

Accord logo

Package leaflet: Information for the patient

Loratadine 10mg tablets

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 tablets belong to a group of medicines called antihistamines.

Loratadine tablets are used to relieve:

- allergy symptoms such as runny and blocked nose, sneezing, watery eyes (e.g. in hayfever)
- a skin condition with pale or red irregular raised patches and severe itching (urticaria)

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)
- the patient is a **child under two years** of age.

Warnings and precautions

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

- you have **liver** problems
- the patient is a **child** with **kidney** disease
- you are about to have **skin tests**. Stop taking this medicine at least 48 hours before skin testing.

Other medicines and Loratadine tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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.

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. Loratadine tablets are not recommended in pregnancy or breast-feeding.

Driving and using machines

Loratadine tablets do not cause drowsiness in most people. However, you should not drive or carry out skilled tasks, such as using machinery, until you are certain that you are unaffected in this way.

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 medicinal product.

3 How to take Loratadine tablets

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

Swallow the tablets **whole with water** with or without food.

Doses:

- **Adults (including older people) and children over 12 years of age:** One tablet once daily
- **Children 2 to 12 years of age:**
 - Body weight over 30kg:** One tablet once daily
 - Body weight under 30kg:** Not recommended
- **Children aged less than 2 years:** Not recommended
- **Patients with serious liver problems:**
 - **Adults and children with a body weight over 30kg:** One tablet every other day.
 - **Children with a body weight of 30kg or less:** A more suitable dosage form e.g. oral solution, should be taken.

Length of treatment

Loratadine tablets should improve your symptoms, but as with all medicines people may find it does not work for them. If after three days of taking Loratadine tablets your symptoms have not improved, speak to your doctor or pharmacist.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Take the container and any remaining tablets with you to show the doctor. Signs of an overdose include sleepiness, fast heart beat and headache.

If you forget to take Loratadine tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

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.

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

• **an allergic reaction:** swelling of the face, lips, tongue or throat, narrowing of the airways causing difficulty breathing, shock, collapse, rash, itching.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

The most commonly reported side effects in adults and children over 12 years of age 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
- convulsion
- fast or irregular heartbeat
- nausea (feeling sick)
- dry mouth
- upset stomach
- liver problems
- hair loss
- tiredness

The frequency of the following side effect is not known:

- weight gain

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.

No special precautions for storage.

Do not take this medicine after the expiry date stated on the carton. 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 substance (the ingredient that makes the tablet work) is loratadine. Each tablet contains 10mg of loratadine.
- The other ingredients are lactose monohydrate, microcrystalline cellulose (E460), maize starch, magnesium stearate.

What Loratadine tablets look like and contents of the pack

Loratadine tablets are white, or almost white, round, flat, uncoated tablets debossed with 'KH' on one side and a central division line on the reverse.

Pack size is: 30

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

Accord Healthcare Limited

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