

Desotem[®]

Desloratadine

COMPOSITION:

Desotem[®] 5 Tablet: Each film coated tablet contains Desloratadine BP 5 mg.

Desotem[®] Syrup: Each 5 ml syrup contains Desloratadine BP 2.5 mg.

PHARMACOLOGY:

Desotem[®] is a preparation of Desloratadine. Desloratadine is a non-sedating, long acting tricyclic histamine antagonist with selective H₁-receptor antagonist activity. Desloratadine also inhibits histamine release from human mast cell.

INDICATION:

Desotem[®] is indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis such as sneezing, nasal discharge & itching, congestion/stuffiness as well as ocular itching, tearing and redness, itching of palate and coughing. Desotem[®] is also indicated for the relief of symptoms associated with chronic idiopathic urticaria such as the relief of itching and the size & number of hives.

DOSE & ADMINISTRATION:

Desotem[®] 5 Tablet: Adults and children 12 years of age and over: 1 tablet daily.

In adult Patients with liver or renal impairment: A starting dose of one 5 mg tablet every other day is recommended based on pharmacokinetic data.

Desotem[®] Syrup:

Child 6-11 months of age	: 2 ml once daily.
Child 1-5 years of age	: 2.5 ml once daily.
Child 6-11 years of age	: 5 ml once daily.
Adults & >12 years of age	: 10 ml once daily.

CONTRA-INDICATION:

Desloratadine is contraindicated in patient having hypersensitivity to this medication or to any of its ingredients or Loratadine.

WARNING AND PRECAUTION:

Use of Desloratadine is not recommended in patient with Hepatic and renal impairment and also in Pregnancy and lactation.

SIDE EFFECTS:

Less common side effects may include headache, nausea, fatigue, dizziness, pharyngitis, dyspepsia and myalgia.

USE IN PREGNANCY & LACTATION:

Use in Pregnancy: Pregnancy Category C. The safe use of Desloratadine during pregnancy has not been established. Therefore, Desloratadine is not to be used during pregnancy unless clearly indicated.

Use in Lactation: Desloratadine passes into breast milk, therefore a decision should be made whether to discontinue nursing or to discontinue Desloratadine taking into account the importance of the drug to the mother.

USE IN CHILDREN & ADOLESCENTS:

The safety and effectiveness of Desloratadine in pediatric patients under 6 months of age have not been established.

DRUG INTERACTION:

No clinically relevant adverse effects have been reported.

OVERDOSE:

No clinically relevant adverse effects have been reported.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. keep out of reach of children.

PACKING:

Desotem[®] 5 Tablet: Each box contains 10 X 10's tablets in Alu-PVC blister pack.

Desotem[®] Syrup: Each bottle contains 60 ml syrup and 10 ml measuring cup.



Manufactured by

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