

Leaflet: information for the user

loratadine cinsa 10 mg tablets

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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What loratadine cinsa is and what it is used for
2. What you need to know before you take loratadine cinsa
3. How to take loratadine cinsa
4. Possible side effects
5. How to store loratadine cinsa
6. Contents of the pack and other information

1. What loratadine cinsa is and what it is used for

loratadine cinsa belongs to a class of drugs known as antihistamines.

Loratadine helps to reduce allergy symptoms by stopping the effects of a substance called “histamine”, which is produced in the body when you have an allergy to something.

loratadine cinsa relieves the symptoms associated with allergic rhinitis (e.g. hay fever), such as sneezing, runny or itchy nose and stinging or itching of the eyes, in adults and children over 6 years of age who weigh more than 30 kg.

loratadine cinsa can also be used to help relieve the symptoms of urticaria (such as itching, redness and the number and size of skin wheals).

You must talk to your doctor if you feel worse or if you do not feel better after 7days.

2. What you need to know before you take loratadine cinsa

Do not take loratadine cinsa:

- If you are allergic (hypersensitive) to loratadine or any of the other ingredients of loratadine cinsa (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking loratadine cinsa:

- If you have liver disease (See section 3. How to take loratadine cinsa).
- If you are going to have any type of allergy skin test. Do not take loratadine cinsa in the 2 days prior to having these tests because this medicine may affect the results.

If you are affected by one of the above conditions (or if you are not sure), talk to your doctor before taking loratadine cinsa.

Children and adolescents

Do not administer loratadine cinsa 10 mg to children under 6 years of age or children aged 6 to 12 years who weigh less than 30 kg. There are other formulations that are more suitable for children aged 6 to 12 years who weigh less than 30 kg.

Children younger than 2 years.

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

Other medicines and loratadine cinsa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The side effects of loratadine may increase when it is used in conjunction with other medicines that alter the levels of some liver enzymes, or if your liver is not functioning properly. In clinical studies, no increase was observed in the side effects of loratadine with medicines that altered the levels of these enzymes. However, it is important that you tell your pharmacist about any other medicine that you are taking while you are taking loratadine cinsa.

loratadine cinsa with food, drink and alcohol

loratadine cinsa can be taken with or without food.

loratadine has not been shown to increase the effects of alcoholic drinks.

Pregnancy and breast-feeding

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.

Pregnancy:

As a precautionary measure, taking loratadine cinsa is not recommended if you are pregnant.

Breast-feeding:

Do not take loratadine cinsa if you are breast-feeding, as loratadine is excreted in breast milk.

Driving and using machines

In clinical trials assessing driving ability, no reduced function was observed in patients receiving loratadine.

At the recommended dose, loratadine is not expected to cause drowsiness or reduce alertness. However, on rare occasions some people do experience drowsiness, which may affect their ability to drive or use machines.

loratadine cinsa contains lactose

This medicine contains lactose. If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

3. How to take loratadine cinsa

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children over 12 years of age:

Take 1 tablet once a day with a glass of water, with or without food.

Doses for children aged 6 to 12 will be determined according to weight:

- **Body weight over 30 kg:**
Take 1 tablet once a day with a glass of water, with or without food.
- **Body weight of 30 kg or less:**
Do not administer loratadine cinfra 10 mg. There are other presentations that are more suitable for children aged 6 to 12 years who weigh 30 kg or less.

loratadine cinfra is not recommended for children under 6 years of age.

Patients with severe liver problems who weigh more than 30 kg:

Take one tablet (10 mg) once a day on alternate days with a glass of water and with or without food.

Method of administration:

The tablets can be taken with or without food.

The tablet can be divided into equal doses.

If you take more loratadine cinfra than you should:

You will not experience any serious problems, but you may feel drowsy, suffer from palpitations or have a headache.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately or call the Toxicology Information Service, telephone +34 91 562 04 20, specifying the medicine and the amount ingested.

If you forget to take loratadine cinfra:

Do not take a double dose to make up for a forgotten dose.

If you forget to take your dose, take it as soon as possible, and then return to your normal dosage schedule.

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

4. Possible side effects

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

The most commonly reported side effects in adults and adolescents over 12 years old (can affect more than 1 in 10 patients) include:

- drowsiness,
- headache,
- increased appetite,
- difficulty sleeping.

The most commonly reported side effects in children aged 6 to 12 years (can affect more than 1 in 10 patients) include:

- headache,
- restlessness,
- tiredness.

The following very rare adverse events have also been reported during the post-marketing surveillance of loratadine (they may affect up to 1 in 10,000 patients):

- serious allergic reaction (including swelling),
- dizziness,
- seizures,
- irregular or fast heart beats,
- nausea (feeling sick),
- dry mouth,
- upset stomach,
- liver problems,
- hair loss,
- skin rash,
- tiredness.

Unknown frequency (cannot be estimated from available data):

- Weight gain.

If you get any side effects, talk to your doctor or pharmacist, even if it is a possible side effect not listed in this leaflet.

5. How to store loratadine cinfa

Keep this medicine out of the sight and reach of children.
Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. If in doubt, ask your pharmacist how to dispose of medicines you no longer require. This helps to protect the environment.

6. Contents of the pack and other information

What loratadine cinfa contains

- The active substance is loratadine. Each tablet contains 10 mg of loratadine.
- The other ingredients are: lactose monohydrate, maize starch, povidone and magnesium stearate.

What loratadine cinfa looks like and contents of the pack

loratadine cinfa are round, white, or almost white grooved tablets on one side and marked with the code “L” on the other side.

Each pack contains 20 tablets (packaged in PVC/Al blisters).

Marketing authorisation holder and manufacturer

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10 - Polígono Industrial Areta.
31620 Huarte (Navarre) – Spain

This leaflet was last revised in: Junio 2021.