



PACKAGE LEAFLET: INFORMATION FOR THE USER

**LORATADINE TABLETS
10MG
TAJ PHARMA**

(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 has 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 talk to a doctor if you do not feel better or if you feel worse after 10 days.

WHAT IS IN THIS LEAFLET:

1. What Loratadine 10 mg Tablets (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 belong to a class of medicines known as antihistamines.

Antihistamines help to reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced in the body.

The tablet relieves symptoms associated with allergic rhinitis (for example, hayfever) such as sneezing, runny or itchy nose and burning or itchy eyes.

The tablet may also be used to help relieve symptoms of urticaria (itching and redness), which is often known as hives or nettle rash.

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)
- if you are pregnant or breastfeeding
- if you have phenylketonuria (a metabolism disorder)

Warnings and precautions:

Talk to your doctor or pharmacist before taking Loratadine:

- if you have severe liver disease
- if you have to undergo any skin tests, it may be necessary to stop taking this medicine at least 2 days before the test to make sure the result of the test is correct.

Children

Loratadine is not recommended for children younger than 2 years old as efficacy and safety have not been established. Do not give Loratadine to children between 2 and 12 years old who weigh less than 30 kg. There are other more suitable formulations.

Other medicines and Loratadine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Potential interaction may occur with medicines that make some liver enzymes less active resulting in elevated levels of loratadine. This may cause an increase in adverse events.

Loratadine with food, drink and alcohol

The tablets can be taken with or without a meal.

The tablets will normally disintegrate in the mouth in contact with saliva, therefore water or other liquids are not normally needed.

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

Pregnancy, breast-feeding and fertility

The use of Loratadine during pregnancy and breast-feeding is **not recommended**. 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 before taking this medicine.

If you are nursing a baby, taking Loratadine is not recommended, because loratadine is excreted in breast milk.

Driving and using machines

In clinical studies that assessed driving ability, no impairment was observed in patients receiving loratadine.

At the recommended dose, Loratadine are not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

Loratadine contain lactose.

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

Loratadine contains less than 7 mg **sorbitol** in each orodispersible tablet.

Loratadine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially 'sodium-free'.

Loratadine contain 0.5 mg aspartame in each orodispersible tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. HOW TO TAKE LORATADINE

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

Loratadine is intended to be put on the tongue (see below) and for oral use.

Loratadine break easily, so you should handle the tablets carefully and with dry hands only.

Method of use

1. Tear one blister unit along the perforations.
2. Peel open the backing in direction of the arrow and take the tablet out carefully. The tablet should not be pushed through the backing.
3. Put the tablet on your tongue as soon as it is removed from the packaging. It will melt in your mouth directly. Water is not required to swallow the tablet.

Loratadine are dispersed in your mouth in contact with saliva and can be therefore taken without water. They have a sweet orange taste.

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 (four and half stone).

If in doubt weigh your child and then follow the instructions in the table.

Do not give to children under 2 years or who weigh less than 30kg (four and half stone).

The recommended dose is:

Adults and children over 12 years: take one tablet once a day.

Children of 2 to 12 years who weigh more than 30 kg (four and half stone):

Take one tablet once a day.

Children of 2 to 12 years who weigh less than 30 kg (four and half stone): Do not give this medicine.

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

Duration of treatment:

You must contact a doctor if your symptoms do not improve or even get worse after 10 days.

If you take more tablets than you should:

If you take more Loratadine than recommended, contact your doctor or pharmacist. Taking more tablets than

recommended may cause drowsiness, rapid heartbeat and headache.

If you forget to take Loratadine:

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten tablet.

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.

The most commonly reported side effects in adults and children over 12 years of age are:

- drowsiness
- headache
- increased appetite
- difficulty sleeping

The most commonly reported side effects in children aged 2 to 12 years are:

- headache
- nervousness
- tiredness

Very rare side effects (may affect up to to 1 in 10,000 people) have also been observed during the marketing of loratadine:

- severe allergic reactions (including swelling)
- dizziness
- convulsion
- fast or irregular heartbeat
- nausea (feeling sick)
- dry mouth
- upset stomach
- liver problems
- hair loss
- rash
- tiredness

Not known, frequency cannot be estimated from the available data:

- weight increased

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.

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Do not throw away 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

Each uncoated tablet contains:

Loratadine USP	10mg
Excipients	q.s.

The other ingredients are sweet orange flavour, aspartame, citric acid anhydrous, silica colloidal anhydrous, maize starch dried, lactose anhydrous, magnesium stearate, croscarmellose sodium, mannitol, sorbitol, crospovidone, silica colloidal hydrated, polysorbate 80, povidone, microcrystalline cellulose.

What Loratadine looks like and contents of the pack

Loratadine tablets are white, round and flat.

PVC/PVDC/Al blisters.

Pack sizes: Blisters: 7, 14, 28, 30, 50, 90, 100 and 500mg modified-release tablets.

Not all pack sizes may be marketed.



7. MANUFACTURED IN INDIA BY:

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