

Package leaflet: Information for the user

Loradis 10 mg Tablets loratadine

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.
- 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.

What is in this leaflet

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

1. What Loradis is and what it is used for

Loradis belongs to the group of antihistamines and is used to treat complaints in certain allergic conditions associated with an elevated release of histamine. Loradis is used to treat the complaints of allergy-related rhinitis (e.g. hay fever) and for urticaria of unknown origin (chronic, idiopathic urticaria; nettle rash of unknown origin).

2. What you need to know before you take Loradis

DO NOT take Loradis

- 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 Loradis

- if you suffer from serious liver dysfunction
- if you are planning on having a skin test performed. The use of Loradis should be discontinued at least 48 hours before skin tests are performed, since antihistamines such as Loradis 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 has not been established.

Other medicines and Loradis

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").

Loradis with alcohol

The effect of alcohol is not enhanced by the use of Loradis.

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.

Animal experiments have not produced any indication of foetal damage. Data suggest that the use of loratadine during pregnancy does not lead to problems with the foetus. As a precautionary measure, it is preferable to avoid the use of Loradis during pregnancy.

As loratadine is excreted in breast milk, it is recommended that breast-feeding women refrain from using Loradis.

Driving and using machines

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

It is therefore advisable, after using Loradis, to wait for your individual reaction to appear, before driving or operating machines.

Loradis 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 Loradis

Always take this medicine exactly as your doctor 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 Loradis once daily (equivalent to 10 mg of loratadine).

Use in children and adolescents

Children from 2 to 12 years

Body weights of more than 30 kg:

1 tablet of Loradis 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 Loradis in children less than 2 years old has not been established.

Patients with severe liver disease

An initial dose of 1 tablet of Loradis (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 Loradis is too strong or too weak.

If you take more Loradis 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 Loradis, please inform your doctor or pharmacist at once.

If you forget to take Loradis

Do not take a double dose to make up for a forgotten tablet.

If you forgot to take a tablet on time, take it as soon as possible. Then continue the treatment as recommended.

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
- fit (convulsion)
- increase in heart rate (tachycardia), palpitation
- nausea, dry mouth, gastritis
- liver dysfunction
- rash, loss of hair (alopecia)

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 Loradis

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 Loradis 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 Loradis 10 mg tablets looks like and contents of the pack

White, round, flat tablets with a score line.

Loradis 10 mg tablets are available in packs containing 7, 20, 50 and 100 tablets.

Marketing Authorisation Holder and Manufacturer

[to be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark: Loradis

Germany: Loratadin STADA allerg 10 mg Tabletten

This leaflet was last revised in 12/2014.