

CLARITINE* Tablets and Syrup

Brand of loratadine

Long-Acting, Non-Sedating Antihistamine

DESCRIPTION: Each CLARITINE Tablet contains 10 mg micronized loratadine and the inactive ingredients corn starch, lactose and magnesium stearate.

Each 5 ml of CLARITINE Syrup contains 5 mg of micronized loratadine and the inactive ingredients propylene glycol, glycerin, citric acid monohydrate, sodium benzoate, sugar, peach flavor and purified water.

ACTIONS: Loratadine is a potent long-acting tricyclic antihistamine with selective peripheral H₁-receptor antagonistic activity.

INDICATIONS AND USAGE: CLARITINE products are indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration.

CLARITINE products are also indicated for relief of symptoms and signs of chronic urticaria and other allergic dermatologic disorders.

DOSAGE AND ADMINISTRATION:

Adults and Children 12 years of age and over:

CLARITINE Tablet: One Tablet [10 mg] once daily.

CLARITINE Syrup: Two teaspoonful [10 ml] once daily.

Children 2 to 12 years of age:

Body Weight >30 kg – 10 ml [10 mg], (two teaspoonsful), CLARITINE Syrup once daily.

Body Weight ≤30 kg – 5 ml [5 mg], (one teaspoonful), CLARITINE Syrup once daily.

DRUG INTERACTIONS: When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies. Claritine can be administered independently of the meals.

Increases in plasma concentrations of loratadine has 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 metabolism should be coadministered with caution until definitive interaction studies can be completed.

Drug/Laboratory Test Interactions: CLARITINE products should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

ADVERSE REACTIONS: CLARITINE products have no clinically significant sedative properties at the daily recommended dose of 10 mg.

Most commonly reported side effects include fatigue, headache, somnolence, dry mouth, gastrointestinal disorders such as nausea, gastritis, and also allergic symptoms like rash.

During the marketing of CLARITINE products, alopecia, anaphylaxis, abnormal hepatic function, tachycardia and palpitations have been reported very rarely.

Similarly, the incidence of adverse effects associated with CLARITINE Syrup has been comparable to that of placebo. In controlled pediatric clinical trials, the incidence of treatment-related headache, sedation and nervousness, which were rarely reported events, was similar to that of placebo.

CONTRAINDICATIONS: CLARITINE products are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their components.

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

Safety & efficacy of CLARITINE products has not yet been established in children younger than 2 years of age.

USAGE DURING PREGNANCY AND IN NURSING MOTHERS: Safe use of CLARITINE Products during pregnancy & lactation has not been established; therefore, use only if potential benefit justifies potential risk to fetus.

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 drug.

OVERDOSAGE INFORMATION: Somnolence, tachycardia and headache have been reported with overdoses. A single acute ingestion of 160 mg produced no adverse effects. In the event of overdose, treatment, which should be started immediately, is symptomatic and supportive.

Treatment: Consider standard measures to remove any unabsorbed drug in the stomach, such as adsorption by activated charcoal administered as a slurry with water. The administration of gastric lavage should be considered Physiologic saline solution is the lavage solution of choice, particularly in children. In adults, tap water can be used; however, as much as possible of the amount administered should be removed before the next instillation. Saline cathartics draw water into the bowel by osmosis and, therefore, may be valuable for their action in rapid dilution of bowel content. Loratadine is not cleared by hemodialysis to any appreciable extent. After emergency treatment, the patient should continue to be medically monitored.

HOW SUPPLIED:

CLARITINE Tablets are available in packages of 10, 21, 30 and 100 tablets

CLARITINE Syrup 1mg/ml in bottles of 100 and 120 ml.

STORAGE:

Store between 2° and 30°C.

Blister pack tablets should be protected from excessive moisture.

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