

Lorine®

PACKAGE LEAFLET: INFORMATION FOR THE USER

LORINE 10 mg TABLETS
LORINE 1mg/ml Syrup
Loratadine

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, pharmacist, or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better, if you feel worse or if your symptoms change.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. WHAT LORINE IS AND WHAT IT IS USED FOR
2. BEFORE YOU TAKE LORINE
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1. WHAT LORINE IS AND WHAT IT IS USED FOR

Lorine belong to a class of medicines known as antihistamines. Antihistamines help to reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced in the body.

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

Lorine may also be used to help relieve symptoms of urticaria (itching and redness) which is often known as hives or nettle rash.

2. BEFORE YOU TAKE LORINE

Do not take Lorine:

- If you are allergic (hypersensitive) to loratadine or any of its other ingredients (listed in section 6)
- If you are pregnant or breastfeeding

Take special care with Lorine

Before taking Lorine, tell your doctor or pharmacist:

- If you have liver disease.
- If you are scheduled to have any skin tests for allergies you should not take this medicine for two days before having these tests, because this medicine may affect test results.

Children:

Do not give Lorine tablet to children younger than 6 years old or to children who weigh 30 kg or less. There are other formulations (syrup) more suitable for children younger than 6 years or with body weight of 30 kg or less.

Children under 2 years of age:

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

Taking other medicines

If you are taking any other medicines, including medicines taken without a prescription, please consult your pharmacist or doctor before use.

Pregnancy and Breast-feeding

If you are pregnant, taking Lorine is not recommended.

If you are nursing, taking Lorine is not recommended. Loratadine is excreted in breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Taking Lorine with food and drink

Lorine can be taken with or without a meal.

Driving and using machinery

At the recommended dose, Lorine 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 machinery.

Important information about the ingredients of Lorine

Lorine tablets contain lactose and Lorine syrup contains Sucrose. If you have an intolerance to some sugars, please speak to your pharmacist or doctor before taking this medicine.

3. HOW TO TAKE LORINE

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Do not give to children under 2 years.

For Lorine tablet:

Age	How much to take	How often to take
Adults and children 6 years of age and older with a body weight greater than 30 kg.	One tablet	Once daily
Body weight 30 kg or less: do not give Lorine tablet. There are other formulations (syrup) more suitable for children younger than 6 years or who weigh 30 kg or less.		
If you have severe liver problems your doctor or pharmacist may advise you to take the recommended amount every other day. If this applies to you follow their instructions.		

For Lorine syrup:

Age	How much to take	How often to take
Adults and children over 12 years.	2 x 5 ml spoonfuls	Once daily
Children of 2 to 12 years who weigh more than 30 kg.	2 x 5 ml spoonfuls	Once daily
Children of 2 to 12 years who weigh 30kg or less.	1 x 5 ml spoonful	Once daily
Patients with serious liver problems: Adults and children with a body weight above 30 kg: take 2 x 5 ml spoonfuls of syrup once every two days. Adults and children with a body weight 30 kg or less: take 1 x 5 ml spoonful of syrup once every two days.		

Length of treatment

Lorine should improve your symptoms, but as with all medicines people may find it does not work for them. If after three days of taking Lorine your symptoms have not improved, speak to your doctor or pharmacist.

If you take more than you should

If you (or someone else) take Lorine more than you should, 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 heart beat and headache.

If you forget to take your medicine

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.

4. POSSIBLE SIDE EFFECTS

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

Stop taking Lorine 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:

- Nervous system: tiredness, sleepiness, inability to sleep, headache, nervousness, dizziness.
 - Heart: fast or irregular heart beat.
 - Stomach and intestines: increased appetite, feeling or being sick, diarrhoea, indigestion, dry mouth.
 - Liver: abnormal liver function (seen in blood tests).
 - Skin: hair loss (alopecia).
- If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

5. HOW TO STORE LORINE

Keep out of the reach and sight of children.

Do not store above 30° C.

Do not use Lorine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

For Lorine syrup: This medicine will be expired after 30 days from the first opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lorine contains:

- Lorine tablet contains 10mg Micronized Loratadine as an active ingredient.
- Lorine Syrup, each 5ml contains 5mg Micronized Loratadine as an active ingredient.

Other ingredients:

- Lorine tablets: maize starch, lactose, magnesium stearate.
- Lorine syrup: citric acid monohydrate, peach flavour, glycerol, propylene glycol, sodium benzoate, sucrose granular and purified water.

What Lorine looks like and content of the pack:

- Lorine tablets: A white to off-white, oval, biconvex tablet with crescent logo on one side and on the other side with score, letters "SP" and number "136".

Pack Sizes:

- Lorine tablet:
10 tablets in 1 blister strip per unit carton.
20 tablets in 2 blister strips per unit carton.
30 tablets in 3 blister strips per unit carton.
- Lorine syrup: Clear, colourless to light-yellow syrup; free from foreign matter.
For Lorine Syrup: 100 ml amber glass bottle with child resistant cap.

Marketing Authorization Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant
Saudi Arabia

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Lorine is a trade mark
34LR875

To report any side effects):

For Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2340.
- Reporting hotline: 19999.
- E-mail: npc.drug@sfd.a.gov.sa
- Website: <https://ade.sfd.a.gov.sa>

For UAE

- Pharmacovigilance & Medical Device section
- P.O.Box: 1853
- Tel: 80011111
- Email: pv@moh.gov.ae
- Drug Department, Ministry of Health & Prevention Dubai

For Oman

- Department of Pharmacovigilance & Drug Information
- Directorate General of Pharmaceutical Affairs & Drug Control
- Ministry of Health, Sultanate of Oman
- Phone Nos. 22357687 / 22357686
- Fax: 22358489
- Email: dg-padc@moh.gov.om
- Website: www.moh.gov.om

This is a medication

- A medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medication.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medications out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists