

Package leaflet: Information for the Patient

[Product Name]

Loratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, or pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must contact a doctor or pharmacist if your symptoms worsen or do not improve.

WHAT IS IN THIS LEAFLET:

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

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

This medicine contains loratadine, which belongs to a group of drugs called antihistamines. These medicines help to relieve the symptoms of some allergies.

This medicine is used to relieve:

- symptoms of hayfever and other allergies such as sneezing, runny nose and burning, itchy eyes
- symptoms of skin allergies such as rash, itching or urticaria (hives).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE THIS MEDICINE

This medicine can be taken by adults and children aged 6 years and over **provided they weigh over 30 kg**.

Some people should not take this medicine or should talk to their pharmacist or doctor first.

Do not take if you:

- Are allergic (hypersensitive) to loratadine or any of the other ingredients in the medicine, listed in section 6.

Talk to your pharmacist or doctor before taking if you:

- Have liver problems. You may need to take a lower dose.

Pregnancy and breastfeeding and fertility

- **Do not take** if you are pregnant or breastfeeding.

Other important information

- If you are going to have skin tests to identify allergies, stop taking this medicine at least 48 hours before the tests.

Driving and using machines

Tests have shown that this medicine does not cause drowsiness in the vast majority of people using it. Therefore it will not normally affect your ability to drive or operate machinery. However there may be very rare exceptions and if you experience dizziness, nausea or drowsiness, do not drive or operate machinery.

This medicine contains lactose

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

Other medicines and this medicine

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines taken without a prescription. There is a potential for loratadine to interact with other drugs including ketoconazole, erythromycin, and cimetidine.

3. HOW TO TAKE THIS MEDICINE

AGE	DOSE
Adults and children 6 years of age and over with a body weight of more than 30 kg	Swallow one tablet daily with water.
<p>Do not give to children under 6 years of age or to children weighing less than 30kg. As a guide, the average 9 year old child weighs approximately 30 kg (equivalent to 4 and a half stone). Check your child's weight if you are not sure. For children under 6 years or with a body weight of 30 kg or less a syrup form of this medicine may be more suitable.</p>	
If you have severe liver problems: Adults and children 6 years and over weighing more than 30 kg (Check with your pharmacist or doctor)	Swallow one tablet every other day with water
DO NOT EXCEED THE RECOMMENDED DOSE	

If symptoms worsen or do not improve, talk to your doctor or pharmacist.

If you take more of this medicine than you should: Talk to a doctor straight away, or contact your nearest hospital casualty department. Take the carton and this leaflet with you. You may get a headache, dry mouth, constipation, blurred vision, have a rapid heartbeat or feel sleepy.

If you forget to take a dose of this medicine: Take the recommended dose as soon as you remember; wait at least 24 hours before taking another tablet. Do not take a double dose to make up for the missed doses.

4. POSSIBLE SIDE EFFECTS

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

Serious side effects

Stop taking the tablets and tell your doctor or go to a casualty department immediately if:

- you get any swelling of the face, lips, tongue, throat or other parts of the body
- you experience any wheezing, difficulty in breathing or have any problems swallowing
- you get a skin rash, or hives on the skin after taking the tablets.

The above symptoms may mean you are having a very rare, serious allergic reaction to this medicine.

- you experience convulsions (fits).

Other possible side effects

If any of the following side effects get serious or concerns you, or you notice any side effects not listed in this leaflet, stop taking the tablets and tell your doctor or pharmacist.

- Headache, nervousness and tiredness in children aged 6 - 12 years.
- Drowsiness, headache, increased appetite and difficulty sleeping in adults and children over 12.
- Very rare side effects are severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling), dizziness, rapid heartbeat, palpitations, feeling sick (nausea), dry mouth, upset stomach, changes in liver function, rash, hair loss and tiredness.
- Weight increase: Frequency 'not known'.

Reporting 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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THIS MEDICINE

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

This product does not require any special storage conditions.

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

Do not throw away any medicines via 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 is in this medicine:

The active ingredient is: Loratadine, 10 mg per tablet.

The other ingredients are: Lactose monohydrate, maize starch, pregelatinised starch and magnesium stearate.

What this medicine looks like and contents of the pack:

Tablets of this medicine are white oval tablets with a break line and markings 'L' and '10' on one side.

This pack contains 7, 14, 30 or 60 tablets.

Not all pack sizes are marketed.

Marketing Authorisation Holder:

Galpharm Healthcare Ltd, Wrafton, Braunton,
Devon, EX33 2DL, United Kingdom

Manufacturer:

Omega Pharma Limited, Elmhirst Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS,
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Omega Pharma Ltd, DMC 02, County Way, Barnsley, South Yorkshire, S70 2JW, United Kingdom

This leaflet was last revised in October 2024

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