

# Benadryl<sup>®</sup> Allergy

## Children's 6+

### 1 mg/ml Oral Solution Cetirizine

- This medicine is used to relieve the symptoms of hay fever and other allergic conditions such as pet allergies, dust allergies and skin reactions.
- This medicine is for use by children aged 6 years and over and can also be used by adults.

Read the leaflet carefully before use. Keep this leaflet, you might need it again.

## 1 What the medicine is for

**Benadryl Allergy Children's 6+ 1mg/ml Oral Solution treats children aged 6 years and over and adults:** Suffering from hay fever and year-round allergies such as dust or pet allergies. It can also be used to treat the symptoms of urticaria, also known as hives, where the skin looks blotchy, with white raised wheals (bumps) surrounded by redness.

The medicine contains cetirizine dihydrochloride which is an antihistamine that helps relieve allergy symptoms associated with the above conditions, such as sneezing, runny nose, watery eyes and skin rashes.

## 2 Before giving this medicine to your child

This medicine is suitable for most children aged 6 years and over, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist. If you are an adult taking this product you need to follow the same precautions as listed below for children

### **X** Do not give this medicine...

- If your child has ever had a **bad reaction** to **cetirizine dihydrochloride**, to **hydroxyzine** or **piperazine derivatives** or to any other ingredients of this medicine (See section 6).
- If your child has **serious kidney problems**.

If these apply to your child now or in the past, **get advice from a doctor or pharmacist without giving Benadryl Allergy Children's 6+ 1mg/ml Oral Solution**.

### **!** Talk to your doctor or pharmacist...

- If your child has **liver** or **kidney problems**, as they may need to take a lower dose.
- If your child is an **epileptic** or at **risk of convulsions (fits)**.
- If your child has difficulty **passing urine**, please ask your doctor for advice.

If these bullet points apply to your child, **talk to a doctor or pharmacist**.

### If you are an adult taking this medicine:

The following additional warning is included in case an adult takes this product.

- If you are pregnant or breast-feeding, think you may be pregnant or planning on have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **!** Special warnings about this medicine

- In most people this product does not cause drowsiness. However, there are rare exceptions and you should take care when you use this product for the first time. If this product makes you feel drowsy, do not drive or operate machinery.
- As with all antihistamines, it is advisable to avoid excessive alcohol consumption when taking this medicine.
- You should stop taking this product for 3 days before undergoing a skin allergy test because antihistamines can affect the results of the test.

### **!** Some of the ingredients can cause problems

- Methyl (E218) and propyl (E216) parahydroxybenzoate may cause allergic reactions which could possibly be delayed.
- This medicine contains 2.25g sorbitol in each 5ml which is equivalent to 450mg/ml. Sorbitol is a source of fructose. If your doctor has told you that your child has an intolerance to some sugars or if your child has been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before your child receives this medicine. Sorbitol may cause

gastrointestinal discomfort and a mild laxative effect.

- This medicine contains less than 1mmol sodium (23mg) per 5ml, that is to say essentially 'sodium-free'.
- This medicine contains 250mg propylene glycol (E1520) in each 5ml dose, which is equivalent to 50mg/ml.
- This medicine contains 0.013 mg benzyl alcohol in each 5ml which is equivalent to 0.0026mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding, or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

## 3 How to give this medicine to your child

Check the following tables to see how much medicine to give.

- For oral use only.
- Do not give more than the stated dose shown in the tables.

### **i** Children under 6 years old:

This medicine is not recommended for children aged under 6 years old.

### **i** Children aged 6 - 12 years:

Age	Dosage
<b>Children aged 6-12 years</b>	■ Give one 5ml spoonful in the morning and one 5ml spoonful in the evening.

### **i** Adults and children aged 12 years and above:

Age	Dosage
<b>Adults and children aged 12 years and above</b>	■ Give two 5ml spoonfuls once a day.

If symptoms persist or worsen, stop use and consult your doctor or pharmacist.

### **!** If anyone has too much

If anyone has too much contact a doctor or your nearest Accident and Emergency Department (Casualty) taking this leaflet and pack with you.

turn over ▶



### If you forget to give the medicine

If you forget to give a dose, give the next dose when needed provided that you do not give more than the recommended dose in 24 hours.

**Do not** give a double dose.

## 4 Possible side-effects

Benadryl Allergy Children's 6+ 1mg/ml Oral Solution can have side-effects, although not everybody gets them.

### If your child experiences any of the following, stop giving this medicine and seek immediate medical help:

- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalised Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with this medicine.
- Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- Bruising or bleeding more easily than normal.
- Convulsions (fits) or hallucinations.
- Loss of consciousness.

### If your child experiences any of the following, stop giving this medicine and talk to your doctor:

- Confusion.
- Abnormal liver function tests.
- Rapid heartbeat.

### Other effects which may occur include:

Common (May affect up to 1 in 10 people):

- Headache or dizziness.
- Drowsiness or tiredness.
- Restlessness.
- Dry mouth, sore throat.
- Upset stomach, abdominal pain, diarrhoea, nausea.
- Runny nose.

Uncommon (May affect up to 1 in 100 people):

- Agitation.
- Unusual weakness.
- Feeling of general discomfort or uneasiness.

- Pins & needles.

Rare (May affect up to 1 in 1,000 people):

- Aggression, depression.
- Weight gain.
- Difficulty sleeping.
- Movement disorders including tremor, muscle spasm and tics.

Very rare (May affect up to 1 in 10,000 people):

- Taste disorder.
- Feeling abnormal, cough.
- Blurred vision, eye swelling, eye movement disorder.
- Difficult, painful or involuntary urination.

Other effects which may occur but it is unknown how often:

- Vertigo, increased appetite.
- Amnesia, memory impairment.
- Inability to pass urine.
- Eye pain.
- Joint pain.
- Pruritus (intense itching) when you stop giving this medicine.
- Nightmares.

In very rare cases people have thought about committing suicide and if you feel this when then stop taking the medicine and see your doctor. Cases of impotence in adults have also been reported.

### Reporting of side-effects

If your child experiences 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

The following details are applicable for Malta: ADR Reporting [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

By reporting side-effects, you can help provide more information on the safety of this medicine.

## 5 Storing this medicine

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

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 protect the environment.

## 6 Further information

### What's in this medicine?

**The active ingredient in Benadryl Allergy Children's 6+ 1mg/ml Oral Solution is:** 1mg Cetirizine dihydrochloride in each 1ml.

**Other ingredients are:** Sorbitol (E420), glycerol, propylene glycol (E1520), sodium saccharinate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), banana flavouring (containing benzyl alcohol), sodium acetate, glacial acetic acid and purified water.

### What the medicine looks like

Benadryl Allergy Children's 6+ 1mg/ml Oral Solution is a clear colourless, sugar free oral solution available in 70ml bottles.

### Product Licence holder and manufacturer:

McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

**This leaflet was revised September 2020.**

Benadryl is a registered trade mark.

