



New Zealand Data Sheet

APO-LORATADINE

Loratadine 10mg Tablets

Presentation

APO-LORATADINE 10mg tablets are white, oval tablets (7.6mm x 5.1mm), deep-scored, engraved 'LO' over '10' on one side, 'APO' on the other. Each tablet contains 10mg of loratadine and typically weighs 105mg and

Uses

Actions

Loratadine, a piperidine derivative, is a potent long-acting, non-sedating tricyclic antihistamine with selective peripheral H₁-receptor antagonistic activity. Loratadine has no significant sedative or antimuscarinic activity. Loratadine does not readily penetrate into the CNS. Loratadine exhibits greater affinity for peripheral H₁-receptors than for central H₁-receptors. Loratadine does not exhibit anticholinergic activity in animals.

Pharmacokinetics

Loratadine is rapidly absorbed from the gastro-intestinal tract after oral administration with peak plasma levels occurring about one hour after dosing. Bioavailability is increased and time to peak plasma concentrations delayed when administered with food.

Loratadine is extensively metabolised. The major metabolite, descarboethoxyloratadine (desloratadine or SCH 34117), has potent antihistamine activity and this metabolite corresponds to 1–2% of the dose. Loratadine is approximately 98% bound to plasma proteins. Descarboethoxyloratadine is less extensively bound (approximately 75%). Loratadine and its metabolites have been detected in breast milk but do not appear to cross the blood-brain barrier to a significant extent.

Approximately 82% of the dose is excreted in the urine (40%) and faeces (42%) mainly in the form of metabolites over a 10 day period. Approximately 27% of the dose is eliminated in the urine during the first 24 hours largely in the conjugated form. The half-life of loratadine in normal volunteers is 15 hours, while that of descarboethoxyloaratadine is 12 hours. The terminal elimination phase half-life, based on plasma radioactivity, is approximately 46 hours.

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

Indications

APO-LORATADINE 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.

Dosage and Administration

Adults and children 12 years of age and over:

One APO-LORATADINE tablet once daily.

Children 2 – 12 years of age:

Bodyweight >30kg: one APO-LORATADINE tablet once daily.

Bodyweight <30kg: Half an APO-LORATADINE tablet once daily.

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Contraindications

APO-LORATADINE is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to the drug or its components.

Warnings and Precautions

Do not exceed the recommended dose.

Use in Pregnancy and Lactation

Category B1

The safe use of loratadine during pregnancy or lactation has not been established and therefore the compound should only be used if the potential benefit outweighs the potential risk to the fetus 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 loratadine use.

Use in Children

The safety and efficacy of APO-LORATADINE in children younger than 2 years of age have not been established. Long term safety and efficacy of APO-LORATADINE in children between the ages of 2 and 12 have not been demonstrated. Therefore it is desirable that APO-LORATADINE not be administered to children between the ages of 2 and 12 for longer than 14 days, unless recommended by a physician.

Use in patients with Liver 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 5mg once daily or 10mg every other day is recommended.

Driving/Use of Machinery

APO-LORATADINE is no more likely than placebo to cause sedation. APO-LORATADINE is presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery. However, the individual response should be determined before driving or performing other tasks that require alertness.

Adverse Effects

In clinical trials the incidences of adverse effects associated with APO-LORATADINE have been comparable to that of the placebo. These trials showed that there was no clinically significant sedative or anticholinergic properties. During clinical trials fatigue, sedation, headache and dry mouth were rarely reported. These adverse effects were also reported with similar incidence in placebo-treated patients.

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

Interactions

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

Increases 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). Other drugs known to inhibit hepatic



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function metabolism should be coadministered with caution until definitive interaction studies can be completed.

Laboratory Test Interactions

APO-LORATADINE should be discontinued approximately 48 hours prior to skin testing procedures since antihistamine may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Overdosage

Somnolence, tachycardia and headache have been reported with overdoses of loratadine. A single acute ingestion of 160mg produced no adverse 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 Precautions

Store below 25°C.
Protect from heat, light and moisture.

Medicine Classification

Pharmacy Only Medicine

Package Quantities

Bottles of 100 tablets.
Blister packs of 15 and 30 tablets.

Further Information

Tablets contain Lactose.

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