



PACKAGE LEAFLET: INFORMATION FOR THE USER

Claritine 1 mg/ml syrup

Loratadine

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Read all of 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
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**1. WHAT CLARITINE IS AND WHAT IT IS USED FOR**

Claritine belongs to a group of medicines known as antihistamines. Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine, produced in the body.

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

Claritine can also be used to help relieve symptoms of hives (a very itchy skin rash with bumps).

It relieves symptoms throughout the day enabling you to perform your usual daily activities and sleep well.

**2. BEFORE YOU TAKE CLARITINE**

**Do not take Claritine**

- if you are allergic (hypersensitive) to loratadine or any of the other ingredients of Claritine.

**Take special care with Claritine**

Talk to your doctor or pharmacist before taking Claritine:

- if you have a liver disease.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Laboratory tests:**

The administration of Claritine must be discontinued 2 days before allergy testing, because this medicine may affect the test results.

**Taking Claritine with food and drink**

Claritine can be taken with or without a meal.

Claritine has not been shown to increase the effects of alcoholic beverages.

**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.

Ask your doctor or pharmacist for advice before taking any medicine.

**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 machines.

**Important information about some of the ingredients of Claritine**

Claritine syrup contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. HOW TO TAKE CLARITINE**

Always take Claritine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Adults and children aged 12 years and older:**

Take 2 teaspoons (10 ml) of syrup once daily, with or without food. You do not need water or another fluid to swallow the syrup.

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

**Body weight above 30 kg:**

Take 2 teaspoons (10 ml) of syrup once daily, with or without food. You do not need water or another fluid to swallow the syrup.

**Body weight of 30 kg or less:**

Take 1 teaspoon (5 ml) of syrup once daily, with or without food.

You do not need water or another fluid to swallow the syrup.

**Patients with serious liver problems:**

**Adults and children with a body weight above 30 kg:**

Take 2 teaspoons (10 ml) of syrup once every two days, with or without food. You do not need water or another fluid to swallow the syrup.

**Adults and children with a body weight of 30 kg or less:**

Take 1 teaspoon (5 ml) of syrup once every two days, with or without food.

You do not need water or another fluid to swallow the syrup.

Claritine is not suitable for children younger than 2 years.

**If you take more Claritine than you should**

Take Claritine exactly as prescribed to you. Accidental overdose is not expected to cause any serious problems.

Sleepiness, increased heart rate and headache have been reported in cases of overdose with Claritine.

If you have taken more Claritine than you should, immediately contact your doctor, pharmacist.

**If you forget to take Claritine**

If you forget to take a dose, you should take it as soon as you remember. Continue your usual dosing schedule.

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

**If you stop taking Claritine**

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

**4. POSSIBLE SIDE EFFECTS**

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

The most commonly reported side effects in children aged 2 to 12 years are headache, nervousness and fatigue. The most commonly reported side effects in adults and adolescents are sleepiness, headache, increased appetite and difficulty sleeping.

Since the introduction of Claritine on the market very rare cases of serious allergic reaction, dizziness, irregular or increased heart rate, nausea (feeling sick), dry mouth, feeling of heaviness in the stomach, liver problems, hair loss, skin rash and fatigue have been reported. It is not possible to determine the frequency of these reactions.

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.

**5. HOW TO STORE CLARITINE**

Keep out of the 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**

- The active substance is loratadine 1 mg/ml.
- The other ingredients are propylene glycol (E1520), glycerol (E422), anhydrous citric acid, sodium benzoate (E211), sucrose, artificial peach flavour and purified water.

**What Claritine looks like and contents of the pack**

Claritine syrup is a clear, colourless to pale-yellow syrup in amber glass bottles containing 60, 70, 100 or 120 ml with a sealed, child-resistant polypropylene cap. A 5 ml plastic measuring spoon is included. Not all pack sizes may be marketed.

Marketing authorisation holder: Bayer Consumer Care AG, Basel-Switzerland

Marketing authorization number: BE 159835

Manufacturer & Batch Releaser: Schering-Plough Labo N.V. Industriepark 30, B-2220 Heist-op-den-Berg, Belgium.

Contact your doctor or pharmacist for any information on this medicinal product.

Medicinal product subject to medical prescription.

**This leaflet was last revised in Sept 2011**

(THIS IS A MEDICAMENT)

- 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 for you.
- 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

