

Package leaflet: Information for the user

Loratadine Accord 10 mg tablets loratadine

For medicines available only on prescription:

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:

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 or if your symptoms change. See section 4.

What is in this leaflet:

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

1. What Loratadine Accord is and what it is used for

The full name of your medicine is Loratadine Accord tablets.

What Loratadine Accord is

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

How Loratadine Accord works

Loratadine Accord helps 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 Accord should be taken

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

Loratadine Accord may also be used to help relieve symptoms of urticaria (itching, redness and number and size of hives).

The effect of Loratadine Accord 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 Accord

Do not take Loratadine Accord if

- You are allergic (hypersensitive) to loratadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Loratadine Accord if:

- You have liver disease.
- You are scheduled to have any skin tests for allergies. Do not take Loratadine Accord 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 Accord.

Children

Do not give Loratadine Accord tablet 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 or with a body weight of 30 kg or less.

Children under 2 years of age:

The safety and efficacy of Loratadine Accord have not been established. No data are available.

Other medicines and Loratadine Accord

The side effects of Loratadine Accord 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 Accord with alcohol

Loratadine Accord has 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 Accord during pregnancy.

Do not take Loratadine Accord 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 Accord is 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 Accord contains lactose

Loratadine Accord contains lactose; thus if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Loratadine Accord

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.

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. If in doubt weigh your child and then follow the instructions in the table.

Do not give to children who weigh 30 kg or less. There are other formulations more suitable for children younger than 6 years or with a body weight of 30 kg or less. Not recommended for children under 2 years old.

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 30 kg	1 x tablet	Once daily
Children who weigh 30 kg 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 you take more Loratadine Accord than you should

If you take more Loratadine Accord 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 Accord

- 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 medicine, ask your doctor or pharmacist.

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 HPRC 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 Accord

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that 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 Accord contains

- The active substance is loratadine. Each tablet contains 10 mg loratadine.
- The other ingredients are lactose monohydrate, cellulose, microcrystalline (E460), maize starch, magnesium stearate (E470b).

What Loratadine Accord looks like and contents of the pack

Loratadine Accord are white or almost white, 8 mm round, flat, uncoated tablets debossed with “KH” on one side and a score line on the reverse.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Loratadine Accord is available in clear polyvinylchloride (PVC)-aluminium blister packs with 7, 10, 14, 20, 28, 30, 50, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Accord Healthcare Ireland Limited,
Euro House, Euro Business Park,
Cork, T45 K857,
Ireland

Manufacturer:

Accord Healthcare Polska Sp.z.o.o.
Ul. Lutomińska 50,
95-200, Pabianice, Poland

Or

Accord Healthcare B.V.
Winthontlaan 200,
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Or

Laboratori Fundació DAU
C/ C, 12-14 Pol. Ind. Zona Franca,
Barcelona, 08040 Barcelona, Spain

Or

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000, Malta

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

Name of the member state	Name of the medicinal product
Bulgaria	Loratadine Акорд 10 мг таблетки
Estonia	Loratadine Accord
Finland	Loratadine Accord 10 mg tabletti
Germany	Loratadin Accord 10 mg Tabletten
Ireland	Loratadine Accord 10 mg Tablets
Latvia	Loratadine Accord 10 mg tabletes
Lithuania	Loratadine Accord 10 mg tabletės
The Netherlands	Loratadine Accord 10 mg tabletten
Norway	Loratadine Accord
Sweden	Loratadine Accord 10 mg tabletter

This leaflet was last approved in 07/2022