Product Name: Loratadine Oral Solution
Pack: 100ml
Leaflet Size L:170 x H:330 mm

330 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Loratadine 5 mg/5 ml Oral Solution
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, pharmacist or nurse has told you. Throughout this leaflet, your medicine is called Loratadine oral solution.

- 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better, if you feel worse or if your symptoms change. See section 4.

What is in this leaflet:

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

1. What Loratadine oral solution is and what it is used for

Loratadine oral solution belongs to a group of medicines called antihistamines. Loratadine oral solution 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. Loratadine oral solution is used in both adults and children over 2 years of age to relieve the symptoms of hayfever such as sneezing or runny nose and burning, itchy eyes. It may also used to help relieve symptoms of urticaria (itching and redness), which is often known as hives or nettle rash

The effect of Loratadine oral solution 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 Loratadine oral solution Do not

Do not take Loratadine oral solution

- if you are allergic (hypersensitive) to Loratadine or any of the other ingredients of Loratadine oral solution (listed in section 6).
- if you are pregnant, planning to become pregnant or are breast-feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Loratadine oral solution

- If you have severe liver problems
- If you are scheduled to have any skin test for allergies. Do not take Loratadine oral solution for 48 hours before having these tests. This is because it may affect test results.

Children

Do not give Loratadine oral solution to children younger than 2 years old.

Other medicines and Loratadine oral solution

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The side effects of Loratadine oral solution 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.

Loratadine oral solution with alcohol

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

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant or if you are breast-feeding. Loratadine is excreted in breast milk. 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. It is preferable to avoid the use of Loratadine oral solution during pregnancy.

Driving and using machines

In clinical trials that assessed driving ability, no impairment was observed in patients receiving Loratadine. At the recommended does, Loratadine oral solution does not normally cause drowsiness. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines. If affected do not drive or use machines.

Loratadine oral solution contains maltitol

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

Loratadine oral solution contains sodium benzoate

This medicine contains 0.001 g sodium benzoate in each 1 ml of syrup.

Loratadine oral solution contains propylene glycol

This medicine contains 0.1 g propylene glycol in each 1 ml of syrup.

Information on sodium content

This medicine contains less than 1mmol sodium (23mg) per 1 ml of syrup, that is to say essentially 'sodium-free'.

3. How to take Loratadine oral solution

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

Taking this medicine

- Water or other liquid is not required to swallow the syrup.
- The syrup may be taken with or without food.

Giving this medicine to children

It is important to know how much your child weighs to make sure that you give the correct amount of medicine. For example, a 9 year old child weighs about 30kg (4st 7lb). If in doubt weigh your child and then follow the instructions in the table. Loratadine oral solution is to be taken only by mouth, and is not to be taken by children aged under 2 years.

The spoon provided holds 5 ml of your medicine should be used to measure the required dose. The recommended dose is as shown in the table below:

Adults and Children over 12 years of age	10ml (10mg) of the oral solution once daily (2 x 5ml spoonful)
Children 2 to 12 years of age with:	
Body weight more than 30 kg (4st 7lbs)	10ml (10mg) of the oral solution once daily (2 x 5ml spoonful)
Body weight 30 kg (4st 7lbs) or less	5ml (5mg) of the oral solution once daily (1 x 5ml spoonful)
If you have severe liver problems your doctor or pharmacist may advise you to take the recommended amount every other day. If this applies to you follow their instructions.	

If you take more Loratadine oral solution than you should

If you may have taken more Loratadine oral solution than you should, talk to a doctor or pharmacist immediately. Take the bottle and any remaining syrup with you. Symptoms of overdose include headache, have a rapid heart beat or feel sleepy.

If you forget to take Loratadine oral solution

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for the next dose. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Loratadine oral solution can cause side effects, although not everybody gets them.If you get any of these serious side effects, stop taking this medicine. See a doctor immediately

- Severe allergic reaction which causes difficulty in breathing or dizziness
- Angioedema (Swollen skin of hands, feet, eyes, lips)
- Convulsion

The most commonly reported side effects (may affect up to 1 in 10 people) in adults and children over 12 years of age are:

- drowsiness
- headache
- increased appetite
- difficulty sleeping

The most commonly reported side effects (may affect up to 1 in 10 people) in children aged 2 through 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:

- hair loss
- liver problems
- faster heart beats
- rash
- fatigue (tiredness)
- nausea (feeling sick)
- gastritis (an inflammation of the lining of the stomach)
- dizziness
- palpitation (irregular heartbeats)
- dry mouth
- upset stomach

The frequency of the following side effect is not known:

- Weight increased

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.

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 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 LORATADINE ORAL SOLUTION

- Keep out of the sight and reach of children
- Do not use Loratadine oral solution after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Shelf life after first opening container is 3 months.
- Do not use Loratadine oral solution if you notice any defects or signs of deterioration. If unsure, consult your doctor or pharmacist before taking it.
- 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Loratadine oral solution contains

- The active substance is Loratadine.
- The other ingredients are propylene glycol (E1520), sodium benzoate (E211), disodium edetate, maltitol (lycasin 80/55), glycerol (E422), citric acid monohydrate, menthol, flavour peach and sucralose.

What Loratadine oral solution looks like and contents of the pack

Loratadine oral solution is a clear, colourless liquid contained in either amber coloured glass bottles with a tamper proof child resistance cap or amber coloured transparent PET bottles with a tamper proof child resistance cap.

Pack size: 100 ml

Marketing Authorisation Holder

Torrent Pharma (UK) Ltd., 3rd Floor, Nexus Building, 4 Gatwick Road, Crawley, West Sussex, RH10 9BG, United Kingdom

Manufacturer : Torrent Pharma (UK) Ltd., 3rd Floor, Nexus Building, 4 Gatwick Road, Crawley, West Sussex, RH10 9BG, United Kingdom Or Kleva Pharmaceuticals S.A. 189 Parnithos Ave.,Acharnai Attiki, 13675, Greece

This leaflet was last amended 08/2021.

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This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.

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