

Package Leaflet: Information for the User

Clarityn 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.
- 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 Allergy tablets are and what they are used for
2. What you need to know before you take Clarityn Allergy Tablets
3. How to take Clarityn Allergy Tablets
4. Possible side effects
5. How to store Clarityn Allergy Tablets
6. Contents of the pack and other information

1. What Clarityn Allergy tablets are and what they are used for

The full name of your medicine is Clarityn Allergy 10 mg Tablets.

What Clarityn Allergy Tablets are

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

How Clarityn Allergy Tablets work

Clarityn Allergy tablets help 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 Allergy Tablets should be taken

Clarityn Allergy tablet 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 Allergy Tablets 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 Allergy Tablets 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 Allergy Tablets

Do not take Clarityn Allergy Tablets 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 Allergy Tablets if:

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

Children

Do not give Clarityn Allergy Tablets 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 Allergy Tablets

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

Clarityn Allergy Tablets with alcohol

Clarityn Allergy Tablets have not been shown to add to the effects of an alcoholic drink.

Pregnancy and breast-feeding

Do not take Clarityn Allergy Tablets if you are pregnant.

Do not take Clarityn Allergy Tablets if you are breast-feeding. Loratadine is excreted in breast milk.

Driving and using machines

At the recommended dose, Clarityn Allergy Tablets are 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 Allergy Tablets contains lactose

Clarityn Allergy Tablets 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 Allergy Tablets

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.

Giving this medicine to children

Clarityn Allergy syrup may be preferable 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 7lb). 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 30 kg (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.

If you take more Clarityn Allergy Tablets than you should

If you take more Clarityn Allergy Tablets 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 Allergy Tablets

- 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 product, 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
- dizziness
- 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 (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

Malta: ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira Website: www.medicinesauthority.gov.mt e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Clarityn Allergy Tablets

- This medicinal product does not require any special storage conditions.

- Keep this medicine out of the sight and reach of children.
- 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 the 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 to protect the environment.

6. Contents of the pack and other information

What Clarityn Allergy Tablets contain

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

What Clarityn Allergy Tablets looks like and contents of the pack

Clarityn Allergy tablets are white, to off-white, oval tablets with flask and bowl, scoreline and the number "10" on one side.

Clarityn Allergy tablets are available in pack sizes of 5, 7, 10, 14, 15, 20, 21, 28, 30, or 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Merck Sharp & Dohme Limited

Hertford Road

Hoddesdon

Hertfordshire

EN11 9BU

United Kingdom

Manufacturer:

Schering-Plough Labo NV

Heist-op-den-Berg

Belgium

Schering-Plough

Rue Louis Pasteur, 2

F-14200 Herouville Saint Clair

France

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