Momento®

Desloratadine
Tablet/Syrup

Description
Momento® (Desloratadine) is a potent, rapidly effective, long-acting, non-sedative antihistamine with selective H_1 receptor histamine antagonist activity. It is an orally administered drug. Each tablet contains Desloratadine INN 5 mg.
Each 5 ml Syrup contains Desloratadine INN 2.5 mg.

Indications and Usage
Allergic Rhinitis: Momento® is indicated for the relief of the nasal and non-nasal symptoms of allergic rhinitis (Both seasonal and perennial) in patients 2 years of age and older.

Chronic Idiopathic Urticaria: Momento® is also indicated for the symptomatic relief of pruritus, reduction in the number of hives, and size of hives, in patients with chronic idiopathic urticaria 2 years of age and older.

Dosage and Administration

Adult & over 12 years :
Syrup : 10 ml (2 teaspoonful) once daily
Tablet : One tablet (5 mg) once daily

Child 6-11 years:
Syrup : 5 ml (1 teaspoonful) daily
Tablet : 2.5 mg (half of one 5 mg tablet) once daily

Child 2-5 years:
Syrup : 2.5 ml (1/2 teaspoonful) daily

or as directed by the physician

In patients with liver or renal impairment, a starting dose of one tablet every other day is recommended based on pharmacokinetic data.

Adverse Effects
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, and somnolence. Less common side effects may include headache, nausea, dizziness, dyspepsia, pharyngitis etc.

Contraindications
Momento® is contraindicated in patients who are hypersensitive to this medication or to any of its ingredients, or to Loratadine.

Precautions
Pregnancy Category C: Desloratadine was not teratogenic in rats or rabbits at doses higher enough to produce an AUC, which is 210-230 times the AUC in human at the recommended daily oral dose. There are, however, no adequate and well-controlled studies of Desloratadine in pregnant women. Because animal reproduction studies are not always predictive of human response, Desloratadine should be used during pregnancy only if clearly needed.
Nursing Mothers: Desloratadine passes into breast milk, therefore a decision should be made whether to discontinue nursing or to discontinue Momento®, taking into account the importance of the drug to the mother.
Paediatric Use: The safety and effectiveness of Desloratadine in pediatric patients under 2 years of age have not been established.
Geriatric Use: In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Drug Interactions
Concomitant administration of Erythromycin, Ketoconazole, Azithromycin, Fluoxetine, and Cimetidine with Desloratadine increased the plasma concentration of Desloratadine. But there were no clinically relevant changes in the safety profile of Desloratadine.

Overdosage
No clinically relevant adverse events were reported. In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended. Desloratadine and 3-hydroxydesloratadine are not eliminated by hemodialysis.

Storage
Store between 2° and 25°C. Heat sensitive. Avoid exposure at or above 30°C.

Commercial Pack
Momento® Tablet : Each Box contains 10 blister strips of 10 tablets. Each tablet contains Desloratadine INN 5 mg.
Momento® Syrup : 60 ml syrup in amber glass bottle, each 5 ml contains Desloratadine INN 2.5 mg.

BEXIMCO PHARMA
Manufactured by
BEXIMCO PHARMACEUTICALS LTD.
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