

Clarityn[®] Rapide

Allergy 10mg Tablets
Loratadine
Fast Dissolving Tablets



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, if you feel worse or if your symptoms change. 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* 10 mg Tablets. *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 group 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 Rapide Allergy 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 and redness) which is often known as hives or nettle rash.

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).
- you are pregnant or breastfeeding.

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 Rapide Allergy* 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.

Giving this medicine to children

Clarityn Allergy Syrup may be preferred for children. It is important to know how much your child weighs to make sure that you give the correct amount of medicine. For example, a 9 year old child weighs about 30kg (4st 7lbs). If in doubt weigh your child and then follow the instructions in the table.

Do not give to children under 2 years or who weigh 30 kg (4st 7lb) or less.

How much to take

Age	How much to take	How often to take
Children of 2 to 12 years who weigh more than 30kg (4st 7lb)	1 x tablet	Once daily
Adults and children over 12 years	1 x tablet	Once daily

If you have severe liver problems your doctor or pharmacist may advise you to take the recommended amount every other day. If this applies to you follow their instructions.

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 gain

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

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 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 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), anhydrous citric acid, mint flavour.

What *Clarityn Rapide Allergy* looks like and the contents of the pack

Clarityn Rapide Allergy is a white, round tablet-shaped unit, marked with "C10". The technical term for these units is "oral lyophilisates", which are a kind of fast dissolving tablet.

Clarityn Rapide Allergy is available in pack sizes of 7, 8 or 10 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

MAH: Bayer plc, 400 South Oak Way, Reading, RG2 6AD, UK.

Manufacturer: Aesica Pharmaceuticals GmbH, Alfred-Nobel-Str. 10, 40789 Monheim, Germany.

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Bayer