

PATIENT INFORMATION LEAFLET

Loratadine 5 mg/5 ml Syrup Loratadine

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take your medicine 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.
- You must contact a doctor if your symptoms worsen or do not improve after a few days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Loratadine is and what it is used for
2. Before you take Loratadine
3. How to take Loratadine
4. Possible side effects
5. How to store Loratadine
6. Further information

1. WHAT LORATADINE IS AND WHAT IT IS USED FOR

Loratadine 5 mg/5 ml Syrup ('Loratadine') belongs to a group of medicines called antihistamines. It works by counteracting the effects of histamine which is produced naturally by your body's defence system, but may be over-produced in allergic reactions.

Loratadine is used to relieve the **symptoms of hayfever** (allergic rhinitis) in adults and children over the age of 2 years, which include:

- sneezing
- irritated, runny or blocked nose
- itchy, red and watering eyes

It is also used to relieve the **symptoms of skin allergies** in adults and children (over the age of 2 years), which include:

- rash, itching and urticaria (hives).

2. BEFORE YOU TAKE LORATADINE

DO NOT TAKE Loratadine if you are:

- allergic to Loratadine, or any of the other ingredients of Loratadine 5 mg/5 ml Syrup (see Section 6 and end of Section 2).
- pregnant or planning to become pregnant.
- breast-feeding, as Loratadine can pass into breast milk.

Take special care with Loratadine if:

- you have severe liver problems
- you have an hereditary intolerance to some sugars.

Loratadine should not be taken for 48 hours before a skin test, since it may affect the results.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including

medicines obtained without a prescription. There are some medicines which may increase the risk of side effects.

Especially, tell your doctor if you are taking any of the following:

- cimetidine (for stomach problems)
- erythromycin (an antibiotic)
- ketoconazole or fluconazole (for fungal infections)
- quinidine (for heart problems)
- fluoxetine (for depression).

Taking Loratadine with food and drink

You must avoid excessive alcohol consumption while you are taking this medicine, as with all antihistamine medicines.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

Loratadine is not recommended in pregnant or breast-feeding women.

Driving and using machines

Loratadine does not usually cause drowsiness at the recommended dose. However, individuals react differently, so do not drive or operate machinery until you know how it affects you.

Important information about some of the ingredients of Loratadine

Loratadine also contains:

- **sucrose:** It contains 3.0 g of sucrose per 5 ml dose which may be harmful to the teeth. Tell your doctor before taking this medicine if you have an intolerance to some sugars or diabetes mellitus.

3. HOW TO TAKE LORATADINE

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Loratadine is to be taken only by mouth, and is not to be taken by children aged under 2 years.

The spoon provided holds 5 ml of your medicine.

Shake the bottle well before use.

The usual dose is:

Adults and children over 12 years:	Two 5 ml spoonfuls once daily
Children aged 2 to 12 years: weighing more than 30 kg weighing less than 30 kg	Two 5 ml spoonfuls once daily One 5 ml spoonful once daily
Patients with severe liver problems: Adults and children more than 30 kg Children weighing less than 30 kg	Two 5 ml spoonfuls on alternate days One 5 ml spoonful on alternate days

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Do not exceed the stated dose

If you take more Loratadine than you should:

If you or your child may have taken too much of this medicine, talk to a doctor or pharmacist immediately. You or the child may feel drowsy, have a headache or rapid heartbeat.

If you forget to take Loratadine

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for the next dose. Do not take a double dose to make up for the forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

Swelling of the face, mouth, lips or throat can be signs of an allergic reaction. If this happens to you, STOP taking Loratadine and tell your doctor immediately, or go to your nearest hospital. Take the bottle with you if you can.

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:

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

The following not known side effect (cannot be estimated from the available data) has also been seen during the marketing of loratadine:

- 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. By reporting side effects

you can help provide more information on the safety of this medicine.

5. HOW TO STORE LORATADINE

Keep out of the sight and reach of children, and do not store above 25°C.

Do not use Loratadine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Use within 6 months after opening.

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. FURTHER INFORMATION

What Loratadine contains

- The **active ingredient** is Loratadine: 5 mg in each 5 ml of syrup.
- The **other ingredients** are: sucrose, glycerol (E422), propylene glycol, sodium benzoate (E211), citric acid monohydrate, peach flavour and purified water (see end of Section 2 for further information).

What Loratadine looks like and contents of the pack

Loratadine is a colourless solution, with the taste of peach. It is available in pack sizes of 60 ml, 100 ml and 150 ml amber glass bottles, and includes a 5 ml spoon.

Marketing Authorisation Holder and Manufacturer
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

PL 04917/0067

This leaflet was last updated in 11/2017.