

Alaron®

Loratadine

Description

Alaron® is a preparation of Loratadine which is long acting non-sedative anti-histamine with selective peripheral H₁ receptor antagonistic activity.

Indications

Alaron® is indicated for the relief of

- Symptoms associated with seasonal and perennial allergic rhinitis, such as sneezing, nasal discharge and itching, and ocular itching and burning.
- Symptoms and signs of chronic urticaria and other allergic dermatological disorders.

Dosage and administration

Tablet:

Adults and children over 12 years of age: One **Alaron®** tablet (10 mg) once daily.

Children of 2 to 12 years (body weight more than 30kg): One **Alaron®** tablet (10 mg) once daily.

Children of 2 to 12 years (body weight less than 30kg): Half **Alaron®** tablet (5 mg) once daily.

Suspension:

Adults and children over 12 years of age: Two teaspoonfuls of **Alaron®** suspension (10 ml) once daily.

Children of 2 to 12 years (body weight more than 30kg): Two teaspoonfuls of **Alaron®** suspension (10 ml) once daily.

Children of 2 to 12 years (body weight less than 30kg): One teaspoonful of **Alaron®** suspension (5 ml) once daily.

Use in patients with liver impairment or renal insufficiency (GFR<30 ml/min):

Patients with severe liver impairment or renal insufficiency should be administered a lower initial dose. The dose should be-

Adults and children ≥ 6 years of age: 10 mg (one **Alaron®** tablet) every other day as starting dose.

Children 2 to 5 years of age: 5 mg (half of **Alaron®** tablet) every other day as starting dose. Sudden withdrawal of Loratadine is not hazardous but symptoms may reappear within 24 to 48 hours.

Use in pregnancy and lactation

Loratadine is pregnancy category B. The safe use of Loratadine during pregnancy or lactation has not been established and therefore the compound should only be used if the potential benefit outweighs the potential risk to the fetus or the infant. Since Loratadine is excreted into 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 Loratadine use.

Side effects

The most common side effects of loratadine were fatigue, dizziness, dry mouth, headache, sedation, nausea and pruritus. Gastrointestinal side effects reported during paediatric trials may have been slightly more frequent in the younger patients (less than or equal to 30 kg) but in older children (greater than 30 kg) is similar to placebo. In case of acute overdose

the adverse reaction like nausea, vomiting, hypotension, tachycardia, ataxia and drowsiness have been reported.

Contraindications

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

Warnings and precautions

The dose should not exceed the recommended dose. Loratadine is no more likely than placebo to cause sedation. However, individual response should be determined before driving or performing tasks requiring alertness. Patients with severe liver impairment or renal insufficiency (GFR < 30ml/min) should be given a lower initial dose because they may have reduced clearance of Loratadine.

Drug interactions

In contrast to many other histamine H₁ receptor antagonists, Loratadine has no potentiating effects when administered concomitantly with alcohol. Concomitant therapy with drugs that inhibit or are metabolized by hepatic cytochromes P450 3A4 and 2D6 may elevate the plasma concentration of either drug and this may result in adverse effects. Cimetidine inhibits both enzymes while erythromycin and ketoconazole inhibit P450 and 3A4. These drugs increase Loratadine serum concentrations but no adverse effects are reported. Quinidine, fluconazole, or fluoxetine are also known to inhibit either P450 3A4 or 2D6.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Alaron® 10 tablet: Each tablet contains Loratadine USP 10 mg

Alaron® suspension: Each 5 ml contains Loratadine USP 5 mg

Packaging quantities

Alaron® tablet: Carton of 100's pack in blister.

Alaron® suspension: Bottle of 60 ml.

® Registered Trade Mark



ACI Limited

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