

Emilora

long-Acting, Non-Sedating Antihistamine

Composition:

Emilora Tablets: Each tablet contains 10 mg micronized loratadine

Emilora Syrup: Each 5 ml contains 5 mg micronized loratadine

Properties:

loratadine is a potent long-acting, non-sedating tricyclic antihistamine with selective peripheral histamine H1-receptor antagonistic activity.

Pharmacokinetics:

Emilora is rapidly and well absorbed from the gastrointestinal tract. The onset of antihistaminic effect after oral administration of loratadine occurred within 1-3 hours, with peak effects occurring in about 8-12 hours and duration of action lasting in excess of 24 hours. Emilora is almost completely metabolized in the liver with elimination half-life of about 12-15 hours. The elimination of the metabolites is equally same through both the urine and feces.

Indications:

Emilora is an antihistamine, indicated for the symptomatic relief of nasal allergies, particularly seasonal allergic rhinitis (hay fever), sneezing, nasal discharge (rhinorrhea), itching and burning eyes. Emilora is also indicated for the treatment of chronic urticaria and other allergic dermatologic disorders.

Dosage and Administration:

Emilora can be administered with or without food.

Adults and Children 12 years of age and over:

The recommended dose is one Emilora tablet 10 mg once daily.

or Emilora syrup 10ml (2 teaspoonsful) once daily.

Children 2 to 12 years of age:

Body weight > 30kg: Emilora syrup 10mg/10ml (2 teaspoonsful) once daily.

Body weight < 30kg: Emilora syrup 5mg/5ml (1 teaspoonful) once daily.

Emilora is not recommended for children below 2 years of age.

Contraindications:

Emilora should not be administered to patients hypersensitive to loratadine. Emilora should be avoided in patients with a history of acute prophyria.

Precautions:

As with other anti-histamine, Emilora should be used with caution in prostatic hypertrophy, urinary retention, glaucoma, hepatic disease and epilepsy.

In case of severe liver impairment, Emilora should be administered at a lower initial dose because of the reduced clearance of loratadine. The recommended dose in this case is Emilora 5 mg or 5 ml once daily, or 10 mg or 10 ml every other day.

Use in Pregnancy and Lactation:

Emilora should not be given to pregnant women or during breast-feeding.

Side Effects:

Emilora has no clinically significant sedative and antimuscarinic properties at the recommended daily dose of 10 mg. The most commonly reported side effects include fatigue, headache, somnolence, dry mouth, gastrointestinal disturbances and rarely rash.

Tachycardia and syncops have been reported rarely. Some isolated and rare side effects include palpitation, and arrhythmias, hypotension, bronchospasm, angioedema, and nausea, photosensitivity reactions, extrapyramidal effects, depression, sleep disturbances, agitation, cramp, sweating, myalgia, paraesthesia, blood disorder, abnormal hepatic function and alopecia.

Children and elderly are more susceptible to side effects.

Drug Interactions:

-The plasma concentration of loratadine have been reported to increase when administered concomitantly with erythromycin, ketoconazole, or cimetidine due to inhibition of hepatic metabolism of loratadine. Such increase has no clinically significant effect.

Drug/Laboratory Test Interactions:

Emilora should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Driving or Operating Machinery:

Studies in healthy volunteers have not revealed effects on alertness or reaction time. Patients should be advised, however, not to exceed the recommended daily dose.

Overdosage:

The treatment in case of overdose with loratadine is symptomatic. Induced vomiting by the administration of ipecac syrup, if vomiting is unsuccessful within 15 minutes of indigestion, gastric lavage should be performed together with the usual supportive measures.

Presentation:

Emilora 10mg tablets in packs of 10 and 20 tablets.
Emilora Syrup 5mg/5ml in bottles of 100 ml.

Store below 25°C in dry place. Protect from light.

THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, 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 for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacist



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