



Package leaflet: Information for the User
Clarityn 1 mg/ml syrup
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 syrup.

What Clarityn is

Clarityn syrup contains 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 in adults and children over the age of 2 years.

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 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 to children younger than 2 years old.

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:

Maltitol liquid: This medicine contains 3 g maltitol liquid in each 5 ml of the syrup which is equivalent to 600.69 mg/ml. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sorbitol: This medicine contains 700 mg sorbitol in each 5 ml of the syrup which is equivalent to 140 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Propylene glycol: This medicine contains 250 mg propylene glycol in each 5 ml of the syrup which is equivalent to 50 mg/ml.

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 5 ml of the syrup, that is to say essentially 'sodium-free'.



Sodium benzoate: This medicine contains 2.5 mg sodium benzoate in each 5 ml of the syrup which is equivalent to 0.5 mg/ml.

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.

How much to take:

Adults and children over 12 years of age:

Take once daily 10 ml (measuring cup filled to 10 ml line).

Children aged 2 to 12 years are dosed by weight:

Body weight more than 30 kg:

Give once daily 10 ml (measuring cup filled to 10 ml line).

Body weight 30 kg or less:

Give once daily 5 ml (measuring cup filled to 5 ml line).

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 once every other day 10 ml (measuring cup filled to 10 ml line)

Children who weigh 30 kg or less:

Give once every other day 5 ml (measuring cup filled to 5 ml line).

However, you should talk to your doctor, pharmacist or nurse before taking this medicine.

Taking this medicine

- Water or other liquid is not needed to swallow the syrup
- The syrup may be taken with or without food.

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

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

- 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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: 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.
- Do not freeze. Keep the bottle in the outer carton in order to protect from light. Do not use this medicine after the expiry date which is stated on the bottle after EXPIRY. The expiry date refers to the last day of that month.
- Clarityn syrup is to be used within 1 month after opening.
- Do not use this medicine if you notice any change in the appearance of the syrup.
- 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 to protect the environment.

6. Contents of the pack and other information

What Clarityn contains

- The active substance is loratadine. Each 10 ml of the syrup contains 10 mg loratadine.



- The other ingredients are disodium edetate (E386), sodium dihydrogen phosphate dihydrate (E339), maltitol liquid (E965), propylene glycol (E1520), glycerol (E422), phosphoric acid (E338), sodium benzoate (E211), sorbitol liquid (E420), sucralose (E955), artificial mixed berry flavour and purified water.

What Clarityn looks like and contents of the pack

Syrup.

Clear colourless to light yellow syrup.

Clarityn syrup is available in opaque white plastic bottles of 60, 120 or 150 ml with a tamper-evident, child-proof plastic cap. A measuring cup with 5 ml and 10 ml dosing lines is included.

Not all bottle sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Bayer Limited, The Atrium, Blackthorn Road, Dublin 18.

Manufacturer:

Berlimed S.A.

Poligono Industrial Santa Rosa

Calle Francisco Alonso No.7

28806 Alcalá de Henares (Madrid)

Spain

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

Belgium, Luxemburg, Netherlands, Portugal: Claritine

Ireland, Italy, Sweden: Clarityn

France, Greece, Spain: Clarityne

UK: Clarityn (Allergy)

This leaflet was last approved in March 2017.