Desloratadine 5mg Tablets

Uses
Desloratadine Tablets are indicated in adults and adolescents aged 12 years and older for the relief of symptoms associated with allergic rhinitis and urticaria.

Dose and method of administration
Adults and adolescents (12 years of age and over): The recommended dose of Desloratadine 5 mg Tablets is one tablet once a day.
Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 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 the allergen exposure periods.
Paediatric population: There is limited clinical trial efficacy experience with the use of desloratadine in adolescents 12 through 17 years of age.
The safety and efficacy of Desloratadine Tablets in children below the age of 12 years have not been established.

Method of administration: Oral use. The tablet should be swallowed with a sufficient amount of fluid (e.g. one glass of water). The dose can be taken with or without food.

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

Undesirable side effects
In clinical trials in a range of indications including allergic rhinitis and chronic idiopathic urticaria, at the recommended dose of 5 mg daily, undesirable effects with desloratadine were reported in 3% of patients in excess of those treated with placebo. The most frequent adverse reactions reported in excess of placebo were fatigue (1.2%), dry mouth (0.8%) and headache (0.6 %).
In a clinical trial with adolescent patients, 12 through 17 years of age, the most common adverse event was headache. Other undesirable effects reported during the post marketing period in paediatric patients with an unknown frequency included QT prolongation, arrhythmia, bradycardia, abnormal behaviour and aggression.

Special warnings and precautions for use
In the case of severe renal insufficiency, Desloratadine Tablets should be used with caution.
Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interactions
No clinically relevant interactions were observed in clinical trials with desloratadine tablets in which erythromycin or ketoconazole were co-administered.
In a clinical pharmacology trial, desloratadine tablets taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol. However, cases of alcohol intolerance and intoxication have been reported during post marketing use. Therefore, caution is recommended if alcohol is taken concomitantly.

Effects on ability to drive and use machines
Desloratadine has no or negligible influence on the ability to drive and use machines. Patients should be informed that most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, it is recommended that patients are advised not to engage in activities requiring mental alertness, such as driving a car or using machines, until they have established their own response to the medicinal product.

Pregnancy and lactation
A large amount of data on pregnant women (over 1,000 pregnancy outcomes) indicate no malformative nor fetal/neonatal toxicity of desloratadine. As a precautionary measure, it is preferable to avoid the use of desloratadine during pregnancy. Desloratadine has been identified in breastfed newborns/infants of treated women. The effect of desloratadine on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from desloratadine therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Overdose
In case of an overdose the symptoms may be the same as undesirable side effects but their magnitude can be higher.
Treatment: Consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.
Desloratadine is not eliminated by hemodialysis; it is not known if it is eliminated by peritoneal dialysis.

How to store
Store at room temperature. Keep out of reach of children. Do not take this medication after the expiry date.