

Loratadine 10mg Tablets

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.

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

1. What Loratadine Tablets are and what they are used for

The full name of your medicine is **Loratadine 10 mg Tablets**.

What Loratadine Tablets are

This medicine contains the active substance loratadine which belongs to a class of medicines called "antihistamines".

How Loratadine Tablets work

Loratadine Tablets help 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.

When Loratadine Tablets should be taken

Loratadine Tablets relieve symptoms associated with allergic rhinitis (for example, hay fever), such as sneezing, runny or itchy nose, and burning or itchy eyes.

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

The effect of Loratadine Tablets 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 Tablets

Do not take Loratadine Tablets

- if you are allergic to loratadine or any of the other ingredients of this medicine (listed in section 6)
- if you are **pregnant** or planning to become pregnant
- if you are **breast-feeding** currently.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Loratadine Tablets

- if you have **liver disease**
- if you are scheduled to have any skin tests for allergies. Do not take Loratadine tablets for two days before having these tests. This is because it may affect test results.

If any of the above applies to you (or you are not sure), please tell your doctor, pharmacist or nurse before taking Loratadine Tablets.

Children

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 over 6 years, but who weigh less than 30kg, a syrup form of this medicine may be more suitable.

Children under 2 years of age: The safety and efficacy of Loratadine Tablets have not been established. No data are available.

Other medicines and Loratadine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines taken without a prescription.

This is particularly important if you are taking

- Cimetidine (for stomach problems)
- Erythromycin (an antibiotic)
- Ketoconazole or fluconazole (for fungal infections)

The side effects of Loratadine Tablets 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 Tablets with alcohol

Loratadine Tablets have 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 before taking this medicine.

Pregnancy: Do not take Loratadine Tablets if you are pregnant.

Breast feeding: Do not take Loratadine Tablets if you are breast-feeding. Loratadine is excreted in breast milk.

Driving and using machines

In clinical trials that assessed driving ability, no impairment was observed in patients receiving loratadine. At the recommended dose, Loratadine Tablets 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. Please make sure you are not drowsy before performing these activities.

Loratadine Tablets contains lactose

Loratadine Tablets contain lactose; thus if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Loratadine Tablets

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

Try to get into the habit of taking it at the same time every day. This will make it easier for you to remember.

The Central breakline of the tablet is only there to help you the break the tablet if you have difficulty swallowing it whole.

Use in children



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 over 6 years, but who weigh less than 30kg, a syrup form of this medicine may be more suitable. If in doubt, weigh your child and then follow the instructions in the table.

Not recommended for children under 2 years old.



Product:	Loratadine 10mg Tablets
Item Code:	P1696T
Size:	210 x 297 mm
Min. Point size:	9pt
O. Artwork	20/04/21
Proof No.	2
Amendment Date	28/04/21

Colours Used	
	Process Black
	Keyline - does not print

The recommended dose is

Age	Dose
Adults and children 6 years and older who weigh more than 30kg (4st 7lb)	10 mg once daily (swallow one tablet daily with water)
Children weighing less than 30 kg	Not recommended
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 Tablets than you should

If you may have taken more Loratadine Tablets than you should, talk to your doctor or pharmacist immediately. No serious problems are expected however, you may get a headache, have a faster heart beat or feel sleepy.

If you forget to take Loratadine Tablets

If you have forgotten to take your tablet, take it as soon as you remember and continue as usual. **Do not take a double dose** to make up for a forgotten dose.

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

4. Possible side effects

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

Stop taking Loratadine Tablets and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- severe allergic reaction which cause difficulty in breathing or dizziness (including swelling).
- fast or irregular heartbeat
- serious allergic reaction which causes swelling of the face or throat

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 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:

- convulsion
- upset stomach (abdominal pain, burning feeling in the stomach between meals or at night and nausea (with or without vomiting)
- feeling tired
- skin rashes
- hair loss
- nausea (feeling sick)
- dry mouth
- liver problems

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

- weight gain

Reporting of 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 Loratadine Tablets

- Keep this medicine out of the sight and reach of children.
- Do not take Loratadine Tablets after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.
- Do not use this medicine if you notice any change in the appearance of the tablet.
- Store in the original package.
- 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 to protect the environment.

6. Contents of the pack and other information

What Loratadine Tablet contains

- The active substance is loratadine. Each tablet contains 10 mg loratadine.
- The other ingredients are lactose monohydrate, maize starch, colloidal anhydrous silica, croscarmellose sodium, talc and magnesium stearate.

What Loratadine Tablets look like and contents of the pack

Loratadine Tablets are white coloured, circular, flat beveled uncoated tablets, with central breakline on one side and 'L' on other side.

Loratadine Tablets are available in blister strips in pack size of 7, 10, 14, 20 and 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Crescent Pharma Limited,
Key House, Sarum Hill,
Basingstoke, RG21 8SR,
United Kingdom

This leaflet was last revised in April 2021.

125 mm

Package leaflet: Information for the user

P1521T

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375mm

Crescent
PHARMA LIMITED

Product:	Loratadine 10mg Tablets
Item Code:	P1521T
Size:	140 x 375 mm
Min. Point size:	9pt
O. Artwork	12/10/20
Proof No.	6
Amendment Date	08/09/21

Colours Used	
	Process Black
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125 mm

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