Aeriallerg Syrup

desloratadine

Description :
Each 1 ml of Aeriallerg contains 0.5 mg of desloratadine.

The inactive ingredients :
Sorbitol powder, propylene glycol, sodium benzoate, EDTA disodium, saccharin sodium, ß-cyclodextrin, citric acid monohydrate, sodium hydroxide, FD &C yellow No6 dye, orange liquid flavor

Actions:
Aeriallerg is a non-sedating long-acting histamine antagonist with potent, selective peripheral H_1-receptor antagonist activity. Aeriallerg has demonstrated antiallergic, antihistaminic, and anti-inflammatory activity.

Indications and Usage:
Aeriallerg is indicated for the rapid relief of symptoms associated with allergic rhinitis, (including intermittent and persistent allergic rhinitis) such as sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness, itching of palate and coughing.
Aeriallerg is also indicated for the relief of symptoms associated with chronic idiopathic urticaria such as the relief of itching and the size and number of hives.

Dosage and Administration:
Children 1 through 5 years of age :2.5 ml (1.25 mg) Aeriallerg syrup once a day, with or without a meal, children 6 through 11 years of age:5ml (2.5 mg) Aeriallerg syrup once a day with or without a meal. In adults and adolescents (12 years of age and over): 10 ml (5 mg) Aeriallerg syrup once a day with or without a meal.
Intermittent allergic rhinitis (presence of symptoms for less then 4 days per week or for less then 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks) continued treatment may be proposed to the patients during allergen exposure periods.

Drug Interactions:
No clinically relevant interactions with Desloratadine was observed in clinical trials. *There was no effect of food or grapefruit juice on the disposition of desloratadine.*
Desloratadine syrup taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol

Adverse Effects:

In clinical trials in paediatric population, Desloratadine syrup was administered to a total of 246 children aged 6 months through 11 years, the overall incidence of adverse events in children 2 through 11 years of age was similar for Desloratadine syrup and the placebo groups in infants and toddlers aged 6 to 23 months the most frequent adverse events reported in excess of placebo were diarrhea (3.7%), fever (2.3%) and insomnia (2.3%)

In clinical trials in a range of indications including allergic rhinitis and chronic idiopathic urticaria , at the recommended dose of 5mg daily, undesirable effects with desloratadine tabs were reported in 3% of patients in excess of those treated with placebo. The most frequent adverse events reported in excess of placebo were fatigue (1.2%), dry mouth (0.8%), and headache (0.6%).

Very rare cases of hypersensitivity reactions (including anaphylaxis and rash) tachycardia, palpitations, psychomotor hyperactivity, seizures, elevations of liver enzymes, hepatitis, and increased bilirubin have been reported during the marketing of desloratadine.

Contraindications:
Hypersensitivity to the active substance or to any of the excipients or to loratadine.

Precautions:
Efficacy and safety of desloratadine Syrup in children under 6 moths of age have not been established.

Effects on ability to drive and use machines:
No effects on the ability to drive and use machines have been observed.

Usage during pregnancy and lactation:
No overall effect on rat fertility was observed with desloratadine at an exposure that was 34 times higher than the exposure in humans at the recommended clinical dose.
No teratogenic or mutagenic effects were observed in animal trials with desloratadine. Since no clinical data on exposed pregnancies are available with desloratadine, the safe use of desloratadine Syrup during pregnancy has not been established. desloratadine Syrup is not to be used during pregnancy unless the potential benefits outweigh the risks.
Desloratadine is excreted into breast milk, therefore the use of desloratadine Syrup is not recommended in breast-feeding women.

Overdosage Information:
In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.
Based on a multiple dose clinical trial in adults and adolescents, in which up to 45mg of desloratadine was administered (9 times the clinical dose), no clinically relevant effects were observed.
Desloratadine is not eliminated by hemodialysis; it is not known if it is eliminated by peritoneal dialysis.

How supplied
Aeriallerg syrup 0.5 mg / ml in bottles of 125 ml .

Storage Conditions:
Don't store above 30ºC.