, who experience attack of asthma, bronchospasm, acute rhinitis, urticaria or edema after use of similar drugs (e.g., aspirin or other NSAIDs). It is also contraindicated in patients with active or suspected hemorrhage, Crohn's disease or Ulcerative Colitis, patients with serious heart diseases, kidney function impairment (GFR < 30ml/min), & severe liver function impairment.

**Side Effect**
Dyspepsia, diarrhea, fatigue, & headache, nausea, vomiting, & abdominal pain. Less common Side Effect: Flatulence, urticaria, pruritus, purpura, rhinitis, bronchospasm, insomnia, & tinnitus.

**Use in Pregnancy & Lactation**
Use of Dexibuprofen should be avoided during the pregnancy. Dexibuprofen should be used with cautions in nursing mothers.

**Use in Children**
Patients below 18 years of age have not been established.

**Preparation**
400 mg Tablet.

# Xten™

**Active Ingredient**
Tenoxicam.

**Indication**
- Rheumatoid Arthritis
- Osteoarthritis
- Ankylosing Spondylitis
- Post-operative pain
- Acute gout
- Primary dysmenorrhoea

**Dosage & Administration**
For all indications except primary dysmenorrhoea, post-operative pain & acute gout, a daily dosage of 20 mg should be given at the same time of day.
The recommended dose for primary dysmenorrhoea is 20 to 40 mg once daily. For post-operative pain the recommended dose is 40 mg once daily up to five days & for acute attacks of gout the recommended dose is 40 mg once daily for two days followed by 20 mg once daily for a further five days.

**Contraindication & Precaution**
Hypersensitivity to Tenoxicam or any component of the product or other non-steroidal anti-inflammatory drugs (NSAIDs); in whom salicylates or other NSAIDs induce symptoms of asthma, rhinitis or urticaria; suffering from gastritis, gastric & duodenal ulcer.

**Side Effect**
The following undesirable effects have been reported in few cases:
Gastrointestinal tract: gastric, epigastric & abdominal discomfort, dyspepsia, heartburn, nausea. Central nervous system: dizziness, headache.

**Drug Interaction**
Tenoxicam may have the following drug interactions:
*Acetylsalicylate & Salicylates:* Salicylates increase the clearance & volume of distribution of NSAIDs including Tenoxicam
*Anti-platelet agents & SSRIs:* There is an increased risk of gastrointestinal bleeding when anti-platelet agents & selective serotonin-reuptake inhibitors (SSRIs) are combined with NSAIDs.
*Diuretics & antihypertensives:* No clinically significant interaction between Tenoxicam & Frusemide was noted, but Tenoxicam attenuates the blood pressure lowering Effect of Hydrochlorothiazide. As known from other NSAIDs, Tenoxicam might attenuate the antihypertensive effects of alpha-adrenergic blockers & ACE-inhibitors.
No interactions have been reported between Tenoxicam & centrally acting alpha agonists or calcium channel blockers.
There was no clinically relevant interaction when Tenoxicam was administered together with Atenolol.

**Use in Pregnancy & Lactation**
Treatment during the third trimester of pregnancy should be avoided.
There is no evidence of adverse reactions in breast-fed infants of mothers taking Tenoxicam.

**Use in Children**
Not yet established

**Preparation**
20 mg Tablet.

# Xylocon®

**Active Ingredient**
Oxymetazoline.

**Indication**
Relief of nasal congestion associated with acute & chronic rhinitis, common cold & Sinusitis.

**Dosage & Administration**
Adults & children 6 years of age : 2 to 3 drops of Xylocon® 0.05% in each nostril twice daily, in

the morning & evening. Children 2-5 years of age : 2 to 3 drops of Xylocon® 0.025% in each nostril twice daily in the morning & evening. Oxymetazoline HCl should generally be used for no longer than 3-5 days.

**Contraindication & Precaution**
MAO inhibitor, Tricyclic antidepressant. Patients sensitive to other nasal decongestants may be sensitive to this medication also.

**Side Effect**
Stinging, burning, sneezing, increased nasal discharge, drying of the nostrils, & altered taste.

**Drug Interaction**
Causes hypertensive crisis if used simultaneously with MAO inhibitor or Tricyclic antidepressant.

**Use in Pregnancy & Lactation**
Safe in the third trimester of a normal pregnancy. Caution should be exercised when administering to a nursing mother.

**Preparation**
0.05% Nasal Drops for adults, 0.025% Paediatric Nasal Drops for children.

# Zanthin™

**Active Ingredient**
Astaxanthin

**Indication**
Astaxanthin is indicated as strong antioxidant. Also indicated in –
•Internal beautification & skin improvement
• Improvement of cardiovascular health
•Improvement of brain & central nervous system health
• For healthy immune system

**Dosage & Administration**
The recommended daily dosage is fairly standardized at a 4 mg per day. Following is a table of recommended dosages:
Dosage Use 2-4 mg Antioxidant, Cardiovascular Health, Immune System Enhancer 4-8 mg Internal Beauty & Skin Improvement, Strength & endurance, Brain & Central Nervous System Health, Eye Health 4-12 mg Arthritis, Silent in ammation(C-reactive protein), Internal Sunscreen

| Dosage | Use |
|---|---|
| 2-4 mg | Antioxidant, Cardiovascular Health, Immune System Enhancer |
| 4-8 mg | Internal Beauty & Skin Improvement, Strength & endurance, Brain & Central Nervous System Health, Eye Health |
| 4-12 mg | Arthritis, Silent in ammation(C-reactive protein), Internal Sunscreen |
| | |

**Contraindication & Precaution**
Astaxanthin is contraindicated in those hypersensitive to any component of an Astaxanthin containing supplement. Pregnant women & nursing mothers should avoid Astaxanthin containing supplements.

**Side Effect**
No reports have been found regarding Astaxanthin.

**Drug interaction**
There are no known adverse reactions when taken in conjunction with medications.

**Use in pregnancy & Lactation**
Both pregnant women & lactating mother should avoid Astaxanthin containing supplements.

**Preparation**
2 mg & 4 mg tablet.

# Zesup®

**Active Ingredient**
Zinc Sulphate.

**Indication**
**Zesup®** is indicated in zinc deficiency and/or zinc losing conditions. Zinc deficiency can occur as a result of inadequate diet or malabsorption, excessive loss of zinc can occur in trauma, burns, diarrhoea & protein losing conditions. A zinc supplement is given until clinical improvement occurs but it may need to be continued in severe malabsorption, metabolic disease or in zinc losing states. It is indicated in the following conditions -
Recurrent Respiratory Tract Infections, Diarrhoea, Loss of appetite, Severe growth retardation, Deformed bone formation, Impaired immunological response, Acrodermatitis enteropathica, Parakeratotic skin lesions, Defective & delayed wound healing, Anaemia, Night blindness & Mental disturbances.

**Dosage & Administration**
**Zesup®** Syrup:
Child under 10 kg : 5 ml (1 teaspoonful) 2 times daily.
Child between 10 - 30 kg : 10 ml (2 teaspoonful) 1-3 times daily.
Adults & child over 30 kg : 20 ml (4 teaspoonful) 1-3 times daily.

This drug is most Effective if they are taken at least 1 hour before or 2 hour after meals. However, if it causes stomach upset, this may be taken with a meal. This medicine should be used regularly to get the most benefit from it.

**Contraindication & Precaution**
It is contraindicated in those who are hypersensitive to any component of the ingredient of this zinc containing supplement. In acute renal failure zinc accumulation may occur; so doses adjustment requred if needed.

**Side Effect**
Zinc may cause nausea, vomiting, diarrhoea, stomach upset, heartburn & gastritis.

**Use in Pregnancy & Lactation**
Zinc is used during pregnancy & lactation at a dose of 20 mg per day. Zinc crosses the placenta & is present in breast milk.

**Drug Interaction**
Concomitant intake of a Tetracycline & Zinc may decrease the absorption of both the Tetracycline & Zinc. Similarly concomitant administration of Zinc & Quinolone may also decrease the absorption of both. Concomitant intake of Penicillamine & Zinc may depress absorption of Zinc.

**Preparation**
100 ml Syrup.

# Zif®

**Active Ingredient**
Ferrous Sulphate, Zinc Sulphate & Folic Acid.

**Indication**
Treatment & prophylaxis of Iron, Folic Acid & Zinc deficiency specially during pregnancy & lactation.

**Dosage & Administration**
1 capsule daily. 2 capsule may be required in more severe cases.

**Contraindication & Precaution**
Hypersensitivity, care should be taken in haemochromatosis, haemolytic anaemia or red cell aplasia.

**Drug Interaction**
Tetracycline, penicillamine, antacids & zinc accumulation could exist.

**Use in Pregnancy**
Should be avoided during first trimester of pregnancy.

**Side Effect**
Dark stools, nausea, gastrointestinal irritation, anorexia, vomiting, discomfort, constipation & diarrhoea, allergic reactions.

**Preparation**
Each timed release capsule contains dried Ferrous Sulphate 150 mg, Folic Acid 500 mcg & Zinc Sulphate Monohydrate 61.80 mg.

# Zif-CI™

**Active Ingredient**
Carbonyl Iron + Folic Acid + Zinc.

**Indication**
Treatment & prophylaxis of Iron, Folic Acid & Zinc deficiency especially during pregnancy & lactation.

**Dosage & Administration**
Adult : One capsule daily before food or as directed by the physician.

**Contraindication & Precaution**
Known hypersensitivity to any of its component or those with Iron overload. Special care should be taken in patient with Iron overload states, such as haemochromatosis, haemolytic anaemia or red cell aplasia. In patients with renal failure there may be the risk of Zinc accumulation.

**Side Effect**
Nausea, anorexia, vomiting, discomfort, constipation, diarrhoea may occur. Patients may complain of dark stool. Rarely allergic reactions.

**Drug Interaction**
Carbonyl Iron: Tetracycline antibiotics, quinolone antibiotics, levodopa, levothyroxine, methyldopa & penecillamine. Folic Acid: Phenobarbital, phenytoin & primidone.

**Use in Pregnancy & Lactation**
Use of any drug during the first trimester of pregnancy should be avoided if possible. Thus administration of Iron during the first trimester requires definite evidence of Iron deficiency. Prophylaxis of Iron deficiency where inadequate diet calls for supplementary Zinc & Folic Acid is justified during the remainder of pregnancy.

**Preparation**
Each TR capsule contains Elemental Iron 50 mg as Carbonyl Iron, Folic Acid 0.50 mg & Zinc Sulphate Monohydrate 61.80 mg.



# Zif® Forte

**Active Ingredient**
Carbonyl Iron, Folic Acid , Vitamin B-Complex, Vitamin C (as Ascorbic Acid) & Zinc Sulphate Monohydrate.

**Indication**
It is indicated for the treatment & prophylaxis of Iron, Folic Acid, Vitamin B-Complex, Vitamin C & Zinc deficiency especially during pregnancy & lactation. It is also indicated for the geriatric patients with generalized weakness due to vitamins & minerals deficiency.

**Dosage & Administration**
Adult: One Capsule daily before food or as directed by the physician.

**Contraindication & Precaution**
It is contraindicated in patients with known hypersensitivity to any of its component or those with Iron overload. Special care should be taken in patients with Iron overload states, such

as haemochromatosis, haemolytic anaemia or red blood cell aplasia. Failure to response to the treatment requires further investigations to exclude other causes of anaemia. In patients with renal failure there may be the risk of Zinc accumulation.

**Side Effect**
Gastrointestinal irritations such as nausea, anorexia, vomiting, discomfort, constipation & diarrhoea may occur. Patients may complain of dark stool. Carbonyl Iron pellets incorporated into the capsules to reduce the possibility of gastrointestinal irritations. Rarely there may be allergic reactions.

**Use in Pregnancy & Lactation**
Use of any drug during first trimester of pregnancy should be avoided if possible. Thus administration of Iron during the first trimester requires definite evidence of Iron deficiency. Prophylaxis of Iron deficiency where inadequate diet calls for supplementary Zinc & Folic Acid is justified during the remainder of pregnancy.



**Drug Interaction**
Carbonyl Iron decreases the absorption of tetracycline antibiotics, quinolone antibiotics, levodopa, levothyroxine, methyldopa & penicillamine. Folic Acid interacts with antiepileptics, so plasma concentrations of phenobarbital, phenytoin & primidone are possibly reduced.

**Preparation**
Each capsule contains Elemental Iron 50 mg (as Carbonyl Iron INN), Folic Acid BP 0.50 mg, Thiamine Mononitrate USP 2 mg, Riboflavin USP 2 mg, Pyridoxine Hydrochloride BP 1 mg, Nicotinamide USP 10 mg, Vitamin C (as Ascorbic Acid) USP 50 mg & Zinc Sulphate Monohydrate USP 61.80 mg.

# Zifolet™

**Active Ingredient**
Folic Acid & Zinc.

**Indication**
Prophylaxis & in the prevention of Zinc & Folic Acid deficiencies.

**Dosage & Administration**
One tablet daily or as recommended by the physician.

**Contraindication**
Zinc is contraindicated in patients having hypersensitivity to Zinc. Folic Acid is contraindicated in untreated cobalamine deficiency.

**Side Effect**
Abdominal pain, dyspepsia, nausea, vomiting, fever & respiratory distress.

**Drug Interaction**
Large amount of Calcium decreases the absorption of Zinc.

**Use in Pregnancy & Lactation**
Recommended.

**Preparation**
Each film coated tablet contains Folic Acid 5 mg & Zinc 20 mg.

# Ziliron-B®

**Active Ingredient**
Iron (III) Hydroxide Polymaltose Complex, Folic Acid, Vitamin B-complex & Zinc Sulphate Monohydrate.

**Indication**
For the prevention & treatment of Iron, Folic

Acid, Zinc & Vitamin B-Complex deficiencies.

**Dosage & Administration**
One capsule daily. Two capsules may be required a day in severe cases or as directed by the physician.

**Contraindication & Precaution**
Contraindicated in patients with a known hypersensitivity to any of the ingredients of this product. As with all Iron preparations, a dark coloration of the stool may occur which is without clinical significance.

**Side Effect**
Generally well tolerated. Very few allergic reaction may be seen.

**Use in Pregnancy**
Use of any drug during the first trimester of pregnancy should be avoided if possible. Thus administration of Iron during the first trimester requires definite evidence of Iron deficiency. Prophylaxis of Iron deficiency where inadequate diet calls for supplementary Zinc & Folic Acid is justified during the remainder of pregnancy.

**Drug Interaction**
No interactions have been observed. Since, the Iron is complex bound, ionic interaction with foodstuff components (phytates, oxalates, tannin, etc.) & concomitant administrations of medicaments (tetracyclines, antacids) are unlikely to occur.

**Preparation**
Each capsule contains Iron (III) Hydroxide Polymaltose Complex INN 188 mg equivalent to elemental Iron 47 mg, Folic Acid BP 0.5 mg, Thiamine Hydrochloride BP 5 mg, Riboflavin BP 2 mg, Pyridoxine Hydrochloride BP 2 mg, Nicotinamide BP 20 mg & Zinc Sulphate Monohydrate USP 61.80 mg.

# Zimax®

**Active Ingredient**
Azithromycin.

**Indication**
Bronchitis & pneumonia, sinusitis & pharyngitis/ tonsillitis, otitis media, skin & soft tissue infections, sexually transmitted diseases.

**Dosage & Administration**
Adults: 500 mg once daily for 3 days. Children: 10 mg/kg body weight once daily for 3 days.

**Contraindication & Precaution**
Known hypersensitivity, should not be used in patients with hepatic disease. Avoid concomitant administration with terfenadine or astemizole. Precaution should be taken in patients with more severe renal impairment.

**Side Effect**
Nausea, vomiting, abdominal discomfort (pain/cramps), flatulence, diarrhoea, headache, dizziness & skin rashes, reversible elevations in liver transaminases.

**Drug Interaction**
Antacids, Ergot Derivatives, Digoxin & Cyclosporin, Anti-histamines.

**Use in Pregnancy & Lactation**
The initial treatment of chlamydial cervicitis in pregnancy. In other infections, Azithromycin should be used only when clearly needed. Exercise caution when administering to a nursing woman.

**Preparation**
500 mg Tablet, 250 mg Capsule, 200 mg/5 ml Suspension, 500 mg IV Infusion.

# Zolibac™

**Active Ingredient**
Cefazolin as Cefazolin Sodium USP

**Indication**
Respiratory Tract Infections, Urinary Tract Infections, Skin and Skin Structure Infections, Biliary Tract Infections, Bone and Joint Infections, Genital Infections, Septicemia, Endocarditis and Perioperative Prophylaxis.

**Dosage & Administration**
Usual Adult Dosage
Perioperative Prophylactic Use
To prevent postoperative infection in contaminated or potentially contaminated surgery, recommended doses are:
1 gram IV or IM administered ½ hour to 1 hour prior to the start of surgery
For lengthy operative procedures (e.g. 2 hours or more), 500 mg to 1 gram IV or IM during surgery 500 mg to 1 gram IV or IM every 6 to 8 hours for 24 hours postoperatively.
In surgery where the occurrence of infection may be particularly devastating (e.g. open-heart surgery and prosthetic arthroplasty), the prophylactic administration of Zolibac™ may be continued for 3 to 5 days following the completion of surgery.

**Contraindication & Precaution**
Cefazolin is contraindicated in patients with known allergy to the Cephalosporin group of Antibiotics.

**Side Effect**
Common side effects include: Injection site reactions (pain, swelling, skin rash, or a hard lump), diarrhea, stomach pain, stomach cramps, nausea, vomiting, loss of appetite, skin rash or itching, hives, white patches or sores inside the mouth or on the lips, vaginal itching or discharge, heartburn, gas, rectal itching, confusion, weakness, hypotension, drowsiness, headache and allergic reactions.

**Use in Pregnancy & Lactation**
Pregnancy Category B.
Cefazolin is present in very low concentrations in the milk of nursing mothers. Caution should be exercised when Cefazolin is administered to a nursing woman.

**Drug Interaction**
Probenecid may decrease renal tubular secretion of Cephalosporins when used concurrently, resulting in increased and more prolonged Cephalosporin blood levels.

**Preparation**
1 gm & 500 mg IM/IV Injection.

# Zox®

**Active Ingredient**
Nitazoxanide.

**Indication**
Diarrhoea caused by *Cryptosporidium parvum* & *Giardia lamblia,* Amoebiasis & helminth infections.

**Dosage & Administration**
Age 1 - 3 years : 5 ml (100 mg) twice daily for 3 days, Age 4 - 11 years : 10 ml (200 mg) twice daily for 3 days, Age >12 years : 25 ml or 1 tablet (500 mg) twice daily for 3 days.

**Contraindication & Precaution**
Known hypersensitivity to Nitazoxanide or any other ingredient in the formulations. Should be administrated with caution to patients with hepatic, renal & biliary disease.

**Side Effect**
Abdominal pain, diarrhoea vomiting & headache have been reported rarely.

**Use in Pregnancy & Lactation**
Pregnancy category B. This drug should be used during pregnancy only if clearly needed. Nursing mother: Caution should be exercised when Nitazoxanide is administrated to a nursing woman.

**Drug Interaction**
Caution should be taken when administering Nitazoxanide concurrently with other highly plasma-protein bound drugs.

**Preparation**
500 mg Tablet, 30 ml & 60 ml Suspension (100 mg/5 ml).

# Natural Medicine

SQUARE

SQUARE PHARMACEUTICALS LTD.

HERBAL & AYURVEDIC DIVISION

# Adovas®

**Active Ingredient**
Basak (*Adhatoda Vasica*) with some other herbs.

**Indication**
All kinds of cough, dry irritable cough, allergic & smoker's cough. It is also effective in throat irritation & hoarseness.

**Dosage & Administration**
Adults: 3 teaspoonfuls (15 ml) 2 - 3 times a day. In acute cough, warm water can be added for better result.
Children under 12 years of age: 1-2 teaspoonfuls (5 - 10 ml) 3 times a day.

**Contraindication & Precaution**
There is no evidence available on contraindication but it may happen in patients who are hypersensitive to any of its ingredients.

**Side Effect**
No known side effects.

**Use in Pregnancy & Lactation**
The safety of Adovas syrup in pregnancy has not been established. Therefore, it should be used during pregnancy only under the supervision of a physician.

**Preparation**
100 ml & 200 ml syrup.

# AmCivit®

**Active Ingredient**
Amlaki (*Emblica officinalis*).

**Indication**
- Vitamin C deficiency
- Scurvy
- Anemia in children

**Dosage & Administration**
Children (6 months - 12 years): ½ teaspoonful -1 teaspoonful (2.5ml-5 ml) 2 times daily.
Adult(Above 12 years): 2 - 3 teaspoonful (10 - 15 ml) 2 - 3 times daily or as directed by the physician.

**Contraindication & Precaution**
There is no evidence available on contraindication. Precaution should be taken in patients who are hypersensitive to any of its ingredients.

**Side Effect**
There is no known significant side effect.

**Use in Pregnancy & Lactation**
No adverse effect of Amcivit syrup has been reported.

**Preparation**
100 ml syrup.

# Arubin®

**Active Ingredient**
Ferrous fumarate, *Emblica officinalis, Termanalia chebula* with some other herbs.

**Indication**
- Iron deficiency anemia
- Anemia due to malnutrition

• Loss of appetite

It is the only herbal haematinic, which does not cause constipation like some other iron preparations due to the herbs used in it.

**Dosage & Administration**

Adults: 1 or 2 capsule to be taken 2 times daily with water.

Children: Not recommended under 12 years of age.

**Contraindication & Precaution**

There is no evidence available on contraindication but it may happen in-patients who are hypersensitive to any of its ingredients. Caution should be taken with concomitant use of antacid, calcium supplements & tannin containing herbal preparations. So iron supplements should not be taken within 1 hour before or 2 hours after ingestion of any of the above.

**Side Effect**

Arubin capsules are not known to have any side effects if taken as per prescribed dosage.

**Use in Pregnancy & Lactation**

In the first trimester of pregnancy, adequate iron intake is usually obtained from a proper diet; however, in the second & third trimesters, when iron deficiency is more prevalent because of greatly increased requirements, iron supplements may be recommended. Some clinicians prefer to evaluate the patient before giving routine iron supplementation.

Problems in humans have not been documented with intake of normal daily recommended amounts.

**Preparation**

500 mg Capsule.

# Cardi Q™

**Active Ingredient**

Ubidecarenone (Coenzyme Q10)

**Indications**

Cardi Q is indicated for the treatment and prevention of Neurological Disorders • Myopathy • Muscular Dystrophy • Ataxia • Parkinson's disease • Genetic

Neuromuscular Disease • Alzheimer's disease • Migraine

Cardiovascular Disease: • Congestive Heart Failure (CHF) • Cardiomyopathy • Hypertension • Heart

Protection during Surgery • Angina

Others: • Periodontal Gum Disease • Exercise Performance • Diabetes • Cancer • Asthma • Thyroid

Disorder

**Dosage & Administrations**

1 - 3 capsules daily after meal or as directed by physician.

**Contraindications**

None known.

**Pregnancy and Lactation**

There is a lack of long-term safety data to support the safe use of Ubidecarenone during pregnancy and lactation.

**Side Effects**

Ubidecarenone seems to be safe and relatively well tolerated in recommended dose. Occasionally

gastrointestinal discomfort, dizziness and skin rash may occur but these tend to happen with higher doses.

**Drug Interactions**

Statins: The statin drugs reduce endogenous synthesis of Ubidecarenone in the body. Thus, Ubidecarenone supplement may increase Ubidecarenone levels without adversely

aecting statin
drug's efficacy.
Warfarin: May reduce the effectiveness of warfarin.
Thyroid drugs: May alter the effect of thyroid drugs. Beta blockers: Beta blockers (particularly propanolol) have been reported to inhibit some Ubidecarenone dependent enzymes.
Antidiabetic medications: Ubidecarenone may improve glycemic control in some type II diabetics.
If this occurred, antidiabetic medications may need appropriate dose adjustment.
Doxorubicin: Ubidecarenone may help to reduce the cardiotoxicity of doxorubicin.

**Storage**
Store at cool and dry place below 30° c temperature away from direct sunlight & moisture. Keep
the medicine out of the reach of children. Do not freeze.

**Composition**
Cardi-QTM 50 mg soft gel Capsule: Each capsule contains Ubidecarenone (coenzyme Q10) 50 mg.
Cardi-QTM 100 mg soft gel Capsule: Each capsule contains Ubidecarenone (coenzyme Q10) 100 mg.

# Colmint™

**Active Ingredient**
Peppermint oil
(*Mentha x piperita*).
**Indication**
- Irritable bowel syndrome
- Abdominal pain & spasm
- Abdominal distersion /bloating

**Dosage & Administration**
Adults: 1 capsule 3 times daily 30 to 60 minutes before meal with a glass of water. The dose may be increased to a maximum of 2 capsules 3 times daily or as directed by a physician. Children (8 years & above): 1 capsule 3 times daily or as directed by a physician.

**Contraindication & Precaution**
Contraindicated in patients with achlorhydria & also contraindicated for infants & small children due to the potential risk of spasm of the tongue or respiratory tract. It should not be taken with food or immediately after meals. It should be taken 30 to 60 minutes before meals. Must be swallowed whole, with a little liquid. Capsules must not be chewed or crushed.

**Side Effect**
No known side effects according to Commission E.

**Use in Pregnancy & Lactation**
No known restrictions.

**Preparation**
187 mg (0.2 ml) Softgel Capsule.

# Dubarel™

**Active Ingredient**
Saraca indica with some other herbs.

**Indication**
•Metrorrhagia
•Secondary amenorrhea
•Anovulatory infertility
•Polycystic ovarian syndrome (PCOS)

**Dose & administration**
Children under 12 years: Not applicable.
Above 12 years & Adults: 2 - 3 teaspoonfuls (10 - 15 ml) 2 - 3 times daily after meal for 3 – 6 months or as directed by the physician.
Contraindication/Pre-caution:
No known.

**Side effects**
No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

**Preparation**
100 ml syrup.

# Enerton®

**Active Ingredient**
Extract of *Sida cordifolia*.

**Indication**
- General weakness
- Strength & energy booster
- Superb sports tonic
- Tonic for asthmatic patients

**Dosage & Administration**
Children: Under the age of 12 years: Not recommended.
Adult: 2 - 3 teaspoonfuls (10 - 15ml) 2 - 3 times daily or as directed by the physician.

**Contraindication & Precaution**
There is no evidence available on contraindication. But caution should be taken in hypertension, DM & others CNS stimulants.

**Side Effect**
When used within the recommended dosage range, it is well tolerated.

**Use in Pregnancy & Lactation**
It is not recommended during pregnancy.

**Preparation**
200 ml syrup.

# Eprim® & Eprim® Plus

**Active Ingredient**
Evening primrose oil

**Indication**
Dysmenorrhea Cyclical mastalgia Low breastmilk supply Acne vulgaris Atopic dermatitis & Eczema Pregnancy mask

**Dose & administration**
One or two capsules two to three times daily or as advised by the physician.

**Side Effect**
Adverse effects are rare at recommended dosages. Overdose may cause loose stool and abdominal pain.

**Contraindication & Precaution**
Previously it was not recommended for patients diagnosed with schizophrenia or those already receiving epileptogenic drugs such as phenothiazines. However, a recently published analysis of clinical trials involving polyunsaturated fatty acids in the treatment of schizophrenia did not indicate a clear therapeutic or adverse effect of evening primrose oil supplements on schizophrenic patients.

**Use in Pregnancy & Lactation**
No known restrictions. Non-teratogenic, based on animal studies. LA, GLA, and DGLA are important components of human breast milk, so it is reasonable to assume that evening primrose oil may be taken while nursing. According to World Health Organization (WHO), pregnant or lactating women should get 5% of their total daily caloric intake from EFAs.

**Preparation**
500 mg & 1000 mg Softgel Capsule.

# Eredex™

**Active Ingredient**
Yohimbe (*Pausinystalia yohimbe*).

**Indication**
- Erectile dysfunction (Male impotence)
- Loss of libido
- Exhaustion

**Dosage & Administration**
Adult: 1 tablet 3 times daily or as advised by the physician.

**Contraindication & Precaution**
The drug should not be used by patients with liver & kidney diseases, chronic inflammation of the sexual organs or prostate gland or with a history of gastric or duodenal ulcers.

**Side Effect**
Anxiety states, elevated blood pressure, exanthema, nausea, insomnia, tachycardia, tremor, mania & vomiting.

**Drug Interaction**
Theoretically, Yohimbe may counteract the hypotensive effect of antihypertensive medications, resulting inadequate blood pressure control. It may potentiate pharmaceutical MAO-inhibitors.

**Preparation**
5.4 mg capsule.

# Flemo™

**Active Ingredient**
Undenatured Type II Collagen

**Indication**
- Osteoarthritis
- Rheumatoid arthritis
- Joint pain & inflammation
- Difficulties in flexibility & mobility
- Joint discomfort & stiffness (knee extension)
- Impaired joint function
- Strenuous exercise & sports

**Dosage & Administration**
Orally 1 capsule daily with water or as directed by the physician.

**Contraindication**
Contraindicated in patients with known hypersensitivity to chicken or egg.

**Side Effect**
Undenatured Type II Collagen is generally well tolerated in recommended dose. Over dose may cause constipation and headache.

**Drug Interaction**
Not known.

**Use in Pregnancy & Lactation**
Lack of scientific evidence on the use of Undenatured Type II Collagen during pregnancy or lactation.

**Preparation**
40 mg Capsule.

# Garlin™

**Active Ingredient**
Garlic oil (standardized).

**Indication**
Hyperlipidemia, Atherosclerosis, Mild Hypertension.

**Dose & Administration**
1 - 2 capsules daily for 8 – 18 weeks or as advised by the physician.

**Contraindication**
None known. The World Health Organization cautions against the use of garlic by patients with a known allergy to garlic and those taking Warfarin.

**Side Effect**
Gastro-intestinal symptoms, changes to the flora of the intestine and allergic reactions are rare.

**Use in Pregnancy & Lactation**
None known. Major sulfur containing volatiles from garlic are transmitted to breast milk leading to improved drinking habits of infants.

**Preparation**
10 mg Softgel Capsule

# Gelaseed™

**Active Ingredient**
Flaxseed oil (Linum usitatissimum).

**Indication**
Hyperlipidemia
Constipation

**Dosage & Administration**
One softgel capsule two to three times daily, with a meal. For easier
swallowing, take with water before and during ingestion

**Adverse effects**
Adverse eects are rare at recommended dosages. Overdose may cause
loose stool and abdominal pain.

**Contraindications**
Flaxseed Oil should be used with caution when combined with:
Blood thinning medication (i.e. Warfarin, Coumadin)

**Pregnancy & Lactation**
Flaxseed oil is possibly unsafe when taken by mouth during pregnancy. Some research suggests that axseed oil might
increase the chance of premature birth when taken during the second or

third trimesters of pregnancy.
Children: Flaxseed is possibly safe for children in short-term.

**Preparation**
Softgel capsule 1000 mg.

# Giloba®

**Active Ingredient**
*Ginkgo biloba*.

**Indication**
- Cerebral insufficiency
- Demential syndromes: memory deficit, poor concentration, depression, dizziness & headache
- Vertigo & tinnitus
- Peripheral vascular diseases
- Sexual dysfunction secondary to SSRI use
- Acute cochlear deafness

**Dosage & Administration**
Giloba 60 mg 1 or 2 capsules 2 to 3 times daily or as advised by the physician.

**Contraindication & Precaution**
Ginkgo should always be used with caution in patients taking anticoagulants or antiplatelet agents i.e. warfarin, heparin & aspirin. It is also contraindicated in bleeding disorders due to increase bleeding potential associated with chronic use (6 - 12 months) or before elective surgery. Contraindicated in patients with known risk factors for intracranial hemorrhage.

**Side Effect**
No side Effects following proper administration of designated therapeutic dosages.

**Use in Pregnancy & Lactation**
There is no known restriction on the use of ginkgo in pregnancy & lactation.

**Preparation**
60 & 120 mg Capsule.

# Gintex®

**Active Ingredient**
*Panax ginseng.*

**Indication**
- General weakness & tiredness
- Infertility in men
- Type 2 diabetes mellitus
- Cognitive function & mental performance enhancement

**Dosage & Administration**
One Gintex capsule 1 or 2 times a day or as advised by the physician.

**Contraindication & Precaution**
Ginseng can be taken with any other vitamin, minerals or herbal supplement. No known contraindications according to the German E Commission & World Health Organization (WHO).
Over stimulation & insomnia have also been reported with Ginseng. Anecdotal evidence suggests that excessive doses may mildly elevate blood pressure and/or cause hyper sexuality.

**Side Effect:** Over Ginseng's many years of use, no serious side Effects or drug interactions have been reported.

**Use in Pregnancy & Lactation**
No known restriction according to the American Herbal Product Association & German Commission E.

**Preparation**
500 mg Capsule.

**Drug Interaction**
Concurrent use of licorice, laxatives & antidiabetic agents may result in increased risk of hypokalemia & hypoglycemia. Carbamazepine bio-availability may reduce during concomitant administration of psyllium seed.

**Use in Pregnancy & Lactation**
No adverse Effects of Ispergul have been reported.

**Preparation**
3.5 gm Sachet & 120 gm Container.

# Ispergul®

**Active Ingredient**
Plantago ovata husk.

**Indication**
Constipation, Hemorrhoids, Ulcerative colitis & Hyperlipidemia.

**Dosage & Administration**
For adult: 3.5 gm (1 sachet) 2 to 3 times daily with a glass of water.
Children (6 to 12 year): 2 gm to 3.5 gm (½ to 1 Sachet) 2 to 3 times daily with a glass of water.

**Contraindication & Precaution**
Psyllium is contraindicated in patients who have pathological narrowing in the GIT, intestinal obstruction, fecal impaction, difficulty in swallowing or esophageal narrowing, difficulties in regulating diabetes mellitus.

**Side Effect**
Incorrect administration procedure (with too little fluid) can cause the product to swell & lead to obstruction of the esophagus or intestine, particularly with older people. Patients with exocrine pancreatic insufficiency should avoid use of psyllium due to its inhibitory actions on pancreatic lipase.

# Jorvan™

**Active ingredients**
*Commiphora mukul* (Guggulu) with other herbs.

**Indication**
Rheumatoid arthritis, Osteoarthritis, Neuralgia, Myalgia, Spondylitis, Backache, Joint pain/ Arthralgia, Muscle sprain, Joint stiffness

**Dosage & Administration**
1 capsule 2-3 times a day after meal or as advised by the physician.

**Contraindication**
Jogaraj-guggulu is contraindicated in cases of known allergy to plants or guggulu. It is well tolerated but precaution should be taken in hyperthyroidism, diarrhea, during use of antihypertensive, anti-fungal & lipid lowering medication.

**Side effects**
No severe side effects have been observed with Jogaraj-guggulu during the clinical practice for the last twenty-five years; however, systematic Phase 1 study with this drug is carried out and general tolerability of Jogaraj-guggulu is found good. Maximum tolerable dose is about 9 gm per day. In rare case very high dose than prescribed may lead to stomach irritation, diarrhea, stomatitis & urticaria.

**Pregnancy & lactation**
Jogaraj-guggulu should not be used during pregnancy or lactation.

**Preparation**
500 mg Capsule.

**Side effects**
No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. But in rare case high dose may cause burning sensation, diarrhea or may increase urine output.

**Drug interaction**
Not known.

**Use in pregnancy & lactation**
It should not be taken during pregnancy although medical literature has not reported any adverse effects related to fetal development during pregnancy or to infants who are breast-fed.

**Use in children**
Not known.

**Preparation**
200 ml syrup.

# Lecor™

**Active ingredient**
Extract of Caesalpinia sappan & Woodfordia fruticosa (Patrangasav)

**Indication**
- Leucorrhea
- Cervicitis
- Non-specific vaginitis
- Pelvic inflammatory disease

**Dosage & administration**
Above 12 years & Adult: 3 teaspoonfuls (15 ml) 3 times daily after meal for 15 days.

**Contraindication & precaution**
Not known.

# Livolite®

**Active Ingredient**
Andrographis (*andrographis paniculata*).

**Indication**
- Viral fever, flu
- Common cold
- Sinusitis
- Viral hepatitis

**Dosage & Administration**
1 capsule 3 times daily between meals for 5 to 10 days or as directed by the physician.

**Contraindication & Precaution**
Andrographis is contraindicated in cases of known allergy to plants of the Acanthaceae family.

**Side Effect**
Large oral doses may cause gastric discomfort, vomiting & loss of appetite.

**Drug Interaction**
May have a synergistic effect with Isoniazid.

**Use in Pregnancy & Lactation**
Andrographis should not be used during pregnancy or lactation.

**Preparation**
200 mg Capsule.

# Monera®

**Active Ingredient**
*Bacopa monnieri (Brammi)* with some other ingredients as per BNAF.

**Indication**
• Memory loss.
• Attention Deficit Disorder (ADD)
Attention Deficit Hyperactivity Disorder ( ADHD)
• Dementia
• Alzheimer's disease
•Autistic Spectrum Disorder (ASD)

**Dosage & Administration:**
Children 2 - 5 years: 1/2 teaspoonful (2.5 ml) 2 - 3 times daily after meal for 3 months.
6 – 12 years: 1 teaspoonful (5 ml) 2 – 3 times daily after meal for 3 months.
Above 12 years & Adult: 2 – 3 teaspoonfuls (10 - 15 ml) 3 times daily after meal for 3 months.

**Contraindication & Precaution**
Generally is well tolerated but caution should be taken in hyperthyroidism, fever & acute infection. Patients with medical conditions should talk to their doctors before taking Monera.

**Side Effect**
No side effects in mentioned therapeutic doses.

**Drug Interaction**
Bacopa may potentiate the activity of thyroid stimulating drugs or decrease the effects of anti-thyroid medications. May work to decrease the toxicity of several drugs like morphine & other opiate drugs. It has also been shown to reduce the decline in cognitive function associated with phenytoin, an anti-seizure medication.

**Use in Pregnancy & Lactation**
Women who are pregnant or nursing are advised to consult with a physician prior to use. Although medical literature has not reported any adverse effects related to fetal development during pregnancy or to infants who are breast-fed.

**Preparation**
100 ml Syrup.

# Navit®

**Active Ingredient**
Spirulina (*Arthrospira platensis*).

**Indication**
• Malnutrition
• Immune deficiency
• High Cholesterol
• Allergic reaction
• Skin disorders & hair loss
• Decreased milk supply in lactating mothers

**Dosage & Administration**
4 to 6 Capsules (500 mg each) per day or as per the instruction of an appropriate health care provider.

**Contraindication & Precaution**
Spirulina is contraindicated in those who are hypersensitive to any component of a Spirulina-containing supplement.

**Side Effect**
Occasional gastrointestinal symptoms, such as nausea, have been reported. Also, there are a few reports of allergic reactions to spirulina-containing supplements.

**Use in Pregnancy & Lactation**
Safe as per clinical study.

**Preparation**
500 mg Capsule.

# Ocubil™

**Active Ingredient**
Bilberry (*Vaccinium myrtillus* L).

**Indication**
- Retinopathy (hypertensive & diabetic)
- Night blindness
- Cataracts
- Macular degeneration
- Retinitis pigmentosa
- Hemorrhagic retinopathy

**Dosage & Administration**
1 capsule should be taken 2-3 times daily or as per the instruction of physician.

**Contraindication & Precaution**
None known.

**Side Effect**
None known.

**Drug Interaction**
None known.

**Use in Pregnancy & Lactation**
No known restriction.

**Preparation**
160 mg Capsule.

# Nilagel™

**Active Ingredient**
Nigella Sativa

**Indication**
It is indicated for the treatment of common cold, cough, asthma, bronchitis, muscle spasm,fever, dyspepsia, vomiting, gout, insufficient breast milk, eczema and wound. It is also used to improve immune system, reduce blood sugar, blood pressure & stop hair loss.

**Dosage & Administration**
1 capsule 2-3 times daily or as directed by the registered physician.

**Side Effect**
No side effects have been reported.

**Contraindication & Precaution**
There is no known precaution & contraindication.

**Drug Interaction**
It can be taken with any other vitamins, minerals or herbal supplement.

**Use in Pregnancy & Lactation**
Black seed oil is not recommended during

pregnancy. In lactating mother it should be taken to increase breast milk of mother.

**Preparation**
500 mg Softgel Capsule.

# Pepnor®

**Active Ingredient**
Extract of *Cumin*.

**Indication**
- Dyspepsia or indigestion
- Abdominal gas or flatulence
- Nausea, vomiting & anorexia
- Abdominal colic

**Dosage & Administration**
Children under 12 years: 1- 2 teaspoonfuls (5 - 10 ml) 2 to 3 times daily.
Adult: 2 - 3 teaspoonfuls (10 - 15 ml) 3 times daily or as directed by the physician.

**Contraindication & Precaution**
There is no evidence available on contraindication but it may happen in patients who are hypersensitive to any of its ingredients. Ginger is contraindicated in people suffering from gallstones as it promotes the production of bile. So Pepnor® should be taken carefully in obstructive jaundice.

**Side Effect**
There is no known significant side effect.

**Use in Pregnancy & Lactation**
Pepnor is a very good supplement for lactating mother & pregnant women.

**Preparation**
100 ml Syrup.

# Probio™

**Active Ingredient**
A Probiotic combination (*Lactobacillus acidophilus, Lactobacillus bulgaricus, Bifidobacterium bifidum* & fructo-oligosaccharides).

**Indication**
- Diarrhea
- Lactose intolerance
- Vaginal infection
- Antibiotic related illness

**Dosage & Administration**
Adult: 1- 2 capsules 1-2 times daily or as directed by the physician.
Children(6 month or above): one probio sachet should be taken daily with 3-4 tabel spoonfull of milk, water, or any other suitable liquid at once or as directed by the physician.

**Contraindication & Precaution**
Not known.

**Side Effect**
No side Effects following proper administration of designated therapeutic dosages.

**Use in Pregnancy & Lactation**
There is no known restriction on the use of Probiotics in pregnancy & lactation.

**Preparation**
4 billion probiotics in capsule & sachet.

# Redclov™

**Active Ingredient**
standardized extract of Red clover Isoflavones.

**Indication**
It is indicated for menopausal women, for the relief of menopause symptoms. RedclovTM : Helps to relieve symptoms of menopause such as hot flushes and night sweats Menopause related osteoporosis and bone density loss Maintenance of cholesterol level

**Dosage & Administration**
The recommended dosage is 1-2 capsules per day depending on body weight and on the severity of symptoms. Each RedclovTM capsule should be taken with a meal and at approximately the same time each day.

**Contraindications**
It is recommended that the diet should not be supplemented with Isoflavonoid phytoestrogens during therapy with reproductive hormones including estrogen, progestogen and androgen because of the potential risk of competitive inhibition.

**Drug interaction**
Efficacy of Tamoxifen is decreased if it is used concomitantly with red clover. Caution is advised if anti-coagulants, contraceptives, estrogen and progesterone like drugs are used with red clover.

**Adverse reaction**
No adverse reactions are known at the recommended dosage. Animal data showed that excessive may reduce fertility.

**Use in Pregnancy & Lactation**
Not recommended for use during pregnancy. Isoflavones are secreted in breast milk, so use during lactation is not recommended.

**Preparation**
30 Capsules.

# Reli Balm™

**Active Ingredient**
Extract of Mentha spp. As l-Menthol 80 mg, Extract of Cinnamomum camphora as d-Camphor 45 mg, Eucalyptus Oil 180 mg, & Mint Oil 10 mg.

**Indication**
- Pain in neck and shoulder
- Pains in Muscles and joints
- Relief of minor aches

**Dose & administration**
For adults and children over 12, rub well on the affected area. Repeat 3 to 4 times daily. For children 12 years of age or younger, consult a healthcare professional before use.

**Contraindications**
Not recommended for infant & young children.

**Use in Pregnancy & Lactation**
Should be used with caution or seek the advice of a healthcare professional before use.

**Drug interaction**
Not known.

Precaution
For external use only

**Warnings**
When using this product:
- Use only as directed
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds, damaged or irritated skin
- Do not bandage or cover with wrap or use heating pad
- Do not use 1 hour prior to bathing or within 30 minutes after bathing

**Preparation**
25 gm cream.

# Revatol™

**Active Ingredient**
Grape extract.

**Indication**
•Chronic Obstructive Pulmonary Disease (COPD)
•Asthma
•Pulmonary fibrosis

**Dose & administration**
Children under 12 years: 1 - 2 teaspoonfuls (5 – 10 ml) 2 -3 times daily after meal.
Above 12 years & Adults: 3 - 4 teaspoonfuls (15 - 20 ml) 2 times daily after meal for 4 – 8 weeks or as directed by the physician.

**Contraindication/Pre-caution**
Vitis vinifera is well tolerated but caution should be taken in hypertension, liver disease, alcohol dependence & diabetes. Patients with any medical conditions should talk to their doctors before taking Revatol. Lactobacillus products (e.g., Probiotics) should be taken 2 or more hours apart.

**Side effects**
There are no side effects associated with the use of Vitis vinifera in the above mentioned therapeutic doses. Vitis vinifera has been used safely as an Ayurvedic medicine for hundreds of years. But in very rare case stomach pain, headache, & an allergic reaction have been reported.

**Use in pregnancy & lactation**
Women who are pregnant or nursing are advised to consult with a physician prior to use Revatol. Although medical literature has not reported any adverse effects related to fetal development during pregnancy or to infants who are breast-fed. So, this product should be used only when clearly needed.

**Preparation**
200 ml syrup.

# Silybin®

**Active Ingredient**
Silymarin (*Silybum marianum*).

**Indication**
Acute viral hepatitis, Toxic liver damage for supportive treatment in patients with jaundice, Toxic hepatitis produced by psychotropic agents, Alcohol related liver disease including cirrhosis, Poisoning by A. phalloides.

**Dosage & Administration**
1 capsule should be taken 3 times daily; as a maintenance dose, 1 capsule 2 times daily is sufficient or advised by the physician depending up on the severity. The capsules should be taken whole with some liquid.

**Contraindication & Precaution**
There is no available information about contraindication.

**Side Effect**
A mild laxative Effect has occasionally been observed.

**Use in Pregnancy & Lactation**
No information is available about the use of Silymarin in pregnancy & lactation. Therefore, it should only be used under the supervision of a physician.

**Preparation**
140 mg Capsules.

# Torel™

**Active Ingredient**
l-Menthol, d- Camphor, methyl salicylate & Oleoresin capsicum.

**INDICATION:**
- Muscle pain Sprains
- Headache
- Joint pain & stiffness
- Sprain,strains & sports injuries
- Bruising
- Fibrositis
- Osteoarthritis

**Dose & administration**
Children over 6 years & Adult:
• Clean the aected area.
• Apply a small amount of Torel TM muscle rub (an amount equal to the surface area of the tip of a nger) 3 to 4 times daily or as directed by the physician. Children under 6 years of age: Not to be used.

**Contraindication/ Pre-Caution**
Capsicum preparations are contraindicated for application on injured skin, allergies to aspirin, allergic inammation of skin, eczema, itchy rash & near the eyes.

**Side Effect**
In rare cases hypersensitivity reaction may occur. Inhalation of medicine may cause bronchoconstriction.

**Use In Pregnancy & Lactation**
There is no information available about restriction of this medicine during pregnancy & lactation. May be safely used in pregnancy or breastfeeding providing the benets to the mother outweigh the risks of foetus.

**Preparation**
20 mg cream.

# Ulpep™

**Active ingredients**
*Ferula assafoetida* (Hing) with other herbs.

**Indication**
Gastritis (Wound in lining of the stomach), Hyperacidity, Gastric Ulcer & Duodenal Ulcer, Dyspepsia, Indigestion.

**Dosage & Administration**
One Ulpep capsule 2 times a day just before meal or as directed by the physician.

**Contraindication**
Hingastak churna is contraindicated in cases of known allergy to plants. Though it is well tolerated, precaution should be taken in moderate to severe hypertension & edema as it contains salt in 12.3% concentration.

**Side Effects**
When used within the recommended dosage range, Hingastak Churna is well tolerated. In rare case very high dose than prescribed may lead to stomach irritation, diarrhea, stomatitis & urticaria. However it is best to use this product under medical supervision.

**Use In Pregnancy & Lactation**
Hingastak churna should not be used during pregnancy or lactation.

**Preparation**
500 mg Capsule.

# Uripam™

**Active ingredient**
Saw Palmetto Oil, Pygeum Bark Oil, Korean Ginseng, Zinc Sulphate Monohydrate and Copper Gluconate.
Indication
An advanced blend of minerals & herbs that can help a proactive approach to prostate health. Saw Palmetto supports normal prostate function and healthy urinary flow. It contains Zinc which is required for normal reproductive function.

**Dosage & Administration**
For Adult use only. Usual dosage is 1-2 capsules daily or as advised by the physician.

**Side Effects**
Rare case of gastrointestinal disturbance has been reported. Ingestion on an empty stomach may cause nausea. Hypertension was reported in 3.1% patients taking Saw Palmetto extract.

**Contraindications**
Saw Palmetto is not indicated for advanced BPH with severe urinary retention. It should not be used without first ruling out prostate cancer.

**Precaution**
Saw Palmetto might slow blood clotting. There is some concern that it might cause extra bleeding during and after surgery. Stop using saw palmetto at least 2 weeks before a scheduled surgery.

**Pediatric Use**
Safety and e_ectiveness of Saw Palmetto in pediatric population have not been established.

**Drug Interactions**
Saw Palmetto might slow blood clotting. Taking Saw Palmetto along with medications that also slow clotting including Aspirin, Clopidogrel, Enoxaparin, Heparin, Warfarin etc. might increase the chances of bruising and bleeding.

**Preparation**
160 mg Softgel Capsule.

Table of content by Generic name

# Product Guide

## 9th Edition

Since 1958

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