

Package leaflet: Information for the user

Lorastad 10 mg Tablets loratadine

[For medicines available only on prescription – to be deleted if applicable:]

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.

[For medicines available without a prescription – to be deleted if applicable:]

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 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 {number of} days.

What is in this leaflet

1. What Lorastad 10 mg tablets is and what it is used for
2. What you need to know before you take Lorastad 10 mg tablets
3. How to take Lorastad 10 mg tablets
4. Possible side effects
5. How to store Lorastad 10 mg tablets
6. Contents of the pack and other information

1. What Lorastad 10 mg tablets is and what it is used for

Loratadine, the active substance in Lorastad 10 mg, belongs to the group of antihistamines. Lorastad 10 mg tablets are used to treat the complaints of allergy-related rhinitis (e.g. hay fever, allergy to dust mites) such as sneezing, runny or itchy nose, itchy palate, and itchy, red or teary eyes. Lorastad 10 mg tablets are also used to relieve the symptoms such as itching and hives (associated with chronic urticaria and urticaria of unknown cause (idiopathic urticaria)).

[For medicines available without a prescription – to be deleted if applicable:]

You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days.

2. What you need to know before you take Lorastad 10 mg tablets

DO NOT take Lorastad 10 mg 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 or pharmacist before taking Lorastad

- if you suffer from serious liver dysfunction
- if you are planning on having a skin test performed. The use of Lorastad 10 mg tablets should be discontinued at least 48 hours before skin tests are performed, since antihistamines such as loratadine may otherwise preclude or weaken positive reactions to the skin test.

Children

The efficacy and safety of loratadine in children less than 2 years old have not been established.

Other medicines and Lorastad 10 mg tablets

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

Interaction of loratadine may occur with medicines known to inhibit certain enzymes in the liver resulting in elevated levels of loratadine. This may lead to an increase in adverse events (see section 4. "Possible side effects").

Lorastad 10 mg tablets with alcohol

The effect of alcohol is not enhanced by the use of Lorastad 10 mg tablets.

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.

Use of loratadine during pregnancy does not seem to have any harmful effects on the foetus. As a precautionary measure, it is preferable to avoid the use of Lorastad 10 mg tablets during pregnancy.

As loratadine is excreted in breast milk, it is recommended that breast-feeding women refrain from using Lorastad 10 mg tablets.

Driving and using machines

Some people, in very rare cases, may experience drowsiness, which can result in an impairment of the ability to drive or to operate machines.

It is therefore advisable, to wait and see if you may be affected after using Lorastad 10 mg tablets, before driving or operating machines.

Lorastad 10 mg 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 Lorastad 10 mg tablets

[For medicines available only on prescription – to be deleted if applicable:]

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

[For medicines available without a prescription – to be deleted if applicable:]

Always take this 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.

Mode of administration

For oral use.

The tablet is taken without chewing with a glass of water; it can be taken independent of meals.

Unless otherwise prescribed by your doctor, the recommended dose is

Adults and children aged over 12 years

1 tablet of Lorastad 10 mg once daily (equivalent to 10 mg of loratadine).

Use in children

Children from 2 to 12 years:

- *Body weights of more than 30 kg:*
1 tablet of Lorastad 10 mg once daily (equivalent to 10 mg of loratadine).
- *Body weights of 30 kg or less:*
The 10-mg tablet is not suitable for children with a body weight of less than 30 kg.
The efficacy and safety of Lorastad 10 mg tablets in children less than 2 years old have not been established.

Patients with severe liver disease

An initial dose of 1 tablet of Lorastad 10 mg (equivalent to 10 mg of loratadine) every other day is recommended for adults and children with body weights of more than 30 kg.

Adjusting the dose is not necessary in older people or patients with renal dysfunction.

Please consult your doctor or pharmacist, when you think that the effect of Lorastad 10 mg tablets is too strong or too weak.

If you take more Lorastad 10 mg tablets than you should

After overdose of loratadine, sleepiness, increase in heart rate (tachycardia) and headache have been described.

If you have taken too many tablets of Lorastad 10 mg, please inform your doctor or pharmacist at once.

If you forget to take Lorastad 10 mg tablets

If you forgot to take a tablet on time, take it as soon as possible. Then continue the treatment as recommended. Do not take a double dose to make up for a forgotten tablet.

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.

Side-effects

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

- nervousness
- headache, tiredness, sleepiness

Uncommon (may affect up to 1 in 100 people):

- sleeplessness, increase in appetite

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

- allergic reactions (including serious allergic reaction which causes swelling, especially of the face, mouth, tongue or throat (angioedema) and serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis))
- vertigo (dizziness)
- fit (convulsion)

- increase in heart rate (tachycardia), palpitation (feeling of strong heartbeat)
- nausea, dry mouth, gastritis (inflammation of the stomach)
- liver dysfunction
- rash, loss of hair (alopecia)

Not known (frequency cannot be estimated from the available data):

- 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 national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lorastad 10 mg 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 on the blister strips after "Exp. Date". The expiry date refers to the last day of that month. No special storage conditions are required for this medicine.

6. Contents of the pack and other information

What Lorastad 10 mg tablets contains

The active substance is loratadine.
1 tablet contains 10 mg loratadine.

The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, magnesium stearate.

What Lorastad 10 mg tablets looks like and contents of the pack

White, round, flat tablets with a score line.

Lorastad 10 mg tablets are available in packs containing 1, 5, 7, 10, 14, 15, 20, 21, 30, 50, 60, 90, 100 or 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Stada Arzneimittel AG
Stadastrasse 2-18
D-61118 Bad Vilbel
Duitsland

Manufacturers

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61118 Bad Vilbel
Germany

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Clonmel Healthcare Ltd.
Waterford Road, Clonmel
Co. Tipperary
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This medicinal product is authorised in the Member States of the EEA under the following names:

België:	Loratadine EG 10 mg tabletten
Italië:	Loratadina EG 10 mg compresse
Luxemburg:	Loratadine EG 10 mg comprimés
Nederland:	Lorastad 10 mg

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2022.