

Package leaflet: Information for the patient

Loratadine 10 mg Tablets (loratadine)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Loratadine Tablets are and what they are used for
2. What you need to know before you take Loratadine Tablets
3. How to take Loratadine Tablets
4. Possible side effects
5. How to store Loratadine Tablets
6. Contents of the pack and other information

1. What Loratadine Tablets are and what they are used for

Loratadine belongs to the class of medicines called anti-histamines, which are used to treat various allergic conditions.

Loratadine tablets are used to relieve symptoms associated with seasonal allergic rhinitis (hay fever) and perennial allergic rhinitis (year round allergy symptoms). Symptoms of these conditions can include sneezing, runny nose, nasal itching, in addition to burning, itching and watering of the eyes.

Loratadine tablets are also used to relieve symptoms of chronic idiopathic urticaria (skin rash consisting of hives and wheals).

2. What you need to know before you take Loratadine Tablets

Do not take Loratadine Tablets:

- if you are allergic to loratadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Loratadine tablets if:

- you have severe liver problems
- you are due to have any skin tests for allergies. Do not take Loratadine Tablets for two days before having these tests. This is because it may affect the test results.

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist, or nurse before taking Loratadine Tablets.

Other medicines and Loratadine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines taken without a prescription.

When taken concomitantly, following medicines may increase the level of loratadine in blood and increase its side effects:

- ketoconazole (used to treat fungal infections)
- erythromycin (an antibiotic)
- cimetidine (used in treatment of heartburn)

Loratadine Tablets with food, drink, and alcohol

Loratadine Tablets can be taken with or without food. This medicine has not been shown to add to the effects of an alcoholic drink.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Loratadine if you are breast-feeding as this treatment passes into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Very rarely, this medicine may cause drowsiness or reduced alertness in some people. Hence, you should not perform such tasks that need special attention (including driving a car or operating machinery), until you know how this medicine affects you.

Loratadine Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Loratadine Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Usual doses

Adults (including older people): 10 mg once daily (one tablet once daily)

Hepatic impairment:

Your doctor may prescribe a different dose, if you have severe liver problems.

Use in children and adolescents

Children over 12 years of age: 10 mg once daily (one tablet once daily)

Children aged 2 to 12 years of age:

Body weight over 30 kg: 10 mg once daily (one tablet once daily)

Body weight 30 kg or below: Not recommended

Children aged less than 2 years of age: Not recommended

Taking this medicine

The tablet should be swallowed whole with a drink of water. It may be taken with or without food.

To help you to remember to take your medicine, try to get into the habit of taking it at the same time every day.

If you take more Loratadine Tablets than you should

If you take more Loratadine Tablets than you should, you may develop drowsiness, fast heart beat and headache. **You should seek medical advice immediately. Please take any remaining medicine with you so that your doctor will know what has been taken.**

If you forget to take Loratadine Tablets

If you forget to take Loratadine Tablets, take one as soon as you remember, then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Loratadine Tablets

You must take your medicine for as long as your doctor has told you to. Do not stop taking it even if you feel better, as symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You must stop taking Loratadine tablets immediately and consult your doctor if you develop an allergic reaction to this medicine. This can consist of:

- skin rash or eruptions (including inside the mouth)
- itching
- swelling of the face/tongue/lips/hands/feet
- breathing difficulties.

These side effects are rare (may affect up to 1 in 10,000 people) but are serious.

The most commonly reported side effects in adults and children over 12 years are:

- drowsiness
- headache
- increased appetite
- difficulty sleeping.

The most commonly reported side effects in children aged 2 to 12 years are:

- headache
- nervousness
- tiredness.

The following very rare side effects (may affect up to 1 in 10,000 people) have also been seen during the marketing of loratadine:

- dizziness
- fit (convulsion)

- rapid heartbeat, palpitations (awareness of heart beat/racing)
- nausea (feeling sick)
- dryness of the mouth
- irritation of the stomach lining (gastritis)
- rash
- hair loss
- abnormal liver function.

Frequency not known:

- Weight increased

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Loratadine Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and foil after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Loratadine Tablets contain

- The active substance is loratadine
- The other ingredients are: lactose monohydrate, maize starch, pre-gelatinised maize starch and magnesium stearate.

What Loratadine Tablets look like and contents of the pack

Loratadine 10 mg Tablets are white to off-white, round, uncoated tablets debossed with "R" on one side and "10" on the other.

Loratadine 10 mg Tablets are available as blister strips in pack sizes of 7, 10, 14, 20, 21, 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Ranbaxy (UK) Limited
5th floor, Hyde Park, Hayes 3
11 Millington Road
Hayes, UB3 4AZ
United Kingdom

Manufacturers

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

Alkaloida Chemical Company Zrt.
4440 Tiszavasvári
Kabay János u. 29
Hungary

This leaflet was last revised in November 2017.