

Deslorin[®]

Desloratadine

Presentation

Deslorin[®] Tablets: Each coated tablet contains Desloratadine INN 5 mg

Deslorin[®] Syrup: Each 5ml contains Desloratadine INN 2.5 mg

Uses

Deslorin[®] is used for the relief of nasal and non-nasal symptoms of allergic rhinitis (seasonal and perennial) and management of chronic idiopathic urticaria. Desloratadine is a major active metabolite of Loratadine. It is a long-lasting, non-sedating, selective peripheral histamine H₁-receptor antagonist. It acts by inhibiting the release of pro-inflammatory mediators from human mast cells/basophils.

Dosage and administration

Adult and adolescent over 12 years: In adult and adolescent of 12 years of age and over the recommended dose of Deslorin[®] tablets is 5 mg once daily. In patients with liver or renal impairment, a starting dose of one 5 mg tablet every other day is recommended based on pharmacokinetic data.

Children: 2-5 years 1.25 mg daily and 6-11 years 2.5 mg daily.

Contra-indications, warnings etc

Contra-indications: Deslorin[®] is contra-indicated in patients who are hyper-sensitive to this medication or to any of its ingredients, or to Loratadine.

Side-effects: CNS: Drowsiness (rare), EENT: pharyngitis,
GI: dry mouth, Misc.: allergic reaction including anaphylaxis.

Adverse reactions: Desloratadine was well tolerated during clinical trials involving more than 2000 patients; undesirable effects were reported in 4% of patients in excess of those treated with placebo. Headache (6%), dry mouth (3%) and fatigue (3%) were the most common adverse effects. No excess incidence of somnolence/sedation was reported. No significant ECG or other adverse cardiovascular effects have been reported with Desloratadine. No adverse effect on cardiovascular function was observed in healthy volunteers with Desloratadine in doses of up to 20 mg daily for 14 days or at 45 mg daily for 10 days.

Pregnancy: Deslorin[®] should not be used in pregnancy unless the potential benefits outweigh the risks. Clinical data on pregnancy outcome in women exposed to Desloratadine are not available although no teratogenic and mutagenic effects were observed in animal studies. Pregnancy outcome data after exposure to Loratadine is also too limited to allow an assessment of any teratogenic risk.

Lactation: As Desloratadine is excreted into breast milk it is not recommended for use in breastfeeding women.

Precaution: Desloratadine should be used with caution in patients with severe renal impairment.

Drug interactions: No relevant drug interactions were observed in clinical trials in which erythromycin or Ketoconazole were given together with Desloratadine. However, as the enzyme responsible for Desloratadine metabolism has not been clearly identified, the potential for interactions with other drugs cannot be excluded.

Management of over dosing: In the event of over dose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended. Desloratadine and 3-hydroxydesloratadine are not eliminated by hemodialysis.

Interactions: MAO inhibitors may intensify and prolong effects of anti-histamines. Additive CNS depression may occur with other CNS depressants including alcohol, anti-depressants, opioids, and sedative/hypnotics.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Package quantities

Deslorin® Tablets: Carton of 100 tablets in blister

Deslorin® Syrup: Bottle of 60 ml.

® Registered Trade Mark



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