LORATADINE
CLARITIN* 5 mg/5 mL Syrup

ANTIHISTAMINE

Long-Acting, Non-Sedating Antihistamine

FORMULATION: Each 5 mL of LORATADINE (CLARITIN*) Syrup contains 5 mg 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: LORATADINE (CLARITIN*) 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.

LORATADINE (CLARITIN*) 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:
   LORATADINE (CLARITIN*) Syrup: Two teaspoonfuls, 10 mL once daily.

Children 2 to 12 years of age:
   Body weight >30 kg – 10 mL (10 mg), (two teaspoonfuls), LORATADINE (CLARITIN*) Syrup once daily.
   Body weight ≤30 kg – 5 mL (5 mg), (one teaspoonful), LORATADINE (CLARITIN*) Syrup once daily.

Children 1 to 2 years of age:
   One-half teaspoonful - 2.5 mL (2.5 mg) LORATADINE (CLARITIN*) Syrup once daily.

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

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: LORATADINE (CLARITIN*) products should be discontinued approximately 48 hours prior to skin testing procedures since these drugs may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

ADVERSE REACTIONS: LORATADINE (CLARITIN*) 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 LORATADINE (CLARITIN*) products, alopecia, anaphylaxis, abnormal hepatic function, tachycardia, palpitations and dizziness, have been reported very rarely.
Similarly, the incidence of adverse effects associated with LORATADINE (CLARITIN*) 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:** LORATADINE (CLARITIN*) 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 (5 mL) once daily, or 10 mg (10 mL) every other day is recommended.

Efficacy of LORATADINE (CLARITIN*) has not yet been established in children younger than two years of age. However, the pharmacokinetic profile of loratadine in infants 1 to 2 years of age after the administration of a single 2.5 mg dose of LORATADINE (CLARITIN*) Syrup is similar to that in older children and adults.

**USAGE DURING PREGNANCY AND IN NURSING MOTHERS:** Safe use of LORATADINE (CLARITIN*) products during pregnancy has not been established; therefore, use only if the potential benefit justifies the 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 overdosage, 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.

**AVAILABILITY:** LORATADINE (CLARITIN*) 5 mg/5 mL Syrup - 30 mL and 60 mL bottles.

Store below 30°C.