

# Clarityn®

Allergy 10mg 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, 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 Tablets* relieves symptoms associated with allergic rhinitis (for example, hay fever), such as sneezing, runny or itchy nose, and burning or itchy eyes.

*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 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 with a body weight of 30 kg or less.

Children under 2 years of age:

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

## Other medicines and *Clarityn Allergy Tablets*

The side effects of *Clarityn Allergy Tablets* 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 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

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 Allergy Tablets* during pregnancy.

Do not take *Clarityn Allergy Tablets* 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 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**

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 who weigh 30 kg (4st 7lb) or less. There are other formulations more suitable for children younger than 6 years or with a body weight of 30 kg or less. Not recommended for children under 2 years old.

#### **How much to take:**

Age and weight	How much to take	How often to take
Adults and children 6 years and older who weigh <b>more than 30kg (4st 7lb)</b>	1 x tablet	Once daily
Children who weigh <b>30 kg (4st 7lb) or less</b>	Not recommended.	
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 (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](http://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](http://www.medicinesauthority.gov.mt), e-mail: [postlicensing.medicinesauthority@gov.mt](mailto: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 a score on one side and plain on the other side.

*Clarityn Allergy tablets* are available in pack sizes of 7, 10, 14, 20, 30, or 60 tablets.

Not all pack sizes may be marketed.

##### **Marketing Authorisation Holder and Manufacturer**

###### **Marketing Authorisation Holder:**

Bayer plc  
400 South Oak Way  
Reading  
RG2 6AD  
United Kingdom

Manufacturer:  
Bayer Bitterfeld GmbH  
OT Greppin  
Salegaster Chaussee 1  
06803 Bitterfeld-Wolfen  
Germany

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