



Lorastine Tablets, 10 mg

Each tablet contains:

Loratadine 10 mg

See section 6 for a list of inactive ingredients. See also section 2 under 'Important information about some of this medicine's ingredients'.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information.

Consult your doctor if your symptoms of illness get worse or do not get better.

1. What is this medicine intended for?

Lorastine Tablets are used to treat allergic rhinitis and the symptoms associated with it, such as sneezing, runny or itchy nose, and burning or itchy eyes. They are also used to treat allergy of the skin - hives (urticaria).

How this medicine works

Lorastine Tablets relieve your allergy symptoms by preventing the effects of a substance called histamine, which is produced by the body when you are allergic to something.

Therapeutic group: This medicine contains the active ingredient loratadine which belongs to a class of medicines called "antihistamines".

2. Before using this medicine

x Do not use this medicine if:

- You are allergic (sensitive) to loratadine or to any of the other ingredients of this medicine (see section 6 for a list of inactive ingredients).
--

Special warnings about using this medicine

! Talk to your doctor, pharmacist, or nurse before taking Lorastine Tablets if:

- You have liver disease.
- You are about to have any skin tests for allergies. Do not take Lorastine Tablets for two days before having these tests. This is because the medicine may affect the test results.

If any of the conditions described above apply to you (or if you are not sure), consult your doctor, pharmacist, or nurse before taking Lorastine Tablets.

! Children and adolescents

Do not give Lorastine Tablets to children and infants younger than 6 years old or to children who weigh less than 30 kg. There are other formulations more suitable for children who are under 6 years old or who weigh less than 30 kg.

Children under 2 years old:

There are no safety and efficacy data for Lorastine Tablets in this age group.

! Other medicines and Lorastine Tablets:

! You are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor, pharmacist, or nurse.

The risk of side effects is greater when taking Lorastine Tablets together with medicines that affect the activity of liver enzymes responsible for metabolism of medicines in the liver. However, in clinical studies, no increase in side effects was seen despite taking medicines that affect the activity of these enzymes.

! Using this medicine and food

You can take Lorastine Tablets with or without food.

! Using this medicine and alcohol consumption

Lorastine Tablets have not been shown to increase the effects of an alcoholic beverage.

! Pregnancy, breastfeeding, and fertility

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. Based on existing data, no harm to unborn babies or newborns was observed following use of the medicine, but it is better to avoid taking it during pregnancy.

Loratadine, the active ingredient in this medicine, passes into breast milk so avoid taking this medicine when breastfeeding.

! Driving and using machines

In clinical trials that assessed driving ability, no impairment was observed in patients taking loratadine. At the recommended dose, Lorastine 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.

! Important information about some of this medicine's ingredients

This medicine contains lactose, so if you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine (see also section 6 'Additional information').

3. How to use Lorastine Tablets?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Adults and children over 6 years old who weigh over 30 kg:

One tablet once a day with a glass of water, with or without food.

It is important to know your child's body weight in order to make sure that the dosage is appropriate for him. If you are not sure about your child's weight, weigh the child before using the medicine.

Body weight of 30 kg or less:

Do not give Lorastine Tablets. There is another formulation that is more suitable for children under 6 years old or for those who weigh 30 kg or less.

Lorastine Tablets are not intended for children under 2 years old or for those with body weight of 30 kg or less.

Adults and children with serious liver problems:

If you have severe liver problems, consult your doctor or pharmacist who may advise you to take the recommended dose every other day, with a glass of water, with or without food. If this applies to you, follow their instructions.

Do not exceed the recommended dose.

Method of administration:

The score line on the tablets is only there to help you break the tablet so it is easier to swallow. You must take all the tablet pieces at the same time.

If you have accidentally taken a higher dose, consult your doctor or pharmacist immediately. No serious problems are expected; however, you may get a headache, have a rapid heartbeat or feel sleepy.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember and then continue taking the medicine as usual. Never take a double dose to make up for a forgotten dose.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Lorastine Tablets may cause side effects in some users.

Do not be alarmed by this list of side effects; you may not experience any of them.

The most commonly reported side effects in adults and children over 12 years old are:

- drowsiness
- headaches
- increased appetite
- difficulty sleeping

The most commonly reported side effects in children aged 2 to 12 years old are:

- headaches
- nervousness
- tiredness

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
- dry mouth
- upset stomach
- liver problems
- hair loss
- rash
- tiredness

The frequency of the following side effect is not known:

- weight gain

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store Lorastine Tablets?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not take this medicine of you notice any change in the appearance of the tablet.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient, the medicine also contains: Lactose monohydrate, maize starch, magnesium stearate.

Each tablet contains 71.3 mg lactose (see also section 2, 'Important information about some of this medicine's ingredients').

What the medicine looks like and contents of the pack:

White to off-white, oval tablet embossed with a flask and bowl, a score line, and '10' on one side and plain on the other side.

Authorized pack sizes: 7, 10, or 20 tablets in a pack. Not all pack sizes may be marketed.

Registration holder's name and address: Bayer Israel Ltd., 36 Hacharash Street, Hod Hasharon 45240.

Manufacturer's name and address: Schering-Plough, Labo N.V., Belgium, IndustriePark 30, B-2220, Heist-Op-den-Berg.

Revised in June 2020.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 133-25-25872-00