

Sedno[®]

Desloratadine

COMPOSITION:

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

Sedno[®] Syrup: Each 5 ml syrup contains Desloratadine INN 2.5mg.

DESCRIPTION:

Sedno[®] is a preparation of Desloratadine. 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 and non-nasal symptoms of allergic rhinitis (Both seasonal and perennial) in patients 2 years of age and older. 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 2 years of age and older.

DOSAGE AND ADMINISTRATION:

Adult & over 12 years :

Syrup: 10ml (2 teaspoonful) once daily.

Tablet: One tablet (5mg) once daily.

Child: 6-11 years:

Syrup: 5ml (1 teaspoonful) daily.

Tablet: 2.5mg (half of one 5mg tablet) once daily.

Child 2-5 years:

Syrup: 2.5ml (1/2 teaspoonful) daily.

Or as directed by the physician.

Patients with liver or renal impairment: A starting dose of one **Sedno[®]** Tablet (Desloratadine 5mg) 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 a small percentage of patients are dry mouth, fatigue, myalgia, and somnolence. Less common side effects may include headache, nausea, dizziness, dyspepsia, pharyngitis etc.

CONTRAINDICATIONS:

Sedno[®] 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 a nAUC, 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 in to breast milk, therefore a decisions should be Made whether to discontinue nursing or to discontinue **Sedno**[®], taking in to account the importance of the drug to the mother.

Paediatric Use: The safety and effectiveness of Desloratadine in paediatric 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 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 un absorbed drug. Symptomatic and supportive Treatment is recommended. Desloratadine and 3-hydroxydesloratadine are not eliminated By hemodialysis.

PHARMACEUTICAL PRECAUTION:

Store at a cool and dry place, protect from light. Keep out of reach of children.

HOW SUPPLIED:

Sedno[®] Tablet: Box containing 10x10 tablets in blister pack.

Sedno[®] Syrup: Each PET bottle contains 60 ml syrup and a measuring cup.

Manufactured by :



SQUARE

PHARMACEUTICALS LTD.

BANGLADESH

® Registered Trade Mark.