

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.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

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

What Loratadine Tablets are

Loratadine tablets contain the active substance loratadine which belongs to the class of medicines called "anti-histamines."

How Loratadine Tablets work

Loratadine tablets help to reduce your allergy symptoms by stopping the effects of a substance called "histamine", which is produced in the body when you are allergic to something.

When Loratadine Tablets should be taken

Loratadine tablets relieve symptoms associated with allergic rhinitis (for example, 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 may also be used to help relieve symptoms of chronic idiopathic urticaria (itching and redness) which is often known as hives or nettle rash.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

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.

Children and adolescents

Do not give Loratadine tablets to children younger than 6 years old or to children who weigh 30 kg or less. There are other formulations more suitable for children younger than 6 years or with a body weight of 30 kg or less.

Children under 2 years of age:

The safety and efficacy of Loratadine tablets have not been established. No data are available.

Other medicines and Loratadine Tablets

The side effects of Loratadine Tablets may increase when used together with medicines that alter the performance of some enzymes responsible for drug-metabolism in the liver.

However, in clinical studies, no increase in side effects of loratadine was seen with products that altered the performance of these enzymes.

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.

Loratadine Tablets with alcohol

Loratadine Tablets have 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.

As a precautionary measure, it is preferable to avoid the use of Loratadine tablets during pregnancy.

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

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Driving and using machines

In clinical trials that assessed driving ability, no impairment was observed in patients receiving loratadine. At the recommended dose, Loratadine Tablets are not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

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, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children over 6 years of age with a body weight greater than 30 kg: Take 1 tablet 1 time daily with a glass of water, with or without food.

Children who weigh 30 kg or less:

Do not give Loratadine 10 mg tablets. There are other presentations more appropriate for children under 6 years of age who weigh 30 kg or less.

Children aged less than 2 years of age: Not recommended for children under 2 years old.

Adults and children with severe liver problems:

Adults and children weighing more than 30 kg:

Take 1 tablet 1 time a day and every other day with a glass of water, with or without food.

However, you should talk to your doctor, pharmacist or nurse before taking this medicine.

If worsens, or symptoms persist after 7 days of treatment, you should see a doctor.

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, talk to your doctor or pharmacist straight away. No serious problems are expected however, you may get a headache, have a rapid heartbeat or feel sleepy.

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 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.

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 from 6 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:

- severe allergic reaction (including swelling)
- 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
- tiredness.

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. Each tablet contains 10 mg 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

SUN PHARMA UK LIMITED
6-9 The Square,
Stockley Park,
Uxbridge, UB11 1FW
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 2023.