

Package leaflet: Information for the User

Clarityn® 10 mg 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 or if you feel worse. See section 4.

What is in this leaflet:

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

1. What Clarityn is and what it is used for

The full name of your medicine is Clarityn tablets.

What Clarityn is

Clarityn tablets contain the active substance loratadine which belongs to a class of medicines called “antihistamines”.

How Clarityn works

Clarityn helps 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 Clarityn should be taken

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

Clarityn may also be used to help relieve symptoms of urticaria (itching, redness and number and size of hives). The effect of Clarityn 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 Clarityn

Do not take Clarityn if

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Clarityn if:

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

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Clarityn.

Children

Do not give Clarityn 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 who weigh 30 kg or less.

Children under 2 years of age:

The safety and efficacy of Clarityn have not been established. No data are available.

Other medicines and Clarityn

The side effects of Clarityn, 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.

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

Clarityn with alcohol

Clarityn has 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 Clarityn during pregnancy. Do not take Clarityn 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, Clarityn 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.

Clarityn contains lactose

Clarityn contains 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 Clarityn

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 score line of the tablet is only there to help you break the tablet if you have difficulty swallowing it whole.

How much to take:

Adults and children 6 years of age and older with a body weight greater than 30 kg:

Take one tablet once daily with a glass of water, with or without food.

Body weight of 30 kg or less:

Do not give Clarityn. There are other formulations more suitable for children younger than 6 years who weigh 30 kg or less.

Children under 2 years of age:

Clarityn is not recommended for children younger than 2 years old.

Adults and children with severe liver problems:

Adults and children who weigh more than 30 kg:

Take one tablet once every other day with a glass of water, with or without food. However, you should talk to your doctor, pharmacist or nurse before taking this medicine.

If you take more Clarityn than you should

If you take more Clarityn 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 Clarityn

- If you forget to take your dose, take it as soon as you remember, then continue to take it 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. 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:

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

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 HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Ireland; 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 Clarityn

- Keep this medicine out of the sight and reach of children.
- This medicine does not require any special storage conditions.

- Do not use this medicine after the expiry date which is stated on the blister and 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.
- 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 Clarityn contains

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

What Clarityn looks like and contents of the pack

Tablet.
White, to off-white, oval tablet with flask and bowl, scoreline and the number "10" on one side.
Clarityn tablets are available in pack sizes of 7 tablets.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number:
PPA 465/336/1

Manufacturer

Schering-Plough Labo NV, Industriepark, 30 B-2220, Heist-op-den-Berg, Belgium or Schering-Plough, Rue Louis Pasteur, 2 F-14200 Herouville Saint Clair, France.

Clarityn is a registered trademark of Bayer Consumer Care AG.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Denmark, Finland, Iceland, Ireland, Norway, Sweden: Clarityn
Belgium, Luxembourg: Claritine
Italy: Clarityn
France, Greece, Spain: Clarityne
Germany: Lisino S
Netherlands: Claritine
Portugal: Claritine, Alertrin
UK: Clarityn (Allergy)

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