Oradin®

Loratadine Tablet / Orally Dispersible Tablet / Suspension

DESCRIPTION

Oradin® is a preparation of loratadine. Loratadine is a long acting tricyclic antihistamine with selective peripheral H_1-receptor antagonistic activity and no central sedative or anticholinergic effect.

INDICATIONS

Oradin® provides fast effective relief from the symptoms of hay fever, allergic rhinitis such as sneezing, nasal discharge, itching, ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration. Loratadine is also indicated for the relief of the symptoms associated with idiopathic chronic urticaria. In children over 2 years, loratadine is indicated for the symptomatic relief of seasonal allergic rhinitis and allergic skin conditions such as urticaria, nettle-rash.

DOSAGE AND ADMINISTRATION

Tablet

Adults and children over 6 years of age: 1 tablet (10 mg) once daily.
Children 2-5 years: 1/2 tablet (5 mg) once daily.
Below 2 years of age: Safety and efficacy of loratadine has not been established.

Orally dispersible tablet

Adults and children over 6 years of age:1 Orally dispersible tablet (10 mg) once daily.

Suspension

Adults and children over 6 years of age: 10 mL or 2 teaspoonful (10 mg) of suspension once daily.
Children of 2-5 years: 5 mL or 1 teaspoonful (5 mg) of suspension once daily.
Below 2 years of age: Safety and efficacy of loratadine has not been established.

CONTRAINDICATIONS

Loratadine is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to loratadine or to any of its components.

USE IN PREGNANCY AND LACTATION

There is no experience of the use of loratadine in human pregnancy, hence it should not be used during pregnancy. Loratadine is excreted in breast milk, so it should not be administered to lactating mother.

SIDE-EFFECTS

During controlled clinical studies the incidence of adverse events including sedation and anticholinergic effects observed with 10 mg loratadine was comparable to that observed with placebo. Fatigue, nausea and headache were reported rarely. Scientific studies show that loratadine does not cause drowsiness. It does not affect performance and ability to drive or tasks requiring concentration.

DRUG INTERACTIONS

When administered concurrently with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies. Erythromycin, ketoconazole, cimetidine and amprenavir may increase plasma concentration of loratadine.

OVERDOSAGE

In the event of overdose, treatment which should be started immediately is symptomatic and supportive. The patient should be induced to vomit, even if emesis has occurred spontaneously, but not in the patients with impaired consciousness. Administration of activated charcoal as a slurry with water may be attempted following emesis. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed.

PHARMACEUTICAL PRECAUTION

Suspension: Store in a dry place, at a temperature of 2 °C - 25 °C.
Tablet: Store between 2 °C - 30 °C, protect from excessive moisture. Keep out of reach of children.

PACKAGING

Oradin® Tablet:
Box containing 10 strips of 10 tablets each. Each tablet contains Loratadine USP 10 mg.

Oradin FT® :
Box containing 4 strips of 10 orally dispersible tablets each. Each orally dispersible tablet contains Loratadine USP 10 mg.

Oradin® Suspension:
Bottle containing 60 mL suspension. Each 5 mL contains Loratadine USP 5 mg.

SK+F
Manufactured by
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BANGLADESH

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