

LORASTAD 10 TABLETS

Consumer Medication Information Leaflet (RiMUP)

Active ingredient: Loratadine (10mg)

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What Lorastad 10 Tablets is used for

Lorastad 10 Tablets is used to relieve symptoms associated with an allergic inflammation of the nasal airways occurring during specific seasons (seasonal allergic rhinitis) such as sneezing, watery nose, itching as well as eye itching and burning.

It is also used for the control of symptoms and signs of idiopathic chronic urticaria (a common allergic disorder including red, itchy, lumpy skin rash that occurs year round and the cause of that is not known or that arises spontaneously) and other allergic skin disorders.

How Lorastad 10 Tablets works

Loratadine belongs to a class of medicines known as antihistamines which help to reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced in the body.

Before you use Lorastad 10 Tablets

When you must not use it

- If you have shown hypersensitivity or unusual and unexpected sensitivity to any components of Lorastad 10 Tablets
- Children under the age of 2 years.

Before you start to use it

If any of the situations mentioned below apply to you, you should tell your doctor before taking this drug:

- If you have severe liver problem, you should take the medicine with a lower initial dose.
- If you are pregnant women.
- If you are in breast-feeding.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription. You should tell your doctor if you are receiving other drugs that may increase plasma concentration of Loratadine such as Ketoconazole, Erythromycin or Cimetidine; drugs that inhibit liver metabolism and alcohol.

How to take Lorastad 10 Tablets

How much to take

Always take Lorastad 10 Tablets exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of Lorastad 10 Tablets depending on your condition and whether you are taking other medicines.

- Adults and children ≥ 12 years: 1 tablet (10 mg) once daily.
- Children 2 – 12 years:
For body weight > 30 kg: 1 tablet (10mg) once daily.
For body weight ≤ 30 kg: 1/2 tablet (5mg) once daily.

When to take it

Lorastad 10 Tablets is administered at any time of day, with or without food.

How long to take it

It is important to continue taking Lorastad 10 Tablets for as long as your doctor prescribes it in order to maintain smooth control of your symptoms and signs.

If you forget to take it

Try to take Lorastad 10 Tablets daily as prescribed. If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose.

Just take the next dose at your regular time.

If you take too much (overdose)

If you accidentally take too many tablets, contact your doctor immediately.

Sleepiness, faster heart beat and headache have been reported with overdoses of Loratadine.

While you are using Lorastad 10 Tablets

Things you must do

- Tell your doctor if you become pregnant.
- Safe use of Loratadine products during pregnancy 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.

Things you must not do

If you are scheduled to have any skin tests for allergies, you should not take these tablets for two days before.

Things to be careful of

Use with caution if you concomitantly receive loratadine with drugs known to inhibit hepatic metabolism such as macrolide antibiotic, ketoconazole, cimetidine, ranitidine, or theophylline.

Side effects

Like all medicines, Lorastad 10 Tablets can cause side effects, although not everybody gets them. The following side effects have been reported:

- Fatigue, headache, sleepiness, dry mouth, disorders relating to the stomach and intestines, e.g. feeling sick, inflammation of the lining of the stomach and also allergic symptoms, i.e. rash.
- During the marketing of Loratadine tablet, hair loss,

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anaphylaxis (a severe, whole-body allergic reaction to a chemical that has become an allergen) and abnormal liver function have been reported rarely.

- In controlled clinical trials for infants and children, the incidence of treatment related headache, sedation and nervousness were rarely reported .

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Lorastad 10 Tablets

Storage

The expiry date of this pack is printed on the box. Do not use this pack after this date.

Do not store above 30°C. Store in well-closed container, in a dry place.

Protect from light.

Keep all medicines out of reach of children.

Disposal

Medicines should not be disposed of via wastewater of household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

Lorastad 10 Tablets appears as a white, round-shaped tablet, with fracture line on one side and plain on the other side.

Ingredients

Active ingredient: Loratadine 10 mg. The other ingredients are Lactose monohydrate, Maize starch, Povidone, Purified talc, ethanol 96%, Magnesium stearate and purified water.

MAL No.: MAL06041465AZ

Manufacturer

STELLAPHARM J.V. CO., LTD.

– BRANCH 1 (A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam - Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam.

Product Registration Holder

Stadpharm Sdn. Bhd.

E-9-01, Oasis Square,

Ara Damansara,

No. 2, Jalan PJU 1A/7A,

47301 Petaling Jaya, Selangor.

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