

Sedno[®]

Desloratadine BP

COMPOSITION

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

PHARMACOLOGY

Desloratadine is a potent, rapidly effective, long-acting, non-sedative antihistamine with selective H₁-receptor histamine antagonist activity. It is a non-sedating antihistamine. Desloratadine has effects on the chronic inflammatory response to allergens and no effect on the QT interval of ECG.

INDICATIONS AND USAGE

Allergic Rhinitis: **Sedno[®]** is indicated for the relief of the nasal & non-nasal symptoms of allergic rhinitis (both seasonal and perennial). Chronic Idiopathic Urticaria: **Sedno[®]** 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.

DOSAGE AND ADMINISTRATION

Age group	Tablet
Adult & over 12 years	One tablet (5 mg) once daily
Child: 6-11 years	2.5 mg (half of one 5 mg tablet) once daily

Patients with liver or renal impairment: A starting dose of one **Sedno[®]** Tablet (Desloratadine 5 mg) every other day is recommended.

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

Desloratadine 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 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 Desloratadine, taking into account the importance of the drug to the mother. 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 INTERACTION

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 below 30°C, protect from light & moisture. Keep all medicine out from children's reach.

HOW SUPPLIED

Sedno[®] Tablet: Each box contains 100 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH