

The medicine is dispensed without a doctor's prescription

Lorastine® Syrup 5 mg/5 ml



Each calibrated teaspoon (5 ml) contains:
Loratadine 5 mg

For a list of the inactive ingredients, see section 6. Also see section 2, subsection "Important information about some of the ingredients of the medicine".

Read this leaflet carefully in its entirety before using the medicine.

- This leaflet contains concise information about **Lorastine Syrup**. If you have further questions, refer to your doctor or pharmacist.
- Refer to the doctor if symptoms of the illness worsen or do not improve, or if you feel worse.
- This medicine is not intended for children under two years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of allergic rhinitis and urticaria.

Therapeutic group: Lorastine Syrup contains the active ingredient loratadine, which belongs to the group of medicines called "antihistamines".

2. BEFORE USING LORASTINE SYRUP

Do not use the medicine if:

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

Special warnings regarding use of Lorastine Syrup

Before treatment with Lorastine Syrup, tell your doctor if:

- You are sensitive to any food or medicine.
- You are suffering from a liver disease.
- You are scheduled to have a skin test for allergies. Do not take **Lorastine Syrup** two days before these tests. This is because the medicine may affect the results of the test.
- Do not use this medicine frequently or for a prolonged period without consulting the doctor.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the attending doctor or pharmacist.

Use of the medicine and food

Water or any other fluid is not needed to swallow the syrup.

Lorastine Syrup can be taken with or without food.

Use of the medicine and alcohol consumption

Lorastine Syrup has not been shown to increase the effects of alcoholic beverages.

Pregnancy and breastfeeding

There is not enough information regarding the safety of use of the medicine during pregnancy; therefore, use of **Lorastine Syrup** during pregnancy is not recommended. Nonetheless, the doctor will instruct you to use **Lorastine Syrup** during pregnancy when he decides that the benefit outweighs the potential risks to the unborn baby.

The active ingredient in the medicine, loratadine, is secreted into breast milk and harm to newborns or babies cannot be ruled out. Therefore, avoid using the medicine when breastfeeding.

Driving and operating machinery

At the recommended dosage, **Lorastine Syrup** is not expected to cause drowsiness or decreased alertness. Nevertheless, very rarely, some people feel drowsy, which may affect their ability to drive or operate machinery.

Important information about some of the ingredients of Lorastine Syrup

Lorastine Syrup contains sucrose; therefore, if you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine (also see section 6, "Further information").

Lorastine Syrup contains sodium benzoate as a preservative.

Children

Do not give Lorastine Syrup to children and infants under two years of age.

3. HOW SHOULD YOU USE LORASTINE SYRUP?

Check with the doctor or pharmacist if you are uncertain.

The usual dose is generally:

Adults and children over 12 years of age: 2 teaspoons (10 ml), once a day, with or without food.

The dosage for children aged 2-12 is by weight:

Body weight over 30 kg: 2 teaspoons (10 ml), once a day, with or without food.

Body weight of 30 kg or less: one teaspoon (5 ml), once a day, with or without food.

Lorastine Syrup is not intended for children under two years of age.

Adults and children with severe liver problems:

Adults and children weighing over 30 kg: 2 teaspoons (10 ml), once every other day, with or without food.

Children weighing 30 kg or less: one teaspoon (5 ml), once every other day, with or without food.

Nonetheless, you should refer to your doctor or pharmacist before taking this medicine.

Attention:

Be sure to measure the dose with a measuring teaspoon or with a special measuring cup, dropper, etc.

Do not exceed the recommended dose.

If you accidentally took a higher dosage, refer to your doctor or pharmacist immediately.

No severe problems are expected, but you may suffer from a headache, rapid heartbeat, or feeling of sleepiness. If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take Lorastine Syrup

If you forgot to take this medicine at the required time, take a dose as soon as you remember and consult a doctor. Never take a double dose.

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

If you have further questions regarding use of this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Lorastine Syrup** may cause side effects in some users.

Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

The most common side effects reported by adults and children over 12 years of age are:

- drowsiness
- headache
- increased appetite
- difficulty sleeping

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

- headache
- 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
- dizziness
- fast or irregular heartbeat
- nausea
- dry mouth
- digestive system disturbances
- liver problems
- hair loss
- rash
- tiredness
- seizure

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with your doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health via the online form at the following link:

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.health.gov.il>

5. HOW SHOULD LORASTINE SYRUP BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use **Lorastine Syrup** after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not take this medicine if you notice any change in the appearance of the syrup.
- **Storage conditions:** Store below 25°C. Do not freeze. Keep the bottle in the outer carton to protect from light. After first opening, the syrup is stable for one month.
- Do not throw medicines into the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
Propylene glycol, glycerin, citric acid monohydrate, sodium benzoate, sucrose, artificial peach flavour, purified water.

Lorastine Syrup contains sucrose (also see section 2 "Important information about some of the ingredients of Lorastine Syrup").

Each calibrated teaspoon (5 ml) contains 3 grams sucrose.

What the medicine looks like and the contents of the package:

Clear, colorless to light yellow **syrup**.

The package also contains a calibrated measuring teaspoon.

Authorized package sizes: 60 ml, 120 ml.

Not all package sizes may be marketed.

Registration holder and address:

Bayer Israel Ltd., Hacharash Street 36, Hod Hasharon 45240.

Manufacturer and address:

Schering-Plough, Labo N.V., Belgium, Industriepark 30, B-2220, Heist-Op-den-Berg.

This leaflet was checked and approved by the Ministry of Health in July 2015

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 133.21.28216.00