NEW ZEALAND DATA SHEET

LORA-TABS ALLERGY & HAYFEVER

Loratadine 10 mg tablets

Presentation

White to off white coloured oval shaped biconvex uncoated tablets with breakline and 10 on one side and plain on the other side.

Uses

Actions

LORA-TABS ALLERGY & HAYFEVER is a potent long-acting, non-sedating antihistamine, with selective peripheral H_1-receptor antagonistic activity. Loratadine does not readily penetrate into the CNS. Loratadine exhibits greater affinity for peripheral H_1-receptors than for central H_1-receptors. These properties account for the observed lack of sedation. Loratadine does not exhibit anticholinergic activity in animals.

Pharmacokinetics

Loratadine is well absorbed with peak plasma levels occurring at approximately one hour after dosing. The medicine is almost totally metabolised. It has an active metabolite (SCH 34117); this metabolite corresponds to 1% to 2% of the dose.

In man, loratadine is extensively bound to plasma protein (97% to 99%) and SCH 34117 moderately bound (73% to 76%).

Approximately 40% of the dose is excreted in the urine and 42% in the faeces over a 10 day period. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. The half-life of loratadine in normal volunteers is 15 hours while that of SCH 34117 is 12 hours. The terminal elimination phase half-life based on plasma radioactivity, is approximately 46 hours.

Indications

LORA-TABS ALLERGY & HAYFEVER is indicated for the relief of:

- Symptoms associated with seasonal and perennial allergic rhinitis, such as sneezing, nasal discharge and itching, and ocular itching and burning.
- Symptoms and signs of chronic urticaria and other allergic dermatological disorders.

Onset of action occurs rapidly after oral administration. Symptom relief will begin in as little as 10 to 20 minutes after the first dose, with a mean onset of relief obtainable in 27 minutes in patients receiving 10 mg of loratadine. By 45 minutes, all patients should experience relief.

Dosage and Administration

Adults and children 12 years of age and over:

One LORA-TABS ALLERGY & HAYFEVER tablet once daily.

Children 2-12 years of age:

Bodyweight > 30 kg: one tablet once daily
Bodyweight < 30 kg: ½ tablet once daily.

Contraindications

LORA-TABS ALLERGY & HAYFEVER is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to loratadine, desloratadine or any of the excipients of the tablets (see Further Information).

Warnings and Precautions

Do not exceed the recommended dose.

Loratadine is no more likely than placebo to cause sedation. However, individual response should be determined before driving or performing tasks requiring alertness.

Safety and efficacy of loratadine in children younger than 2 years of age has not yet been established. No data is available.

Patients with severe liver impairment should be administered a lower dose because they may have reduced clearance of loratadine; an initial dose of 5 mg once daily or 10 mg every second day is recommended.

Use in Pregnancy and Lactation

The safe use of LORA-TABS ALLERGY & HAYFEVER during pregnancy and lactation has not been established and therefore, the compound should be used only if the potential benefits to the mother justify the potential risk to the foetus or the infant.

Since loratadine is excreted in breast milk and because of the increased risk of antihistamines for infants, particularly newborns and premature infants, a decision should be made whether to discontinue nursing or discontinue the medicine.

Adverse Reactions

In worldwide controlled clinical studies, the incidence of adverse effects associated with loratadine has been comparable to that of placebo. In these trials, loratadine has shown no clinically significant sedative or anticholinergic properties. Fatigue, sedation, dry mouth, headache, gastrointestinal disorders, such as nausea, gastritis, and also allergic symptoms like rash were rarely reported events with loratadine which were also reported with similar incidence in placebo-treated patients.

During the marketing of loratadine, alopecia, anaphylaxis, abnormal hepatic function, tachycardia, palpitations, dizziness and convulsion have been reported rarely.

Medicine Interactions

When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.

Increase in plasma concentrations of loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in controlled clinical trials, but without clinically significant changes (including electrocardiographic).

Laboratory Test Interactions

Loratadine should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Overdosage

Somnolence, tachycardia and headache have been reported with overdoses. In volunteer studies, single doses of up to 160 mg have been administered without any untoward effects. In the event of overdosage, until further experience is obtained, it is recommended that supportive and symptomatic treatment be started immediately. Consider standard measures to remove and unabsorbed medicine in the stomach, such as absorption by activated charcoal administered as a slurry with water.

For further advice on management of overdose please contact the National Poisons Information Centre (**0800 POISON** or **0800 764 766**).

Pharmaceutical Precautions

Store at or below 30°C.

Medicine Classification

Pharmacy Medicine

Package Quantities

LORA-TABS ALLERGY & HAYFEVER 10 mg tablets: Packs of 10, 30, 60, 90, 100 and 1000 tablets.

Not all pack sizes may be marketed.

Further Information

Each tablet contains 10 mg of the active ingredient loratadine. It also contains lactose, maize starch, colloidal silicon dioxide, magnesium stearate, sodium laurilsulfate, sodium starch glycollate and purified water.

LORA-TABS ALLERGY & HAYFEVER is gluten and sugar free.

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