

Package leaflet: Information for the patient
Loratadin Holsten 10mg 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 after *[To be completed nationally]* days.

What is in this leaflet

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

1. What <Product name> is and what it is used for

<Product name> belong to a group of medicines called antihistamines.

<Product name> is used to treat:

- symptoms of allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example hay fever) such as runny and blocked nose, sneezing, watery eyes.
- a skin condition with pale or red irregular raised patches and severe itching (urticaria)

2. What you need to know before you take <Product name>

Do not take <Product name> and **tell** your doctor if:

- you are **allergic** (hypersensitive) to loratadine or any of the other ingredients (see section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking <Product name> 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.

Children and adolescents

<Product name> is not recommended for **children under two years** of age, as efficacy and safety have not been established. Do not give <Product name> to children who weigh less than 30 kg. There are other more suitable forms to be used.

Other medicines and <Product name>

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.

<Product name> with alcohol

Loratadine has not been shown to add to the effects of an alcoholic drink.

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. <Product name> is not recommended in pregnancy or breastfeeding.

Driving and using machines

After the recommended dose, <Product name> 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.

<Product name> 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.

3 How to take <Product name>

[For medicines available only on prescription:]

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:]

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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

The recommended dose is:

- **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 30 kg:** One tablet once daily
- **Patients with serious liver problems:**
 - **Adults and children with a body weight over 30 kg:** One tablet every other day.

[For medicines available on prescription:]

Duration of treatment

Take <Product name> for as long as your symptoms persist or your doctor instructs.

[For medicines available without a prescription:]

Duration of treatment

If after *[To be completed nationally]* days of taking <Product name> 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 heartbeat and headache.

If you forget to take <Product name>

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 <Product name> 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
- rash
- 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 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 <Product name>

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use 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 to protect the environment.

6 Contents of the pack and other information

What <Product name> 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 <Product name> look like and contents of the pack

<Product name> are white, or almost white, 8mm, round, flat tablets with a central division line on one side.

Pack size:

7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 100

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

Date of revision

2024-03-28