

PACKAGE LEAFLET

Package leaflet: Information for the patient

Loratadine 5 mg / 5 ml syrup (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 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. See section 4.

What is in this leaflet

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

1. What Loratadine is and what it is used for

Loratadine syrup contains the active ingredient loratadine, which belongs to a group of medicines called antihistamines. Loratadine is an anti-allergy medicine. It helps relieve the symptoms of:

- allergic skin reactions like rashes, hives or nettle rash.
- allergic rhinitis (for example seasonal hayfever), such as sneezing, runny or itchy nose and burning or itchy eyes.

2. What you need to know before you take Loratadine

Do not take Loratadine:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Loratadine:

- if you have severe liver problems.
- if you are diabetic, as this medicine contains sucrose (see section ‘Loratadine contains sucrose’ at the end of section 2).

During treatment

If you have an appointment for a skin allergy test, tell your doctor, nurse or hospital staff that you are taking this medicine. It may be necessary to stop taking loratadine for at least 2 days beforehand to make sure the test gives the correct result.

Other medicines and Loratadine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including the following:

- Cimetidine used to treat heartburn or stomach ulcers.
- Antibiotics such as erythromycin or antifungal medicines such as ketoconazole.

Loratadine with alcohol

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

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.

Loratadine **should not** be taken if you are pregnant.

You **should not** breast-feed your baby, as small amounts of loratadine can pass into breast milk.

Driving and using machines

Do not drive or operate machinery if you feel dizzy or drowsy while taking this medicine.

Loratadine contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Each 5 ml spoonful contains 3 g of sucrose. This should be taken into account in patients with diabetes mellitus.

Loratadine also contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

3. How to take Loratadine

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

Swallow the dose of syrup, and then drink some water. You can take this medicine with or without food.

Adults and children and adolescents (older than the age of 12):

The recommended dose is 10 ml (two 5 ml spoonfuls) of syrup once a day.

Children 2 to 12 years of age

The amount to be taken depends on body weight:

Body weight **more than** 30 kg: the recommended dose is 10 ml (two 5 ml spoonfuls) of syrup once a day.

Body weight 30 kg **or less**: the recommended dose is 5 ml (one 5 ml spoonful) of syrup once a day.

Children under age of 2:

Loratadine is not recommended.

If you have liver problems

Your doctor may recommend that you take the medicine less often than recommended above.

If you take more Loratadine than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the bottle and any remaining syrup with you. Symptoms of overdose include sleepiness, headache or a rapid heart beat.

If you forget to take Loratadine

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Loratadine

If you stop taking Loratadine, your symptoms of allergy may come back. Talk to your doctor or pharmacist first before stopping this medicine.

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.

If any of the following happen, **stop taking** Loratadine and tell your doctor immediately or go to your nearest hospital emergency department:

- Severe allergic reactions such as rash, itchy swollen skin, burning eyes, fever, tightness of the chest and difficulty breathing or swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing.
- Fits

This side effect is very rare (may affect up to 1 in 10,000 people) but serious. You may need medical attention.

Other side effects:

Common (may affect up to 1 in 10 people)

- Sleepiness

Uncommon (may affect up to 1 in 100 people)

- Headache
- Inability to sleep
- An increased appetite

Very rare (may affect up to 1 in 10,000 people)

- Irregular, missed heart beats (palpitations) or rapid heart beat
- Feeling sick (nausea)
- Dry mouth
- Stomach upset
- Changes in liver function, which may be seen in blood tests
- Hair loss
- Dizziness
- Tiredness

Not known (frequency cannot be estimated from the available data)

- Weight increased

Additional side effects in children (2 to 12 years of age)

The following additional side effect has been reported in children 2 to 12 years of age:

Common (may affect up to 1 in 10 children):

- Feeling nervous

Headaches and tiredness were also reported more commonly.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Loratadine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Loratadine contains

The active substance is loratadine. Each 5 ml of syrup contains 5 mg of loratadine.

The other ingredients are propylene glycol, glycerol, citric acid monohydrate, sucrose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), purified water and artificial strawberry flavouring (which contains: Flavouring substances and natural flavouring substances, propylene glycol, water, Triacetin E-1518, Ethyl Alcohol, Butylated Hydroxyanisole (BHA) E-320 and Alfa Tocopherol E-307).

What Loratadine looks like and contents of the pack

Your medicine comes as a clear, slightly viscous solution in glass bottles of 60 ml, 100 ml or 120 ml. Not all pack sizes may be marketed. A measuring device is also included. Your pharmacist will dispense the amount of syrup prescribed by your doctor.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, U.K.

Manufacturer

Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, U.K.

McDermott Laboratories Limited, t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Laboratorios Lesvi SA, Avda Barcelona 69, 08970 Sant Joan Despi, Barcelona, Spain.

This medicinal product is authorised in the Member States of the EEA under the following names:

Portugal

Loratadina Mylan

United Kingdom

Loratadine 5 mg / 5 ml Syrup

This leaflet was last revised in: December 2017