

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution is and what it is used for
2. What you need to know before you take Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution
3. How to take Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution
4. Possible side effects
5. How to store Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution
6. Contents of the pack and other information

1. What Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution is and what it is used for

The full name of your medicine is Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution.

What Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution is

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution contains the active substance loratadine which belongs to a class of medicines called "antihistamines".

How Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution works

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution 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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution should be taken

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution 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 medicine 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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution 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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution

Do not take Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution

- 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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution:

- if you have liver disease
- if you are scheduled to have any skin tests for allergies. Do not take Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution 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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution.

Children

Do not give Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution to children younger than 2 years old.

Other medicines and Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution

The side effects of Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution 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.

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution with alcohol

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution 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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution during pregnancy.

Do not take Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution if you are breast-feeding. Loratadine is excreted in breast milk.

Driving and using machines

At the recommended dose, Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution 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.

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution contains sucrose

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution contains 6g of sucrose per dose; this should be taken into account in those patients with diabetes.

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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution

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 medicine.
- The medicine may be taken with or without food.

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	1 x 5ml spoonful	Once daily
Children of 2 to 12 years who weigh more than 30kg (4st 7lb)	2 x 5ml spoonfuls	Once daily
Adults and children over 12 years	2 x 5ml spoonfuls	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 medicine than you should

If you take more Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution 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 medicine

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 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 via the Yellow Card Scheme at: 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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions. 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 'Exp'. The expiry date relates to the last day of that month.
- Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution is to be used within 1 month after opening.
- Do not use this medicine if you notice any changes in the appearance of the medicine.
- 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 Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution contains

- The active substance is loratadine. Each 5ml of the medicine contains 5mg loratadine.
- The other ingredients are propylene glycol E1520, glycerol (E422), sucrose, citric acid anhydrous, sodium benzoate (E211), artificial peach flavouring and purified water.

What Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution looks like and contents of the pack

Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution is a clear, colourless to light yellow solution. Bell's Healthcare Children's Allergy Relief 5mg/5ml Oral Solution is available in amber glass bottles of 100 ml with a tamper-evident, childproof, polypropylene cap. A dosage spoon is included.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Relonchem Ltd.
Cheshire House
Gorsey Lane
Widnes
WA8 0RP
United Kingdom

Manufacturer:

Bell Sons & Co (Druggists) Ltd.
Gifford House
Slaidburn Crescent
Southport
PR9 9AL
United Kingdom

This leaflet was last revised in May 2019.

**PL 20395/0248
C73-0387 Ver.A.**