

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, pharmacist or nurse. 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, 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
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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.

What Loratadine Tablets are

Loratadine Tablets contain the active substance loratadine which belongs to a class of medicines called “antihistamines”.

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 relieves symptoms associated with allergic rhinitis (for example, hay fever), such as sneezing, runny or itchy nose, and burning or itchy eyes.

Loratadine Tablets may also be used to help relieve symptoms of urticaria (itching and redness) which is often known as hives or nettle rash.

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 Tablets if:

- You are allergic (hypersensitive) 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, pharmacist or nurse before taking Loratadine Tablets if:

- You have liver disease.
- You are scheduled 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 apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Loratadine Tablets.

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 old or who weigh 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, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained 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, 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

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 contains lactose

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Loratadine Tablets

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

Giving this medicine to children

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 30kg (4st 7lb). If in doubt weigh your child and then follow the instructions in the table.

Do not give to children under 2 years or who weigh 30 kg (4st 7lb) or less.

There are other formulations more suitable for children younger than 6 years or who weighs 30 kg or less.

How much to take:

Age and weight	How much to take	How often to take
Adults and children 6 years and older who weigh more than 30kg (4st 7lb)	1 x tablet	Once daily
Children who weigh 30 kg (4st 7lb) or less	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 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 your dose, take it as soon as you remember, then continue to take it as usual.
- Do not take a double dose to make up for a forgotten dose.

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

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 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:

- severe allergic reaction (including swelling)
- dizziness
- convulsion
- fast or irregular heartbeat
- nausea (feeling sick)
- dry mouth
- upset stomach
- liver problems
- hair loss

- rash
- 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:

HPRA Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Loratadine Tablets

- This medicinal product does not require any special storage conditions.
- 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 blister after EXP. The expiry date refers to the last day of the month.
- Do not use this medicine if you notice any change in the appearance of the tablet.
- 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 to 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 maize starch, lactose, sodium starch glycolate, magnesium stearate, sodium lauryl sulphate, colloidal anhydrous silica.

What Loratadine Tablets looks like and contents of the pack

Loratadine Tablets are white to off-white uncoated tablets, breakline on one side and 'L' embossed on other side.

Loratadine Tablets are available in pack size of 30 tablets.

Marketing Authorisation Holder

Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland

Manufacturer(s)

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