Purotrol®

Levocetirizine Dihydrochloride

COMPOSITION

Purotrol® Tablet: Each film-coated tablet contains Levocetirizine Dihydrochloride INN 5 mg.
Purotrol® Syrup: Each 5 ml Syrup contains Levocetirizine Dihydrochloride INN 2.5 mg.

PHARMACOLOGY

Purotrol® is a preparation of Levocetirizine Dihydrochloride, the (R) enantiomer of Cetirizine, is a potent and selective antagonist of peripheral H_1-receptors. Levocetirizine has high affinity for human H_1- receptors. It has an affinity 2-fold higher than that of Cetirizine. It dissociates from H_1-receptors with a half-life of 115 ± 38 min.

INDICATION

Purotrol® (Levocetirizine) is indicated in the treatment of seasonal allergic rhinitis (two years & above) perennial and chronic idiopathic urticaria (six months and above).

DOSAGE AND ADMINISTRATION

Adult & children above 12 years of age
Purotrol® *Tablet: 1 tablet (5 mg) daily*
Purotrol® *Syrup: 10 ml (2 teaspoonful,) daily*
Children 6 - 11 years of age
Purotrol® *Tablet: 1/2 tablet (2.5 mg) daily*
Purotrol® *Syrup: 5 ml (1 teaspoonful) daily*
Children 6 months - 5 years of age
Purotrol® *Syrup: 2.5 ml (1/2 teaspoonful) daily*
Children below 6 months of age: Not recommended

Patients with renal impairment: The recommended dose in patients with renal impairment (creatinine clearance 50 - 80 ml/min) is half **Purotrol®** Tablet daily & (creatinine clearance 30-49 ml/min) is one **Purotrol®** Tablet every two days. In those with severe renal impairment (Creatinine clearance <30 ml/min), the dose interval should be increased to every three days. Patients with end stage of renal disease (Creatinine clearance < 10 ml/min) should not be given Levocetirizine. The tablet should be swallowed whole with liquid and may be taken with or without meals.

SIDE EFFECT

Generally Levocetirizine is well tolerated. But in rare cases, somnolence, dry mouth, headache, fatigue and asthenia are reported.

CONTRAINDICATION

Hypersensitivity to Levocetirizine, Cetirizine or its parent compound Hydroxyzine. Patients with severe renal impairment (< 10 ml/min creatinine clearance) should not be administered such medicine.

PREGNANCY & LACTATION

Pregnancy: The safety of Levocetirizine in pregnancy has not been established. Therefore, it should be used with caution during pregnancy and only if the benefits to the mother outweigh any risk to the fetus.
Lactation: Since Levocitirizine is excreted in breast milk, it is recommended for use by the nursing mothers.

GERIATRIC USE

Some dose reduction may be required for renal function impairment.

DRUG INTERACTION

Levocetirizine is not known to have any interaction with other drugs.

OVERDOSE

No clinically relevant adverse events have been reported in case of overdose. However, in such cases, symptomatic and supportive treatment is recommended.

STORAGE

Purotrol® Tablet: Store at a cool and dry place, away from light and moisture. Keep out of reach of children. **Purotrol®** Syrup: Store at a cool and dry place, away from light. Keep out of reach of children.

HOW SUPPLIED

Purotrol® Tablet: Each box contains 50 tablets.
Purotrol® Syrup: Each bottle contains 50 ml syrup with a calibrated measuring cup.

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH