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**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**Loratadine 10 mg
Tablets**
Loratadine

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

This medicine is available without prescription. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. However, you still need to take Loratadine 10 mg Tablets carefully to get the best results from it.

- 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 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 or if you feel worse after taking this medicine.

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 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 10 mg Tablets are and what they are used for

The name of your medicine is Loratadine 10 mg Tablets. It will be referred to as Loratadine Tablets throughout this leaflet.

Loratadine Tablets 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 when you are allergic to something.

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, redness) which is know as hives or nettle rash. Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. What you need to know before you take Loratadine Tablets

DO NOT TAKE Loratadine Tablets

- if you are allergic (hypersensitive) to loratadine or any of the other ingredients of Loratadine Tablets (listed in section 6). An allergic reaction can include skin rash, itching, swelling or breathing difficulties.
- if you are **pregnant** or planning to become pregnant.
- if you are **breast feeding** currently.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Loratadine Tablets

- if you have **severe liver problems**.
- if you have been told that you have an **intolerance** to some sugars.
- if you are due to have skin **tests** for allergies. Do not take Loratadine tablets for two days before having these tests. This is because it may affect the test results.

Children

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

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

Other medicines and Loratadine

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 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.

Laboratory tests

Antihistamines may prevent response to allergens in skin allergy testing, therefore this medicine should be stopped two days prior to such testing.

Taking Loratadine Tablets with food and drink

This medicine may be taken with or without food. Loratadine 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 any medicine.

Pregnancy: the safe use of loratadine during pregnancy has not been established. The use of loratadine during pregnancy is therefore not recommended.

Breast-feeding: loratadine, the active substance in this medicine is excreted in breast milk; therefore the use of Loratadine is not recommended in breast-feeding women.

Driving and using machines

In clinical trials that assessed driving ability, no impairment was observed in patients receiving Ultarin. 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 (milk sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content:

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

3. How to take Loratadine Tablets

Always take Loratadine Tablets exactly as your doctor or pharmacist or nurse has told you. You

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should check with your doctor or pharmacist if you are not sure.

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

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.

Do not give to children under 2 years or who weigh 30 kg (4st 7lb) or less.

There are other formulations more suitable for children younger than 6 years or with a body weight of 30 kg or less. Not recommended for children under 2 years old.

How much to take:

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 x 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 Tablets than you should
If you may have taken more Loratadine than you should, talk to your doctor or pharmacist immediately. Overdose may cause headaches, sleepiness or a faster heart beat. **Immediate medical attention should be sought in the event of an overdose;** take your tablets along to show to your doctor, if possible.

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 product, ask your doctor or pharmacist or nurse.

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

You must stop taking Loratadine Tablets immediately and consult your doctor if you develop any allergic reaction to this medicine. This can consist of

- skin rash or eruptions (including inside the mouth)
- itching
- swelling of the face, tongue, lips, hands, feet
- breathing difficulties
- severe allergic reaction (including swelling)

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

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
- rash
- tiredness
- dry eye

The frequency of the following side effect is not known (i.e. frequency cannot be estimated from the available data):

- weight gain

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, website 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 your tablets 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.
- Store in the original package.
- 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 Tablets contain

- The active substance is Loratadine 10 mg.
- The other ingredients are lactose monohydrate, 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 sizes of 30 tablets.

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Manufacturer
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This leaflet was last revised in 07/2023.

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