

Package leaflet: Information for the User
Clarityn Rapide Allergy 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 Rapide Allergy is and what it is used for
2. What you need to know before you take Clarityn Rapide Allergy
3. How to take Clarityn Rapide Allergy
4. Possible side effects
5. How to store Clarityn Rapide Allergy
6. Contents of the pack and other information

1. What Clarityn Rapide Allergy is and what it is used for

The full name of your medicine is Clarityn Rapide Allergy. Clarityn Rapide Allergy are “oral lyophilisates” which are tablets that dissolve in your mouth instantly.

What Clarityn Rapide Allergy is

Clarityn Rapide Allergy contains the active substance loratadine which belongs to a class of medicines called “antihistamines”.

How Clarityn Rapide Allergy works

Clarityn Rapide Allergy 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 Rapide Allergy 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 who weigh more than 30 kg.

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

The effect of Clarityn Rapide Allergy 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 Rapide Allergy

Do not take Clarityn Rapide Allergy 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 Rapide Allergy if:

- you have liver disease
- you are scheduled to have any skin tests for allergies. Do not take Clarityn Rapide Allergy 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 Rapide Allergy.

Children

Do not give Clarityn to children younger than 2 years old or to children 2 to 12 years old who weigh less than 30 kg. There are other formulations more suitable for children 2 to 12 years old who weigh less than 30 kg.

Other medicines and Clarityn Rapide Allergy

The side effects of Clarityn Rapide Allergy 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 Rapide Allergy with alcohol

Clarityn Rapide Allergy 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 Rapide Allergy during pregnancy.

Do not take Clarityn Rapide Allergy 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 Rapide Allergy 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.

3. How to take Clarityn Rapide Allergy

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 one oral lyophilisate once daily.

Children aged 2 to 12 years are dosed by weight:

Body weight more than 30 kg:

Take one oral lyophilisate once daily.

Body weight 30 kg or less:

Do not give Clarityn Rapide Allergy. There are other formulations more suitable for children 2 to 12 years old who weigh 30 kg or less.

Clarityn Rapide Allergy 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 oral lyophilisate once every other day. However, you should talk to your doctor, pharmacist or nurse before taking this medicine.

Taking this medicine:

- Carefully peel open an individual blister unit.
- Remove the oral lyophilisate from the blister unit, without crushing it.
- Place the oral lyophilisate in your mouth and it will disperse instantly.
- Water or other liquid is not needed to swallow the oral lyophilisate.
- The oral lyophilisate may be taken with or without food.

If you take more Clarityn Rapide Allergy than you should

If you take more Clarityn Rapide Allergy 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 Rapide Allergy

- 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.

The frequency of the following side effect is not known:

- 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 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 Clarityn Rapide Allergy

- Keep this medicine out of the sight and reach of children.
- Store in the original package in order to protect from moisture; this medicine does not require any special storage temperature conditions.
- Do not use this medicine after the expiry date which is stated on the blister after EXPIRY. 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 oral lyophilisate.
- 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 Rapide Allergy contains

- The active substance is loratadine. Each oral lyophilisate contains 10 mg loratadine.
- The other ingredients are gelatin, mannitol (E421), citric acid anhydrous, mint flavour.

What Clarityn Rapide Allergy looks like and contents of the pack

Oral lyophilisate.

White, round, tablet-shaped unit debossed with “C10.”

Clarityn Rapide Allergy is available in pack sizes of 7, 8, 10, 20 or 30 units of oral lyophilisates.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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

Manufacturer:

Schering-Plough Labo NV, Industriepark, 30 B-2220 Heist-op-den-Berg, Belgium

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

Belgium, Luxemburg: Clarityn Reditabs

Greece: Clarityne

Ireland: Clarityn Rapide Allergy

Italy: Clarityn

Portugal: Claritine Zydis

UK: Clarityn Rapide (Allergy)

This leaflet was last approved in December 2017.