

Femastin™

Estriol 1 mg



COMPOSITION

Each tablet contains Estriol USP 1 mg.

MECHANISM OF ACTION

Femastin™ contains the natural female hormone, estriol. Estriol induces the normalization of the vaginal epithelium and thus helps to restore the normal microflora and the physiological pH in the vagina. As a result, it increases the resistance of the vaginal epithelial cells to infection and inflammation. In comparison to other estrogens, estriol is short-acting.

In the years just before and after the menopause (which can be natural or surgically induced) estriol can be used in the treatment of symptoms and complaints related to estrogen deficiency. Estriol is particularly used in the treatment of urogenital symptoms.

PHARMACOKINETICS

After oral administration, estriol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma levels of unconjugated estriol are reached within 1 hr of administration. Nearly all (90%) estriol is bound to albumin in the plasma and unlike other estrogens; estriol is hardly bound to sex hormone-binding globulin. The metabolism of estriol consists mainly of conjugation and deconjugation during enterohepatic circulation. Estriol, a metabolic end product, is mainly excreted via the urine in the conjugated form. Only a small fraction is excreted via the feces, mainly as unconjugated estriol.

INDICATIONS

- a. Atrophy of the lower urogenital tract related to oestrogen deficiency, particularly -
 - For the treatment of vaginal complaints such as dyspareunia, dryness and itching.
 - For the prevention of recurrent infections of the vagina and lower urinary tract.
 - In the management of micturition complaints (such as frequency and dysuria) and mild urinary incontinence.
- b. Pre- and postoperative therapy in postmenopausal women undergoing vaginal surgery.
- c. Climacteric complaints such as hot flushes and night sweating.
- d. A diagnostic aid in case of a doubtful atrophic cervical smear.
- e. Infertility due to cervical hostility.

DOSAGE & ADMINISTRATION

It is important that the total daily dose is taken at one time. It may be taken with or without food.

Atrophy of the lower urogenital tract

4-8 mg/day for the first weeks, followed by a gradual reduction, based on relief of symptoms, until a maintenance dosage (e.g. 1-2 mg/day) is reached.

Pre- and postoperative therapy in postmenopausal women undergoing vaginal surgery

4-8 mg/day in the 2 weeks before surgery; 1-2 mg/day in the 2 weeks after surgery.

Climacteric complaints such as hot flushes and night sweating

4-8 mg/day during the first weeks, followed by a gradual reduction. For maintenance therapy the lowest effective dosage should be used.

A diagnostic aid in case of a doubtful atrophic cervical smear

2-4 mg/day for 7 days before taking the next smear.

Infertility due to cervical hostility

In general 1-2 mg/day on days 6-15 of the menstrual cycle. However, for some patients dosages as low as 1mg/day are sufficient, whereas others may need up to 8 mg/day. Therefore, the dosage should be increased each month until an optimal effect on the cervical mucus is obtained.

OVERDOSAGE

Symptoms that may occur in the case of an acute overdosage are nausea, vomiting and possibly withdrawal bleeding in females. No specific antidote is known. If necessary, a symptomatic treatment should be instituted.

CONTRAINDICATIONS

Pregnancy, Known or suspected estrogen-dependent tumours, undiagnosed vaginal bleeding, untreated endometrial hyperplasia, known or suspected breast cancer.

Warnings

During prolonged treatment with estrogens, periodic medical examinations are advisable. With vaginal infections, a concomitant specific treatment is recommended. In order to prevent endometrial stimulation, the daily dose should not exceed 8 mg nor should this maximum dose be used for longer than several weeks. Patients with any of the following conditions should be monitored: A history of latent or overt cardiac failure, fluid retention due to renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions), severe liver disorders, endometriosis, fibrocystic mastopathy, porphyria, hyperlipoproteinaemia, a history during pregnancy or previous use of steroids of severe pruritus, cholestatic jaundice or herpes gestationis. Estrogen is reported to increase the risk of endometrial carcinoma in postmenopausal women. Use with precaution in gallbladder disorders, hypercalcemia, additional progestin, hypercoagulability, urethral bleeding and mastodynia.

USE IN LACTATION

Use **Femastin™** in breastfeeding women only if really needed, as estriol is excreted in the milk and it may decrease the quality and quantity of the milk production.

ADVERSE DRUG REACTIONS

Breast tension or pain, nausea, spotting, fluid retention and cervical hypersecretion may occasionally occur and be indicative of too high dosage. Headache, hypertension, leg cramps and vision disturbances are seldom observed. In general, most of these adverse reactions disappear after the 1st week of treatment.

Breast enlargement, vaginal candidiasis, change in vaginal bleeding pattern, vomiting, stomach cramps, cholestatic jaundice, chloasma or melasma, erythema multiforme, erythema nodosum, hemorrhagic eruption, mental depression, chorea, increasing or decreasing body weight, edema, changes in libido.

DRUG INTERACTIONS

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 and rifampicin may possibly decrease the effectiveness of estriol.

STORAGE CONDITION

Store in a dry & cool place protected from light & moisture. Keep out of reach of the children.

HOW SUPPLIED

Each box contains 30 tablets in alu-PVDC blister pack.

Manufactured by :



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

TM - Trade Mark.

Revision No.: 00

FemastinTM Cream

Estriol USP 0.1% (1 mg per 1 gm)

Composition: Each gm of cream contains Estriol USP 1 mg

Pharmacology: FemastinTM Cream is a Hormone Replacement Therapy (HRT). It contains the female hormone estriol (an estrogen). During menopause FemastinTM (Estriol) is used in vagina which is slowly released and absorbed into the surrounding area and into the bloodstream.

Indication: FemastinTM cream is indicated for the deficiency of estrogen. During menopause, the amount of estrogens produced by a woman's body gradually drops. Shortage of estrogens causes the vaginal wall to become thin and dry which leads to painful sexual intercourse. FemastinTM cream is used to relieve painful sexual intercourse. FemastinTM is used in postmenopausal women with at least 12 months since their last natural period. If the ovaries are removed surgically (ovariectomy) before menopause, the decrease in estrogen production occurs very abruptly.

Dosage and Administration: FemastinTM cream should be used as per physician's advice. Each dose of cream contains 0.5 mg estriol. For vulvo-vaginal complaints associated with menopause: Initially one dose of cream per day for 3 weeks. Later you may only need one dose of cream twice a week.

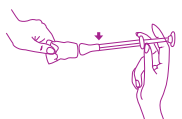
Before surgery: One dose of cream daily 2 weeks before the operation. When having a Pap smear your doctor may recommend a daily application of cream for 7 days.

How to apply the cream: One application (applicator filled to the ring mark) contains 0.5 gm of FemastinTM cream, which contains 0.5 mg estriol.

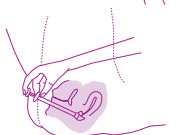
1. Remove cap from the tube, invert it, and use the sharp point to open the tube.
2. Pull the plunger up to the ring. Now attach it to the opening of the tube.



3. Squeeze the tube slowly to fill the applicator to the ring-mark (where the plunger stops).



4. Remove the tube.
5. To apply the cream, lie down; insert the applicator deep into the vagina.
6. Slowly push the plunger all the way in until the applicator is empty.



7. After use, pull the plunger out of the barrel beyond the point of resistance and wash both parts in warm, soapy water. Do not use detergents. Rinse well and dry afterwards. Do not put the applicator in hot or boiling water.

8. The applicator can be re-assembled by fully inserting the plunger into the barrel beyond the point where resistance is felt.

Discard the applicator once the tube is empty. Take FemastinTM cream before taking rest or going to sleep. If you forget a dose, use it as soon as you remember. But if you remember your missed dose at the time of your next dose, do not use an extra dose. Do not use a double dose to make up for the missed dose. This may increase the chance of you getting an unwanted side effect.

Precaution: Patients should keep under doctor's observation for any Hormone Replacement Therapy (HRT). Same role is applicable for the application of FemastinTM cream. Doctor will give continuous advice regarding risks & benefits of the drug. But in case of jaundice, sudden high blood pressure, migraine, severe headache or pregnancy, the use of FemastinTM cream will be stopped immediately. Children's are not allowed to use FemastinTM cream.

Side effects: Local irritation or itching of vagina, Swelling and increased tenderness of the breasts, Increased vaginal discharge, Nausea, Fluid retention in the tissues, usually marked by swollen ankles or feet.

In most patients these side effects will disappear after the first weeks of treatment. Tell your doctor if vaginal bleeding occurs or if any side effect becomes troublesome or persists.

Other side effects which may occur with HRT are benign and malignant hormone-dependent tumors such as endometrial cancer, heart attack and stroke, gall bladder disease, skin problems such as rashes, discoloration or red patches on the skin, various skin diseases with blisters and nodules or bleeding into the skin, venous thromboembolism or deep leg or pelvic venous thrombosis and pulmonary embolism (see Before you use FemastinTM Cream). Using HRT for several years slightly increases the risk of breast cancer.

Contraindication: Do not use FemastinTM Cream if:

- You have or have ever had breast cancer, or if you are suspected of having it, ovarian cancer, heart attack, stroke, angina, liver disease, thrombosis, pulmonary embolism, vaginal cancer.
- You are pregnant or think you may be pregnant
- You have any unexplained vaginal bleeding, blood clotting disorder, endometrial hyperplasia, porphyria, and various kind of allergic reaction.
- Jaundice, migraine pain, high blood pressure & breathing problem
- You have had an allergic reaction to estriol, or any of the other ingredients of FemastinTM

Use in pregnancy & lactation: This medicine is contraindicated during pregnancy & lactation.

Drug-drug Interaction: Interaction is found with Anticoagulants, corticosteroid hormones, succinylcholine, theophyllines, and medicines for epilepsy, medicines for fungal or bacterial infections, viral infections, and herbal preparations containing St John's Wort. As a result irregular bleeding may occur.

Storage: Store below 25°C. Protect from light and moisture. Keep out of reach of children.

How Supplies: FemastinTM cream: Each pack has aluminium tube containing 15 gm cream with a dedicated applicator.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.

Pabna, Bangladesh

TM- Trade Mark

2000008702