

Claritine™

Loratadine - syrup



Package leaflet: Information for the User

CLARITINE 1 mg/ml syrup

Loratadine

Read all information in this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 CLARITINE is and what it is used for
2. Before you take CLARITINE
3. How to take CLARITINE
4. Possible side effects
5. How to store CLARITINE
6. Further information

1. WHAT CLARITINE IS AND WHAT IT IS USED FOR

CLARITINE provides:

- fast relief from hayfever and other seasonal allergy symptoms including sneezing, runny nose and itchy nose, as well as itchy watery red burning eyes.
- fast relief of allergic skin conditions, such as skin itch and hives.

What it does:

CLARITINE contains a long-acting antihistamine, which blocks the action of histamine and relieves allergy symptoms. Histamine is a chemical released by the immune system – the body's defense against invading substances – when the body is affected by substances that you are allergic to (allergens). Symptom relief will be maintained for 24 hours.

CLARITINE does not cause drowsiness. It lets you stay alert and focused while relieving allergy symptoms.

2. BEFORE YOU TAKE CLARITINE

CLARITINE should not be used:

- if you are allergic to loratadine or to any of the other product ingredients (see section 6).

Warning and Precautions

BEFORE you use CLARITINE talk to your doctor or pharmacist if:

- you have severe liver disease

Laboratory tests

Stop taking CLARITINE 48 hours prior to any skin testing procedures.

Interactions with this medication

CLARITINE may interact with drugs known to reduce liver metabolism. If you are taking any medication, it is important to ask your doctor or pharmacist before taking CLARITINE.

Taking CLARITINE with alcohol

Alcohol has not been found to interact with CLARITINE.

Driving and using machines

When taking the recommended dose of CLARITINE you will normally not be sleepy or less alert than usual.

However, in very rare cases some patients may experience dizziness, which may affect their ability to drive or use.

Pregnancy and breast-feeding

If you are pregnant, you are advised against taking CLARITINE.

If you are breast-feeding, you are advised against taking CLARITINE. Loratadine is excreted in breast milk.

If you wish to become pregnant, if you are pregnant or breast-feeding ask your doctor or pharmacist for advice before taking this medicine

3. HOW TO TAKE CLARITINE

Usual dose:

Adults and children aged 12 years and older:

Take once daily 10 ml (measuring cup filled to 10 ml line).

Children aged 2 to 12 years are dosed according to their weight:

Body weight above 30 kg:

Take once daily 10 ml (measuring cup filled to 10 ml line).

Body weight 30 kg or less:

Give once daily 5 ml (measuring cup filled to 5 ml line).

Patients with serious liver problems:

Adults and children who weigh more than 30 kg:

Take 10 ml once every other day.

Children who weigh 30 kg or less:

Give 5 ml of syrup once every other day.

CLARITINE is not suitable for children younger than 2 years.

Overdose:

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

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

In case of drug overdose, contact your Poison Control Centre, doctor or pharmacist as soon as possible, even if there are no symptoms.

Missed Dose:

If you miss taking your dose on time, do not worry; take your dose when you remember. Do not exceed more than one dose in 24 hours.

4. POSSIBLE SIDE EFFECTS

Along with its desired effects, CLARITINE may cause undesirable effects.

Mild side effects that may occur include fatigue, headache, dry mouth, sedation, stomach and digestive discomfort such as gastritis (inflammation of the stomach) and nausea.

Uncommon side effects include: Increase in appetite, coughing, and dizziness. Rarely, you may experience allergic reactions to the medication that may appear as a rash or difficulty in breathing. Additionally, hair loss, abnormal liver function, and abnormally fast heart rate or heart palpitations may occur rarely. Convulsions and seizures may occur very rarely. Uncommon side effects in children include nervousness and nervous ticks as well as side effects involving the stomach or intestines.

SERIOUS SIDE EFFECTS

Stop taking drug and call your doctor or pharmacist, if you notice any of below side effects.

Common : Stomach discomfort - i.e. gastritis (inflammation of the stomach)
Uncommon : Allergic reaction (rash, swelling, difficulty in breathing)

Rare : Fast heart rate or heart palpitations, Liver dysfunction

This is not a complete list of side effects. For any unexpected effects while taking CLARITINE, contact your doctor or pharmacist.

5. HOW TO STORE CLARITINE

- Keep out of reach and sight of children.
- Store not above 30 °C.
- Do not freeze. Keep the bottle in the outer carton in order to protect from light.
- Do not use CLARITINE after the expiry date which is stated on the bottle after {EXP}. The expiry date refers to the last day of that month.
- CLARITINE syrup must be used within 1 month after opening.
- Do not use CLARITINE if you notice any changes in the appearance of the syrup.
- 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 CLARITINE contains:

Active substance: loratadine 1 mg/ml

Other ingredients are:

artificial grape flavour, disodium edetate, glycerol, maltitol, sodium dihydrogen phosphate dihydrate, phosphoric acid, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose.

What CLARITINE looks like and contents of the pack

CLARITINE syrup is a clear, colourless to pale-yellow syrup in 120 ml of white opaque plastic bottle sealed with a polypropylene, push and turn/ tamper evident cap including a plastic laminated liner. Each bottle is supplied with a dosing cup which is a clear Polypropylene, round cup printed and calibrated to measure 5 ml or 10 ml of the syrup.

Marketing authorisation holder:

Bayer Consumer Care AG, Basel-Switzerland

Manufacturer & Batch Releaser:

Famar Montreal Inc.,
Pointe-Claire, Quebec,
Canada.

This leaflet last revised on June, 2016.

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