Loraclear

Loratadine 10 mg tablet

Presentation

Round white biconvex tablet scored on one side and plain on the other side.

Uses

Actions

Loratadine is a potent long-acting, non-sedating antihistamine, with selective peripheral H_1-receptor antagonistic activity. 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 drug is almost totally metabolised. It has an active metabolite (SCH 34117); this metabolite corresponds to 1% to 2% of the dose.

Onset of action occurs rapidly after oral administration. Symptom relief will being 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.

Approximately 40% of the dose is excreted in the urine and 42% in the faeces in 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

Loraclear tablets are 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.

Dosage and Administration

Adults & Children over 12 years: One tablet once daily

Children 2-12 over 30kg: One tablet once daily
Children 2-12 under 30kg: Half a tablet once daily

Contraindications

Loraclear is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to loratadine.

Warnings and Precautions

Do not exceed the stated dose.

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

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.

Safety and efficacy of Loraclear in children younger than 1 year of age has not yet been established.

Effects on Ability to Drive and Operate Machinery

Although this medicine is unlikely to affect the ability to drive or operate machinery, a few people may be impaired and care should be taken.

Use in Pregnancy and Lactation [Category B1]

The safe use of loratadine 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 the nursing or discontinue the drug.

Adverse Effects

In clinical studies, the incidence of adverse effects associated with loratadine has been comparable to that placebo. In these trials, loratadine has shown no clinically significant sedative or anticholinergic properties.

The most commonly reported side effects for loratadine in excess of placebo include headache, sedation, fatigue, nausea and dry mouth.

Adverse effects occurring very rarely during the post-marketing period are listed below:

Immune system disorders: Anaphylaxis

Nervous system disorders: Dizziness

Cardiovascular disorders: Hypertension, hypotension, palpitation, tachycardia, syncope arrhythmia

Gastrointestinal disorders: Dyspepsia, diarrhoea, constipation, abdominal/gastric pain

Hepatobiliary disorders: Abnormal hepatic function

Skin and subcutaneous tissue disorders: Rash, alopecia, pruritus, angioedema

Interactions

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

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

Laboratory Test Interactions

Loraclear 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, treatment, which should be started immediately, is symptomatic and supportive. Discontinuation of use, gastric lavage or induction of emesis (except in patients with impaired consciousness) and support of vital functions are advised.

Pharmaceutical Precaution

Store below 30 °C. Protect from heat, light and moisture.

Medicine Classification

Pharmacy Medicine.

Package Quantities

Packs of 10, 30, 60 and 100 tablets.

Further information

Each tablet contains loratadine 10 mg. Tablets also contain lactose, maize starch, microcrystalline cellulose and magnesium stearate.

Name and Address

AFT Pharmaceuticals Ltd
PO Box 33-203
Takapuna, Auckland

Ph: (09) 488-0232
Fax: (09) 488-0234

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