



BAYER ARTWORK PANEL

Bayer Ref No: **BAY432725**
 Trident Reference No: TR1949353
 Brand: Claritin
 Range: Claritin
 Product: Syrup
 Pack Type: Leaflet
 Pack Size: 60ml Pack
 Action: **B**
 Date: 16/09/20
 Country: UK

Finished Goods Code: **87411702**
 Synaps Request Code: **NPI019201**
 Component Code: **31000642**

CAD Ref No: PIL 238 x 180 Point Claire
 Printer: CCL Montréal
 Packaging Site: Delpharm Montreal Canada QC [CA]
 Substrate: White Paper

Barcode 1 Type: N/A
 Barcode 1 Mag: N/A
 Barcode 2 Type: N/A
 Barcode 2 Mag: N/A
 Pharmacode No/NE: 10001000(391)

Technical & Non Printing Items
 Cutter  Guides

Colours

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ARTWORK APPROVAL PANEL

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Claritin® Allergy 1mg/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, if you feel worse or if your symptoms change. See section 4.

What is in this leaflet:

1. What *Claritin Allergy Syrup* is and what it is used for
2. What you need to know before you take *Claritin Allergy Syrup*
3. How to take *Claritin Allergy Syrup*
4. Possible side effects
5. How to store *Claritin Allergy Syrup*
6. Contents of the pack and other information

1. What *Claritin Allergy Syrup* is and what it is used for

The full name of your medicine is *Claritin Allergy Syrup*.

What *Claritin Allergy Syrup* is

Claritin Allergy Syrup contains the active substance loratadine which belongs to a class of medicines called "antihistamines".

How *Claritin Allergy Syrup* works

Claritin Allergy Syrup 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 *Claritin Allergy Syrup* should be taken

Claritin Allergy Syrup relieves symptoms associated with allergic rhinitis (for example, hayfever), such as sneezing, runny or itchy nose and burning or itchy eyes in adults and children over the age of 2 years.

The syrup 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 *Claritin Syrup* 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 *Claritin Allergy Syrup*

Do not take *Claritin Allergy Syrup*

- if you are allergic (hypersensitive) to loratadine or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or breast-feeding

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking *Claritin Allergy Syrup*.

- if you have liver disease
- if you are scheduled to have any skin tests for allergies. Do not take *Claritin Allergy Syrup* 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 *Claritin Allergy Syrup*.

Children

Do not give *Claritin Allergy Syrup* to children younger than 2 years old.

Other medicines and *Claritin Allergy Syrup*

The side effects of *Claritin Allergy Syrup* 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.

Claritin Allergy Syrup with alcohol

Claritin Allergy Syrup 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 *Claritin Allergy Syrup* during pregnancy.

Do not take *Claritin Allergy Syrup* 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, *Claritin Allergy Syrup* 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.

Claritin Allergy Syrup contains:

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

Sorbitol: This medicine contains 700mg sorbitol in each 5ml of syrup which is equivalent to 140mg/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 taking this medicine.

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

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

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

3. How to take *Claritin Allergy Syrup*

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.

Taking this medicine

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





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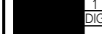

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Giving this medicine to children:

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 under 2 years.

How much to take:

The recommended dose is:

Age	How much to take	How often to take
Children of 2 to 12 years who weigh 30kg (4st 7lb) or less	5ml (measuring cup filled to 5ml line)	Once daily
Children of 2 to 12 years who weigh more than 30kg (4st 7lb)	10ml (measuring cup filled to 10ml line)	Once daily
Adults and children over 12 years	10ml (measuring cup filled to 10ml line)	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 syrup than you should

If you take more *Clarityn Allergy Syrup* 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 your syrup

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:

- 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 via the Yellow Card Scheme at:

<http://www.mhra.gov.uk/yellowcard> or search for MHRA

Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *Clarityn Allergy Syrup*

- 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 relates to the last day of that month.
- Clarityn Allergy Syrup* is to be used within 1 month after opening.
- Do not use this medicine if you notice any changes 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 Allergy Syrup* contains

- The active substance is loratadine. Each 10ml of the syrup contains 10mg 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 berries flavour and purified water.

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

Clarityn Allergy Syrup is a clear, colourless to light yellow syrup.

Clarityn Allergy Syrup is available in white opaque plastic bottles of 60ml with a tamper-evident, childproof plastic cap. A measuring cup with 5ml and 10ml dosing lines is included.

Not all bottle sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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

Manufacturer:

BerilMed S.A.
 Poligono Industrial Santa Rosa
 Calle Francisco Alonso No.7
 28806 Alcalá de Henares (Madrid)
 Spain

This leaflet was last revised in June 2020.

Bayer

