

Claritine™

Loratadine - tablets



Package leaflet: Information for the User

Claritine 10 mg tablets

Loratadine

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1 - WHAT CLARITINE IS AND WHAT IT IS USED FOR

The full name of your medicine is Claritine tablets.

What Claritine is

Claritine tablets contain the active substance loratadine which belongs to a class of medicines called "antihistamines".

How Claritine works

Claritine helps to reduce your allergy symptoms by stopping the effects of a substance called "histamine", which is produced in the body when you are allergic to something.

When Claritine should be taken

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

Claritine may also be used to help relieve symptoms of urticaria (itching, redness and number and size of hives).

The effect of Claritine will last a whole day and should help you to continue your normal daily activities and sleep.

You must talk to a doctor if you do not feel better or if you feel worse.

2 - WHAT YOU NEED TO KNOW BEFORE YOU TAKE CLARITINE

Do not take Claritine if

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Claritine if:

- you have liver disease
- you are scheduled to have any skin tests for allergies. Do not take Claritine for two days before having these tests. This is because it may affect the test results.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before

taking Claritine.

Children

Do not give Claritine 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 a body weight of 30 kg or less.

Children under 2 years of age:

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

Other medicines and Claritine

The side effects of Claritine 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.

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.

Claritine with alcohol

Claritine has not been shown to add to the effects of an alcoholic drink.

Pregnancy and breast-feeding

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

As a precautionary measure, it is preferable to avoid the use of Claritine during pregnancy.

Do not take Claritine if you are breast-feeding. Loratadine is excreted in breast milk.

Driving and using machines

In clinical trials that assessed driving ability, no impairment was observed in patients receiving loratadine. At the recommended dose, Claritine 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 machines.

Claritine contains lactose

Claritine contains lactose; thus if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE CLARITINE

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

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

The score line of the tablet is only there to help you break the tablet if you have difficulty swallowing it whole.

How much to take:

Adults and children 6 years of age and older with a body weight greater than 30 kg:

Take one tablet once daily with a glass of water, with or without food.

Body weight of 30 kg or less:

Do not give Claritine. There are other formulations (syrup) more suitable for children younger than 6 years or who weigh 30 kg or less.

Children under 2 years of age:

Claritine is not recommended for children younger than 2 years old.

Adults and children with severe liver problems:

Adults and children who weigh more than 30 kg

Take one tablet once every other day with a glass of water, with or without food. However, you should talk to your doctor, pharmacist or nurse before taking this medicine.

If you take more Claritine than you should

If you take more Claritine than you should, talk to your doctor or pharmacist straight away.

No serious problems are expected however, you may get a headache, have a rapid heartbeat or feel sleepy.

If you forget to take Claritine

- If you forget to take your dose, take it as soon as you remember, then continue to take it as usual.
- Do not take a double dose to make up for a forgotten dose.

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

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 children over 12 years of age are:

- drowsiness
- headache
- increased appetite
- difficulty sleeping.

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

- headache
- nervousness
- tiredness.

The following **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 (including swelling)
- dizziness
- convulsion
- fast or irregular heartbeat
- nausea (feeling sick)
- dry mouth
- upset stomach
- liver problems
- hair loss
- rash
- tiredness.

The frequency of the following side effect is not known:

- weight increased

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CLARITINE

- Keep this medicine out of the sight and reach of children.
- Store not above 30°C. Protect from excessive moisture.
- Do not use this medicine after the expiry date which is stated on the blister after EXP. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice any change in the appearance of the tablet.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Claritine contains

- The active substance is loratadine. Each tablet contains 10 mg loratadine.
- The other ingredients are lactosemonohydrate, maize starch, magnesium stearate.

What Claritine looks like and contents of the pack

Tablet.

White, to off-white, oval tablet with flask and bowl, scoreline and the number "10" on one side.

Claritine tablets are available in pack sizes of 10, 20 or 30 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder:

Bayer Consumer Care AG,

Basel-Switzerland

Manufacturer & Batch Releaser:

Schering-Plough Labo N.V.

Industriepark 30,

B-2220 Heist-op-den-Berg, Belgium.

This leaflet was last approved in August, 2018.

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 pharmacist who sold the medicament. The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists