

Loratadine 10 mg Tablets

Package leaflet: Information for the user

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 or pharmacist have 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 the leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse or if your symptoms change. 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 a group of drugs called antihistamines which help to relieve the symptoms of some allergies.
- Your medicine is used to relieve symptoms such as sneezing, runny nose and burning, itchy eyes due to hayfever and other allergies. Loratadine tablets can also be taken to relieve symptoms due to urticaria (hives) such as rash, itching and redness. The effect of Loratadine Tablets will last a whole day and should help you to continue your normal daily activities and sleep.
- You must talk to a doctor if you do not feel better or if you feel worse.

2 What you need to know before you take Loratadine Tablets

Do NOT take Loratadine if you:

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

Warnings and precautions

Talk to your doctor or pharmacist before you start taking this medicine if you:

- have severe liver problems (see section 3, 'How to take Loratadine Tablets')

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

Other precautions you should take

This product may prevent a response to allergens in skin allergy testing; therefore you should stop taking this medicine at least 2 days before any such testing.

Children

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.

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

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine. As a precautionary measure, it is preferable to avoid the use of Loratadine Tablets during pregnancy. Do not take Loratadine Tablets if you are breast-feeding as it is excreted in breast milk.

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. Do not drive or operate any tools or machines if affected.

Loratadine with alcohol

Loratadine have not been shown to add to the effects of an alcoholic drink.

Loratadine contains Lactose

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

3 How to take Loratadine Tablets

If your doctor has prescribed this medicine, always take exactly as your doctor has told you. Otherwise follow the instructions below. You should check with your doctor or pharmacist if you are not sure.

The score line of the tablet is only there to help you break the tablet if you have difficulty swallowing it whole

The tablets should be swallowed, preferably with a drink of water.

The usual dose is:

Adults and Children over 12 years of age

One 10 mg tablet once daily.

Children aged 2 - 12 years of age are dosed by weight:

It is important to know how much your child weighs to make sure that you give the correct amount of medicine. For example, a 9-year-old child weighs about 30 kg (4st 7lb). If in doubt weigh your child. Do not give to children who weigh 30 kg (4st 7lb) or less.

Body weight more than 30 kg: 10 mg once daily (one tablet once daily).

Loratadine tablets are not suitable for children with a body weight of less than 30 kg. For children aged 2 years and over but weighing 30 kg or less, a syrup form of this medicine may be more suitable.

Children under 2 years of age

Loratadine is not recommended for children under 2 years of age.

Patients with severe liver problems

Adults and children over 2 years of age

Bodyweight more than 30 kg: 10 mg (one tablet) every other day.

If you take more Loratadine Tablets than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Overdose may cause sleepiness, fast heart rate and headache. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Loratadine Tablets

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. 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.

If the following happens, stop taking Loratadine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- a severe allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing).

This is a very serious but very rare side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

Children aged 2 to 12 years:

Common (may affect up to 1 in 10 people):

- headache
- nervousness
- tiredness (fatigue).

Adults and children over 12 years:

Common (may affect up to 1 in 10 people):

- drowsiness (somnolence)
- headache
- increased appetite
- difficulty sleeping (insomnia).

Very rare (may affect up to 1 in 10,000 people):

- dizziness
- convulsions
- fast or irregular heartbeat (tachycardia, palpitations)
- feeling sick (nausea), dry mouth,

inflammation of the stomach, which may lead to stomach pain, being sick, or loss of appetite (gastritis)

- abnormal liver function (shown by blood test results)
- rash
- hair loss (alopecia)
- tiredness (fatigue)
- severe allergic reaction (including swelling)

Not known (cannot be estimated from available data)

- weight increased

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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. This medicinal product does not require any special storage conditions. Do not transfer the tablets to another container. Do not use this medicine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. 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 ingredient is loratadine 10 mg.
- The other ingredients are lactose, maize starch, pregelatinised starch and magnesium stearate.

What Loratadine tablets look like and contents of the pack:

- White, oval tablets, scored on one side and plain on the other, debossed "L" and "10" on each side of the scoreline.
- The product is available in packs of 5, 7, 10, 14, 15, 20, 28 and 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer: Teva Pharmaceutical Works Private Ltd Company, 13 Pallagi H-4042, Debrecen, Hungary

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