SPMC

Loratadine Tablets USP 10 mg

1. Pharmacology

Loratadine, the active ingredient in Loratadine 10 mg Tablets, is a tricyclic antihistamine with selective, peripheral H1-receptor activity.

2. Indication & Dose

Loratadine 10mg Tablets is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

Adults: one tablet once daily

Paediatric population: Children 6 years of age and older with a body weight greater than 30 kg: One tablet once daily. For appropriate dosing in children younger than 6 years or with body weight of 30 kg or less, there are other formulations more suitable.

Children under 2 years of age: Safety and efficacy of loratadine tablets have not been established. No data are available.

Patients with hepatic impairment: Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine. An initial dose of 10mg every other day is recommended for adults and children weighing more than 30kg.

Patients with renal impairment: No dosage adjustments are required in patients with renal insufficiency.

Elderly: No dosage adjustments are required in the elderly.

Method of administration: Oral use. The tablet may be taken without regard to mealtime.

3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 11.

4. Special warnings and precautions for use

Loratadine 10 mg Tablets should be administered with caution in patients with severe liver impairment. The administration of Loratadine 10 mg Tablets should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index. This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose mal-absorption should not take this medicine.

5. Adverse Drug Reactions

Summary of the safety profile

In clinical trials involving adults and adolescents in a range of indications including allergic rhinitis (AR) and chronic idiopathic urticaria (CIU), at the recommended dose of 10mg daily, adverse reactions with loratadine were reported in 2% of patients in excess of those treated with placebo. The most frequent adverse reactions reported in excess of placebo were somnolence (1.2%), headache (0.6%), increased appetite (0.5%) and insomnia (0.1%).

Tabulated list of adverse reactions

The following adverse reactions reported during the post-marketing period are listed in the following table by System Organ Class. Frequencies are defined as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Experience Term
Immune system disorders	Very rare	Hypersensitivity reactions (including angioedema and anaphylaxis)
Nervous system disorders	Very rare	Dizziness, convulsion
Cardiac disorders	Very rare	Tachycardia, palpitation
Gastrointestinal disorders	Very rare	Nausea, dry mouth, gastritis
Hepatobillary disorders	Very rare	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Very rare	Rash, alopecia
General disorders and administration site conditions	Very rare	Fatigue
Investigations	Not known	Weight increased

Paediatric population

In clinical trials in a paediatric population, children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache (2.7%), nervousness (2.3%), and fatigue (1%).

Reporting of suspected adverse reactions

Suspected adverse reactions should be reported to the NMRA through the national pharmacovigilance reporting system. Furthermore, suspected adverse reactions should be reported via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store.

Interactions

When administered concomitantly with alcohol, Loratadine 10 mg Tablets has 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.

6. Fertility, pregnancy and lactation

6.1. Pregnancy

A large amount of data on pregnant women (more than 1000 exposed outcomes) indicates no malformative nor feto/ 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 10mg Tablets during pregnancy.

6.2. Breast-feeding

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

6.3. Fertility

There are no data available on male and female fertility.

7. Effects on ability to drive and use machines

In clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine. Loratadine has no or negligible influence on the ability to drive and use machines. Although drowsiness occurs rarely with loratadine, patients should be informed that it may affect the ability to drive or use machines in some individuals.

8. Overdose

Overdosage with loratadine increased the occurrence of anticholinergic symptoms. Somnolence, tachycardia, and headache have been reported with overdoses. In the event of overdosage, 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.

9. Storage

Store in a cool (below 30) & dry place, away from light and children. Keep container tightly closed.

10. Shelf life

24 months

11. Composition

Each Tablets Contains 10 mg of Loratadine as the active substance.

Excipients: Lactose monohydrate, Maize starch, Povidone K 30, Crospovidone & Magnesium Stearate.

12. Presentation

Loratadine 10 mg Tablets are white, circular, uncoated tablets, with score mark on one side.

They are available as blister strips in pack size of 100 tablets and bulk of 500 tablets.

13. Marketing Authorization Holder and Manufacturer:

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

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