

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or 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 taking this medicine.

What is in this leaflet

1. What Loratadine Tablets are and what they are used for
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1. WHAT LORATADINE TABLETS ARE AND WHAT THEY ARE USED FOR

The full name of your medicine is Loratadine 10 mg Tablets. The active ingredient is loratadine. Loratadine belongs to a group of medicines called non-sedating anti-histamines. It helps relieve the symptoms of some allergies.

Loratadine Tablets can relieve symptoms such as sneezing, runny or itchy nose; irritation inside the nose and eyes; itchy or burning eyes whether these are caused by hay fever or whether they occur all year around. It is also used to help relieve the symptoms associated with skin conditions such as rash, itching and hives.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LORATADINE TABLETS

Do not take Loratadine Tablets if:

- you have ever had an allergic reaction to loratadine or any of the other ingredients of this medicines (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Loratadine Tablets if:

- you suffer from severe liver problems
- you are due to have any skin tests, as loratadine may interfere with the results. Stop taking this medicine at least 48 hours before skin testing.

Children

Do not give Loratadine Tablets to children younger than 2 years old or to children 2 to 12 years old who weigh less than 30 kg. Liquid formulations are more suitable for children 2 to 12 years old who weigh 30 kg or less.

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.

Loratadine Tablets and alcohol

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

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 this 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. Loratadine is excreted in breast milk.

Driving and using machines

Loratadine should not cause drowsiness. This medicine should not affect your ability to drive or operate machinery, provided that it is used only as recommended. However, very rarely this medicine may cause drowsiness in some people. If this happens to you, you should not drive or operate machinery.

Loratadine Tablets contain lactose

Tell your doctor before taking this medicine if you have been told that you have an **intolerance to some sugars**. This is because Loratadine Tablets contain lactose, a type of sugar.

3. HOW TO TAKE LORATADINE TABLETS

Always take your medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The tablet should be swallowed with water with or without food.

The recommended doses of Loratadine 10 mg Tablets are as follows:

Adults and children over 12 years of age: One tablet once daily.

Children 2 to 12 years of age:

- Body weight over 30 kg: One tablet once daily
- Body weight 30 kg or less: Not recommended. A more suitable dosage form e.g. a liquid preparation should be given to children with body weight 30 kg or less.

Children aged less than 2 years: Not recommended

If you have severe liver problems your doctor or pharmacist may advise you to take the recommended amount every other day. If this applies to you follow their instructions.

If you take more Loratadine Tablets than you should

If you accidentally take too much of your medicine, tell your doctor at once or contact your nearest hospital casualty department immediately. Take your medicine with you. No serious problems are expected however, you may get a headache, have a rapid heartbeat or feel sleepy.

If you forget to take your medicine

If you forget to take a dose, just take the next dose at the usual time. 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, Loratadine Tablets can cause side effects, although not everybody gets them.

Stop taking Loratadine tablets and contact your doctor at once if you notice signs of:

- **an allergic reaction:** allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing

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

- drowsiness
- headache
- increased hunger
- difficulty in sleeping

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

- headache
- tiredness
- nervousness

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)
- convulsion
- liver problems
- dry mouth
- hair loss
- tiredness
- dizziness
- fast or irregular heartbeat
- nausea (feeling sick)
- upset stomach
- rash

Frequency not known: weight increased

If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist immediately.

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. 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 or label. The expiry date refers to the last day of that month. Store the tablets 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 10 mg Tablets contain:

Each tablet contains 10 mg of the active substance, loratadine. The other ingredients are lactose monohydrate, maize starch and magnesium stearate.

What Loratadine 10 mg Tablets look like and the contents of the pack

Loratadine 10 mg Tablets are white, round tablets marked with an "L" on one side and plain on the other side. They are packed in foil blister packs and are available in cartons of 30 tablets.

Marketing Authorisation Holder: Activase Pharmaceuticals Limited, 11 Boumpoulinas Street, Nicosia 2433, Cyprus

Manufacturer: DDSA Pharmaceuticals Limited, 310 Old Brompton Road, London SW5 9JQ, UK

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