SILORA

LORATADINE USP

Compositions:
Each tablet contains Loratadine USP 10 mg.

Pharmacology:
Silora (Loratadine) is a non-sedative long acting tricyclic histamine H1 receptor antagonist with antiallergic properties, devoid of anticholinergic activity. It is rapidly effective and allowing once-a-day administration.

Dosage And Administration:
Adult and child over 6 years: 10mg once daily. Child (2-5 years): 5mg daily. Child (below 2 years): Safety and efficacy of loratadine has not been established.

Contraindications:
Loratadine is contraindicated in patient who have shown hypersensitivity to it and to pregnant & breast feeding mohter.

Warning And Precaution:
There are no special precautions required in young children over 2 years and in the elderly. Renal impairment has no clinically significant effects. Severe hepatic damage alters the pharmacokinetics of loratadine and dose adjustment is necessary.

Side Effects:
Incidence of sedation and antimuscurinic effect is low. The most common effects reported were fatigue, dizziness, dry mouth, headache, nausea and pruritus.

Use in Pregnancy and Lactation:
US FDA Pregnancy Category of Loratadine is B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Loratadine have been shown to be excreted in human milk. So, caution should be exercised when Loratadine is administered to a nursing woman.

Drug Interaction:
Concomitant administration of Cimetidine, Erythromycin, Ketoconazole, Quinine, Fluconazole, and Fluoxetine may result in changes in plasma concentrations of either drug.

Overdosage:
In adults somnolence, tachycardia and headache have been reported with overdose greater than 10 mg. Extrapyramidal signs and palpitations have been reported in children with over doses of greater than 10 mg.

Storage:
Keep in a dry place away from light and heat. Keep out of the reach of children.

Packing:
Silora tablet: Each box contains 5x10 Tablets in blister strips.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.