



**Package leaflet: Information for the user
LORINASE**

Loratadine Micronized USP and Pseudoephedrine Sulfate

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.

What is in this leaflet

1. WHAT LORINASE IS AND WHAT IT IS USED FOR.
2. BEFORE YOU TAKE LORINASE.
3. HOW TO TAKE LORINASE.
4. POSSIBLE SIDE EFFECTS.
5. HOW TO STORE LORINASE.
6. FURTHER INFORMATION.

1. WHAT LORINASE IS AND WHAT IT IS USED FOR.

LORINASE is a medicinal product contains two active substances: Loratadine and Pseudoephedrine. Loratadine is a potent long-acting tricyclic antihistamine with selective peripheral H1-receptor antagonistic activity. Pseudoephedrine sulfate, one of the naturally occurring alkaloids of Ephedra and an orally administered vasoconstrictor, produces a gradual but sustained decongestant effect facilitating shrinkage of congested mucosa in upper respiratory areas. The mucous membrane of the respiratory tract is decongested through the action of the sympathetic nerves.

LORINASE relieves symptoms associated with allergic rhinitis (hay fever), such as:

- Nasal and sinus congestion.
- Sneezing.
- Runny nose.
- Watery, itchy eyes.

LORINASE contains a combination of two medicines: loratadine (an antihistamine) and pseudoephedrine (a decongestant).

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances which the body is allergic to. Decongestants produce narrowing of blood vessels. This leads to clearing of the stuffy or blocked nose.

Your doctor or pharmacist, however, may prescribe LORINASE for another purpose. Ask your doctor or pharmacist if you have any questions about why LORINASE has been prescribed for you.

2. BEFORE YOU TAKE LORINASE

Do not take LORINASE if:

- You have an allergy to LORINASE or any of the ingredients listed at the end of this leaflet.

Do not take LORINASE if you have, or have had, any of the following medical conditions:

- Glaucoma
- Difficulty passing urine
- Severe high blood pressure
- Severe blood vessel disease
- An overactive thyroid gland

Do not take LORINASE if you are taking or within 14 days of discontinuing monoamine oxidase inhibitors (MAOIs), medicines used to treat depression.

For LORINASE tablet:

Do not give LORINASE tablet to children under 12 years of age.

For LORINASE syrup:

Do not give LORINASE syrup to children under 6 years of age.

Do not take LORINASE after the expiry date printed on the pack.

Do not take LORINASE if the packaging is torn or shows signs of tampering.

Before you start to take it, tell your doctor or pharmacist if you have allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- Eye problems (such as high pressure in the eye or glaucoma)
- Stomach ulcer
- Intestinal obstruction
- Prostate or urinary bladder problems
- Heart disease
- Diabetes
- If you are 60 years of age or older, because older adults may be more sensitive to the effects of the medicine.

If you have not told your doctor or pharmacist about any of the above, tell them before you take LORINASE.

The pseudoephedrine in LORINASE is considered a stimulant by sporting bodies. Its use in competing athletes is not recommended.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines should not be taken with LORINASE. These include:

- Heart or blood pressure medicines
- Monoamine oxidase inhibitors, medicines used to treat Depression
- Antacids
- Kaolin

These medicines may be affected by LORINASE, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Taking LORINASE with food

It does not matter if you take LORINASE before or after food.

Pregnancy and breast-feeding

Do not take LORINASE if you are pregnant or breast feeding unless you have discussed the risks and benefits involved with your doctor or pharmacist.

Driving and using machines

Make sure you know how you react to LORINASE before you drive a car or operate machinery.

LORINASE is unlikely to make you drowsy. If you are drowsy, do not drive a car or work with machinery.

3. HOW TO TAKE LORINASE

How much to take

For LORINASE tablet:

The recommended dose of LORINASE in adults and children over 12 years is one tablet every 12 hours.

Do not use in children under 12 years of age.

Swallow the tablet whole with a glass of water. Do not crush, break or chew the tablet before swallowing.

For LORINASE syrup:

Adults and children 6-12 years of age (body weight > 30 Kg): 5 ml syrup (one teaspoonful) twice a day (every 12 hours).

Do not give to children below 6 years of age.

Consult your doctor if symptoms did not improve within 7 days or if symptoms were associated with fever.

Be sure to take LORINASE exactly as your doctor or pharmacist has told you to.

If you do not follow their instructions, you may not get relief from your symptoms.

Do not take more LORINASE than recommended by your doctor or pharmacist.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally. Do not take a double dose to make up for the dose you missed.

If you take too much (overdose)

Immediately telephone your doctor for advice or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much LORINASE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking LORINASE

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking LORINASE.

Tell your doctor or pharmacist if you become pregnant while you are taking LORINASE.

Things you must not do

Do not give LORINASE to anyone else, even if their symptoms seem similar to yours.

Do not use it to treat any other complaints unless your doctor or pharmacist says to.

Stop taking LORINASE 48 hours before you have any skin tests.

Antihistamines may interfere with the results of skin tests.

4. POSSIBLE SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using LORINASE.

LORINASE helps most people with allergies, but it may have unwanted effects in a few people.

Like other medicines, LORINASE can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Most unwanted effects seen with LORINASE have been mild to moderate. These include:

- Trouble sleeping
- Dry mouth
- Headache
- Sleepiness
- Nervousness
- Dizziness
- Fatigue

Other unwanted effects may also occur in some people taking LORINASE.

Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

5. HOW TO STORE LORINASE

Keep your tablets in the blister pack in a dry place until it is time to take them.

If you take your tablets out of the blister pack they will not keep well.

Do not store above 30°C.

For LORINASE syrup

Keep the bottle in a cool dry place.

Do not store above 30°C.

Do not store them or any other medicine in the bath room or near a sink.

Do not leave them in the car on hot days or on window sills.

Keep the tablets where children cannot reach them.

This medicine will be expired after 30 days from the first opening.

If your doctor or pharmacist tells you to stop taking LORINASE or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

6. FURTHER INFORMATION

What LORINASE looks like and contents of the pack

For LORINASE tablet:

LORINASE tablet is a round, flat bevelled edge, uncoated bilayer tablet, having mottled on pink coloured side, engraved with "115" and white plain surface on the other side.

Nature and contents of container: 14/pack

Blisters: Transparent thermoformed PVC/PVDC blister strips with hard tempered aluminium foil lid.

For LORINASE syrup:

A colourless to yellowish syrup with a characteristic strawberry odour and taste, free from foreign matter.

Nature and contents of container: 100ml amber bottle with child resistant cap/unit carton

What LORINASE contains

For LORINASE tablet:

Active ingredients: Loratadine Micronized USP 5mg and Pseudoephedrine sulfate 120mg.

Other ingredients: Lactose Fast Flow NF, Hydroxypropyl Methylcellulose K-15M, Hydroxypropyl Methylcellulose K-4M, Poracrilin Potassium, Magnesium Stearate, Purified Talc, Lactose BP 200, Maize Starch, Sodium Starch Glycolate and Spectracol Erythrosine LK.

For LORINASE syrup:

Active ingredients:

- Loratadine Micronized USP 5mg
- Pseudoephedrine sulfate 60mg

Other ingredients: Fructose, Polyethylene Glycol 1500 (SP), Disodium Edetate, Citric Acid Anhydrous, Sodium Citrate Anhydrous, Sodium Benzoate, Sorbitol Solution 70% Non Cryst, Propylene Glycol, Strawberry Flavour Liquid, Sucralose and Purified Water BP.

Marketing Authorization Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant
Saudi Pharmaceutical Industries & Medical Appliances Corporation.
Saudi Arabia

This leaflet was last revised in November 2016.



To report any side effect(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC)
 - o Fax: +966-11-205-7662
 - o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
 - o Toll free phone: 8002490000
 - o E-mail: npc.drug@sfd.gov.sa
 - o Website: www.sfd.gov.sa/npc

This is a medicament

- A medicament 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 medicament.
- 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 medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists