

PACKAGE LEAFLET: Information for the patient

LORADE

Tablets – 10 mg

(Loratadine)

Read all of this leaflet carefully before you start taking this medicine.

- This medicine is available without prescription. However, you still need to take Lorade carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Lorade is and what it is used for
2. Before you take Lorade
3. How to take Lorade
4. Possible side effects
5. How to store Lorade
6. Further information

1. WHAT LORADE IS AND WHAT IT IS USED FOR

Lorade contains the active substance loratadine, which is part of a group of medicines called antihistamines.

Lorade is used to treat symptoms of :

- allergic rhinitis (e.g. hay fever) such as: sneezing, runny or itchy nose, and burning or itchy eyes;
- chronic idiopathic urticaria (hives of unknown origin).

2. BEFORE YOU TAKE LORADE

Do not take Lorade if:

- you are allergic (hypersensitive) to loratadine or to any of the other ingredients of Lorade;
- you are pregnant;
- you are breastfeeding.

Take special care with Lorade:

- if you have severely impaired liver function;
- if you plan to have a skin test done. You should stop taking Lorade at least 48 hours before having a skin test. Otherwise, antihistamines like Lorade may produce false-negative or weakly positive results in skin tests.

Children:

Do not give Lorade 10 mg to children younger than 2 years of age or to children 2 to 12 years of age who weigh less than 30 kg. There are other formulations more suitable for children younger than 2 years or 2 to 12 years old who weigh less than 30 kg.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The side effects of Lorade 10 mg 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.

Taking Lorade with food and drink

Lorade does not increase the effects of alcohol.

Pregnancy and breastfeeding

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 studies did not indicate that loratadine harms the foetus. The safety of using loratadine during pregnancy has not been established. Therefore, you are advised not to take Lorade during pregnancy.

Loratadine is excreted in breast milk. Therefore, you are advised not to take Lorade if you are breastfeeding.

Driving and using machines

In clinical trials that assessed driving ability, no impairment was observed in patients receiving loratadine. At the recommended dose, this medicine is not expected to cause you to be drowsy or less alert. However, in very rare cases, loratadine may cause drowsiness. This may impair the ability to drive a vehicle or operate machinery.

You are therefore advised to check your individual reaction to Lorade treatment before attempting to drive a vehicle or to use any tools or machines.

Important information about some of the excipients of Lorade

For patients with particular sugar intolerance: Lorade contains lactose.

Please ask your doctor before taking this medicine.

3. HOW TO TAKE LORADE

Always take Lorade precisely as instructed in this package leaflet.

You should check with your doctor or pharmacist if you are not sure.

Please talk to your doctor or pharmacist if the effects of Lorade seem to be too strong or too weak.

Unless otherwise prescribed by a doctor, the usual dose is:

Adults and children over 12 years

1 Lorade tablet, once a day (corresponds to 10 mg loratadine).

Children 2 to 12 years

For children weighing more than 30 kg

1 Lorade tablet, once a day (corresponds to 10 mg loratadine).

For children weighing 30 kg or less

The 10 mg tablet is not suitable for children weighing less than 30 kg.

The efficacy and safety of loratadine in children below the age of 2 years has not been established.

Patients with severe liver damage

A starting dose of 1 Lorade tablet (corresponding to 10 mg loratadine), every second day is recommended in adults and children weighing more than 30 kg.

It is not necessary to adjust the dose in elderly patients or patients with impaired kidney function.

Route of administration

Oral use. The tablets may be taken before or after meals.

If you take more Lorade than you should

Drowsiness, increased heart beat (tachycardia) and headache have been described in association with loratadine overdose.

If you took too many Lorade tablets, please tell your doctor or pharmacist immediately.

If overdose occurs, symptom-oriented supportive treatment should be initiated immediately and continued for as long as required. Activated charcoal dissolved in water may be administered.

Gastric lavage may be considered. Loratadine is not removed by cleaning the blood (haemodialysis) and it is not known whether loratadine is eliminated by peritoneal dialysis. After management of the emergency situation, the patient must remain under medical supervision.

If you forget to take Lorade

Do not take a double dose to make up for a forgotten dose. If you notice on time that you forgot to take a tablet, take the skipped dose as soon as possible. Then continue your treatment as recommended.

If you stop taking Lorade

Your condition may worsen.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lorade can cause side effects, although not everybody gets them.

The following frequencies are usually applied when evaluating side effects:

Very common	more than 1 treated person out of 10
Common	1 to 10 treated persons out of 100
Uncommon	1 to 10 treated persons out of 1,000
Rare	1 to 10 treated persons out of 10,000
Very rare	less than 1 treated person out of 10,000
Not known	frequency cannot be evaluated based on the available data.

Major side effects or signs you should watch for and measures if you are affected:

If you are affected by any of the side effects stated below, stop taking Lorade and consult your doctor as soon as possible.

Immune system:

Very rare: severe allergic reaction (including swelling)

Nervous system:

Common: drowsiness, nervousness

Uncommon: difficulty sleeping

Very rare: vertigo, convulsions, dizziness

Cardiovascular:

Very rare: accelerated heart beat (tachycardia), palpitations or galloping heartbeat

Gastrointestinal tract:

Very rare: nausea, dry mouth, irritation of the mucous membranes of the stomach (gastritis)

Hepatobiliary:

Very rare: liver dysfunction

Skin and connective tissue

Very rare: skin rash, hair loss (alopecia)

General disorders:

Common: headache

Uncommon: increased appetite

Very rare : fatigue

Not known: weight gain

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LORADE

Keep out of the reach and sight of children.

Do not use Lorade after the expiry date which is stated on the packaging.

Store below 25°C!

6. FURTHER INFORMATION

What Lorade contains

The active substance is loratadine.

1 tablet contains 10 mg of loratadine.

The excipients are: lactose monohydrate, maize starch and magnesium stearate.

Contents of the pack

Lorade is supplied in packs of 10, 20 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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