SPMC
LORATADINE TABLETS USP 10 mg

PRESENTATION:
Loratadine tablets USP 10 mg
Pack size - 500 tablets

White Circular, diameter 5.5mm, Flat Beveled tablets with score mark. Each tablet contains 10 mg Loratadine.

MECHANISM OF ACTION:
Loratadine, the active ingredient in Loratadine Tablets, is a tricyclic antihistamine with selective, peripheral H_1-receptor activity.

INDICATIONS AND DOSE:
Symptomatic relief of allergy such as hay fever, chronic Idiopathic urticaria
Child 2–11 years (body-weight up to 31 kg): 5 mg once daily
Child 2–11 years (body-weight 31 kg and above): 10 mg once daily
Child 12–17 years: 10 mg once daily
Adult: 10 mg once daily

These tablets are not suitable in children with a body weight less than 30 kg. Efficacy and safety of Loratadine Tablets in children under 2 years of age has not been established.

CONTRA-INDICATIONS:
Hypersensitivity to the active substance

SIDE EFFECTS:
Significant: Headache, somnolence, drowsiness, fatigue, nervousness.
Cardiac disorders: Palpitation, tachycardia, hypotension.
Gastrointestinal disorders: Dry mouth, abdominal pain, nausea, vomiting, diarrhoea, gastritis.
General disorders and admin site conditions: Malaise.
Hepatobiliary disorders: Jaundice, hepatitis, hepatic necrosis.
Investigations: Elevated liver enzymes, weight gain.
Metabolism and nutrition disorders: Increased appetite.
Nervous system disorders: Dizziness.
Skin and subcutaneous tissue disorders: Rash, alopecia.

SIDE-EFFECTS, FURTHER INFORMATION:
Non-sedating antihistamines such as loratadine cause less sedation and psychomotor impairment than the older antihistamines, But can still occur; sedation is generally minimal. This is because non-sedating antihistamines penetrate the blood brain barrier to a much lesser extent.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Loratadine Tablets should be administered with caution in patients with severe liver impairment. This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.The administration of Loratadine Tablets should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

HEPATIC IMPAIRMENT:
In patients with chronic alcoholic liver disease, the AUC and peak plasma levels (Cmax) of loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-lives for loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

RENAL IMPAIRMENT:
In patients with chronic renal impairment, both the AUC and peak plasma levels (Cmax) increased for loratadine and its active metabolite as compared to the AUCs and peak plasma levels (Cmax) of patients with normal renal function. The mean elimination half-lives of loratadine and its active metabolite were not significantly different from that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite in subjects with chronic renal impairment.

CrCl (mL/min)	Dosage
<30	10 mg every other day.

PREGNANCY:
A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no malformative nor foeto/ neonatal toxicity of loratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of loratadine during pregnancy.

BREAST FEEDING:
Loratadine is excreted in breast milk, therefore the use of loratadine is not recommended in breast-feeding women.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
In clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine. Loratadine tablets has no or negligible influence on the ability to drive and use machines. However, patients should be informed that very rarely some people experienced drowsiness, which may affect their ability to drive or use machines.

INTERACTIONS:
When administered concomitantly with alcohol, Loratadine Tablets have no potentiating effects as measured by psychomotor performance studies. Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of loratadine, which may cause an increase in adverse events.Increase in plasma concentrations of loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in controlled trials, but without clinically significant changes (including electrocardiographic). Paediatric population Interaction studies have only been performed in adults.

FOOD INTERACTION:
Food delays time to peak plasma concentration and increases bioavailability. Increase risk of CNS depression with alcohol.

OVERDOSAGE:
Overdosage with loratadine increased the occurrence of anticholinergic symptoms. Somnolence, tachycardia, and headache have been reported with overdoses.In the event of overdose, general symptomatic and supportive measures are to be instituted and maintained for as long as necessary. Administration of activated charcoal as a slurry with water may be attempted. Gastric lavage may be considered. Loratadine is not removed by haemodialysis and it is not known if loratadine is removed by peritoneal dialysis. Medical monitoring of the patient is to be continued after emergency treatment.

STORAGE:
Keep tightly closed in cool and dry place. Store below 30°C. in the original package in order to protect from light and moisture.

Keep all the medicines away from the reach of children

Manufactured by

State Pharmaceuticals Manufacturing Corporation,
No. 11, Sir John Kotalawala Mawatha,
Kandawala Estate,
Ratmalana, Sri Lanka.