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Loratadine 10mg Tablets

Size : 320 L x 170 W mm
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Fonts : Arial

Fonts Size :

Generic Name font size : 18 pt.
Composition fonts size : 9 pt.

170 mm

320 mm

PHARMA CODE

XXXX

Pharmacode Reading Direction

Package leaflet: Information for the user

Loratadine 10 mg Tablets

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 your 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 10 mg Tablets are and what they are used for
2. What you need to know before you take Loratadine 10 mg Tablets
3. How to take Loratadine 10 mg Tablets
4. Possible side effects
5. How to store Loratadine 10 mg Tablets
6. Contents of the pack and other information

1. What Loratadine 10 mg Tablets are and what they are used for

The name of your medicine is Loratadine 10 mg Tablets. Loratadine 10 mg Tablets contain the active ingredient loratadine which belongs to a group of medicines called antihistamines. Loratadine 10 mg 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.

Loratadine 10 mg Tablets relieve symptoms associated with allergic rhinitis (for example hayfever), such as sneezing, runny or itchy nose, and itchy or burning eyes in adults and children over the age of 6 years who weigh more than 30 kg. Loratadine 10 mg 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 10 mg 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 10 mg Tablets

Do not take Loratadine 10 mg 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 breast-feeding

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking this medicine if:
- you have liver disease,
- you are due to have any skin tests for allergies. Do not take Loratadine 10 mg Tablets for two days before having these tests, as loratadine may interfere with the results.

If any of these apply to you, or you are not sure, talk to your doctor, pharmacist or nurse before taking Loratadine 10 mg Tablets.

Children
Do not give Loratadine 10 mg Tablets to children younger than 6 years of age or to children who weigh less than 30 kg. There are other formulations more suitable for children younger than 6 years or with a body weight less than 30 kg.

Children under 2 years of age: The safety and efficacy of Loratadine 10 mg Tablets has not been established. No data are available.

Other medicines and Loratadine 10 mg Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. The side effects of Loratadine 10 mg 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 10 mg Tablets and alcohol
Loratadine 10 mg Tablets have not been shown to add to the effects of an alcoholic drink.

Pregnancy and breast-feeding
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. As a precautionary measure, it is preferable to avoid the use of Loratadine 10 mg Tablets during pregnancy.

Do not take Loratadine 10 mg Tablets if you are breast-feeding, as 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, this medicine is not expected to cause you to be drowsy or less alert. However, very rarely this medicine may cause drowsiness in some people, which may affect their ability to drive or use machines. If this happens to you, you should not drive or operate machinery.

Loratadine 10 mg Tablets contain lactose
Loratadine 10 mg Tablets contain lactose, a type of sugar. 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 10 mg 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. The tablet should be swallowed with water.

Giving this medicine to children
Do not give to children under 6 years of age or to children weighing less than 30 kg. 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 30 kg, a syrup form of this medicine may be more suitable.

Recommended dose

Age and weight	How much to take	How often to take
Adults and children 6 years and older who weigh **more than** 30 kg (4st 7lb)	1 tablet	Once daily
Children who weigh 30 kg (4st 7lb) **or less**	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 10 mg Tablets than you should
If you take more of your medicine than you should, talk to your doctor or pharmacist straight away. No serious problems are expected, however you may get a headache, have a rapid heartbeat or feel sleepy.

If you forget to take your medicine
If you forget to take a dose, take it as soon as you remember, then continue to take the next dose at the usual time. 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, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Stop taking Loratadine 10 mg Tablets and seek urgent medical advice immediately, if you notice the following:
- Severe allergic reaction (including sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing)

This is a very rare side effect (may affect up to 1 in 10,000 people).

Other side effects
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 of age 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:
- dizziness
- convulsion
- fast or irregular heartbeat
- nausea (feeling sick)
- dry mouth
- upset stomach
- liver problems
- hair loss
- tiredness

The frequency of the following side effect is not known:
- weight increased

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 10 mg Tablets

Keep this medicine out of the sight and reach of children.
Do not use after the expiry date that is stated on the carton or label after EXP. The expiry date refers to the last day of that month.
Store the tablets in the original package.
Do not store above 25°C.
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 10 mg Tablets contain:
Each tablet contains 10 mg of the active substance, loratadine. The other ingredients are lactose monohydrate, maize starch and magnesium stearate.

What Loratadine 10 mg Tablets look like and the contents of the pack
Loratadine 10 mg Tablets are small, white, round tablets. They are packed in foil blister packs and are available in cartons of 5, 7, 10, 14, 20, 21 and 30 tablets.

Marketing Authorization Holder and Manufacturer
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