

Important: Read Carefully!

Clara™

loratadine tablets and syrup

COMPOSITION:

Each Clara™ tablet contains : 10 mg micronized loratadine
Each 5 ml of Clara™ syrup contains : 5 mg of micronized loratadine

(Long-Acting, Non-Sedating Antihistamine)

PROPERTIES:

Loratadine is a long-acting antihistamine characterized as a specific, selective peripheral H₁-receptor antagonist and has been referred to as a "non-sedating" or second generation antihistamine.

INDICATIONS

Clara™ 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.

Clara™ products are also indicated for relief of symptoms and signs of chronic urticaria and other dermatological disorders.

DOSAGE AND ADMINISTRATION:

Clara™ can be administered without regard to meals.

Adults and Children 12 years of age and over	One tablet (10 mg) once daily daily, or Two teaspoonful (10 mg) once daily
Children 2-12 years of age •Body weight >30kg •Body weight <30kg	Two teaspoonful (10 mg) once daily One teaspoonful (5 mg) once daily

OVERDOSAGE INFORMATION:

Somnolence, tachycardia and headache. No specific antidote is available. Treatment is symptomatic and supportive. Loratadine is not eliminated by dialysis.

ADVERSE EVENTS:

Clara™ has no clinically significant sedative properties at the daily recommended dose of 10 mg. Most commonly reported adverse events include: fatigue, headache, somnolence, dry mouth, gastrointestinal disorders such as nausea, gastritis, and also allergic symptoms like rash.

The incidence of adverse events associated with Loratadine 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, were similar to that of placebo.

CONTRAINDICATIONS:

Clara™ products are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their components.

PRECAUTIONS:

There are no adequate or well controlled studies in pregnant and lactating women; therefore loratadine should not be administered in pregnant or lactating women. Safety and efficacy of loratadine in children younger than two years of age have not been established. Patients with severe liver impairment should administer a lower initial dose of 5mg or 5ml once daily, or 10 mg or 10 ml every other day.

DRUG INTERACTIONS:

Increase 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). Drugs that are known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed.

Drug/Laboratory Test Interactions:

Clara™ 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.

PRESENTATION:

Clara™ tablets are available in packs of 10 tablets.
Clara™ syrup 5mg / 5ml in bottles of 100ml.

STORAGE:

Store between 15° to 25°C.

THIS IS A MEDICAMENT

- Medicament is a product that affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



General Medicine

Clara™ is a quality product manufactured by:



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Jamjoom Pharma

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