

Package leaflet: Information for the user

Lorat 10mg Tablets

Loratadine

ROWEX[®]

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

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

1 What Lorat is and what it is used for

Lorat is an antiallergy medicine. It helps control your allergic reaction and its symptoms.

Lorat relieves symptoms associated with, for example, hay fever, allergy to dust mites (allergic rhinitis) such as:

- Sneezing
- Runny or itchy nose
- Itchy palate
- Itchy, red or tearing eyes

Lorat is also used to relieve symptoms such as itching and hives (associated with chronic urticaria of unknown cause).

2 What you need to know before you take Lorat

Do not take Lorat

- if you are allergic to loratadine or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Lorat

- if you have a severe liver disease
- if you have to undergo any **skin tests**, tell your doctor that you are taking Lorat as it may be necessary to stop taking this medicine at least 2 days (48 hours) before the test to make sure the result of the test is correct. You can carry on as usual after the test.

Other medicines and Lorat

Interaction of loratadine may occur with medicines known to inhibit certain enzymes in the liver resulting in elevated levels of loratadine. This may lead to an increase in adverse events (see section 4 'Possible side effects').

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

Lorat with food and drink

Lorat may be taken with or without a meal.

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 any medicine. If you are pregnant, taking Lorat is not recommended. If you are breast-feeding, taking Lorat is not recommended, because loratadine is excreted into human milk.

Driving and using machines

At the recommended dose Lorat is 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.

Lorat contains lactose.

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

continued on the next page >>

3 How to take Lorat

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

Lorat is intended for oral use.

Adults and children over 12 years of age and weighing more than 30kg:

Take one tablet once a day.

Children 2 to 12 years of age and weighing more than 30kg:

Take one tablet once a day.

Children 2 to 12 years of age and weighing less than 30kg:

Take half a tablet once a day.

Children under 2 years of age or weighing less than 30kg:

Lorat should not be given to children under two years of age.

Patients with severe liver problems:

Adults and children with body weight over 30kg should start with a lower dose: Take one tablet every other day. Children weighing 30kg or less should take half a tablet every other day.

If you take more Lorat than you should

If you have taken more Lorat than recommended contact your doctor or pharmacist. Taking more tablets than recommended may cause drowsiness, rapid heart beat and headache.

If you forget to take Lorat

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 dose.

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.

- Children complained more often about headache, nervousness and tiredness (fatigue)
- Adults complained more often about sleepiness, headache, increased appetite and difficulty in sleeping

Very rare side effects (may affect up to 1 in 10,000 people)

- Cases of severe allergic reactions (including swelling of the face or throat, difficulty in breathing, wheezing and itching)

- dizziness, fits
- faster heartbeat, feeling your heartbeat
- feeling sick, dry mouth
- inflammation of stomach lining
- abnormal liver function
- rash, hair loss
- tiredness

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2;
Tel: +353 1 6764971; Fax +353 1 6762517.
Website: www.hpra.ie;
e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Lorat

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage precautions.

Do not use this medicine 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 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 Lorat contains

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

What Lorat looks like and contents of the pack

Lorat 10mg Tablets are white oval tablets, scored and marked 'LT 10' on one face. The tablets can be divided into equal halves. Pack sizes of 30 tablets are available subject to prescription.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Rowex Ltd., Bantry, Co Cork, Ireland

Manufacturer:

Rowa Pharmaceuticals Ltd, Bantry, Co. Cork, Ireland
Salutas Pharma GmbH, Otto-von-Guericke Allee 1,
39179 Barleben, Germany

This leaflet was last revised in February 2015