

Package leaflet: Information for the Patient
CETIRIZINE HYDROCHLORIDE 5mg/5ml SOLUTION
(cetirizine hydrochloride)

The name of this medicine is Cetirizine Hydrochloride 5mg/5ml Solution, which will be referred to as Cetirizine Solution throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others; it may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cetirizine Solution is and what it is used for
2. What you need to know before you take Cetirizine Solution
3. How to take Cetirizine Solution
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1. WHAT CETIRIZINE SOLUTION IS AND WHAT IT IS USED FOR

The active ingredient in your medicine is cetirizine hydrochloride, which belongs to a group of medicines called antihistamines. These are used to relieve the symptoms of seasonal allergic rhinitis (e.g. hay fever), perennial allergic rhinitis (e.g. year round allergies often due to house dust mites or animal allergies) and urticaria (itchy, red, swollen skin). These symptoms include itchy skin rashes; sneezing; itchy, runny or blocked nose; red, itchy and watering eyes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CETIRIZINE SOLUTION

Do not take Cetirizine Solution if you:

- **are allergic (hypersensitive) to cetirizine hydrochloride, hydroxyzine, piperazine derivatives** or any of the **other ingredients** in Cetirizine Solution (these are listed in section 6, contents of the pack and other information)
- **have a severe kidney disease** (severe renal failure with creatine clearance below 10/ml/min) have hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption

Warnings and precautions

Talk to your doctor or pharmacist before taking Cetirizine

- If you have spinal cord lesion or enlargement of the prostate or any predisposing factors for urinary retention.

- If you are an **epileptic** patient or a patient at **risk of convulsions (fits)**,
- If you have renal insufficiency or have **kidney problems**,

Cetirizine Solution can affect the results of allergy skin tests. If you require an allergy test you should stop taking Cetirizine Solution three days before you have the test.

Long term treatment with Cetirizine can increase the risk of tooth decay due to mouth dryness. Appropriate oral hygiene is important in long term use.

Other medicines and cetirizine

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- medication for anxiety or stress (CNS depressants) should be used in caution with cetirizine

Cetirizine with food, drink and alcohol

Cetirizine Solution can be taken with or without food. **Be careful when drinking alcohol** while using Cetirizine. It can increase the effects of drinking. No interactions susceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per ml corresponding to one glass of wine) and cetirizine used at the normal doses. However, as is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to become pregnant ask your doctor or pharmacist for advice before taking this medicine. As with other drugs, the use of Cetirizine Solution should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

You should not take Cetirizine Solution during breast-feeding because cetirizine passes into your breast milk.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Cetirizine Solution at the recommended dose.

If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug. If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Do not drive or operate machinery if the solution makes you feel drowsy.

Cetirizine Solution contains Sorbitol, Sodium, Glycerol, methyl and propyl parahydroxy benzoate.

This product contains **sorbitol**. If you have been told by your doctor that you have intolerance **to some sugars**, contact your doctor before taking this medicinal product.

The daily dose, 10ml, of this product contains approximately 3.2mg of sodium, which may be harmful to people on a low sodium diet. Glycerol can be harmful in high doses; it may cause headache, stomach upset and diarrhoea. Methyl and Propyl parahydroxy benzoate have been known to cause urticaria, or contact dermatitis

3. HOW TO TAKE CETIRIZINE SOLUTION

Always take Cetirizine Solution exactly as your doctor or pharmacist has told you.. You should check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose is:

Adults and adolescents aged 12 years and over: **Take two 5ml spoonfuls (10ml) once daily.**

Children aged between 6 and 12 years: **Take either one 5ml spoonful twice daily, morning and evening, or two 5ml spoonful's once daily.**

Children aged between 2 and 5 years: Take either half of a 5ml spoonful twice daily or one 5ml spoonful once daily.

Not recommended for children under 2 years of age.

Patients with moderate to severe renal impairment: **Patients with moderate or severe renal impairment are recommended to take 5ml once daily.**

If drowsiness occurs, dosage can be taken in the evening

Method of administration

For oral use.

If you take more Cetirizine Solution than you should

If you have accidentally taken more than the recommended/prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining medicine with you.

The most common signs and symptoms of overdose may include feeling unwell, headache, confused, restless, shaky, dizzy, tired or very sleepy. You may also notice a rapid heartbeat, having dilated pupils or blurred vision, and experience headache, itching, diarrhoea, or difficulty urinating.

If you forget to take Cetirizine Solution

If you have forgotten to take your medicine, take it as soon as you remember and then wait 24 hours before taking your next dose. Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cetirizine Solution can cause side effects, although not everybody gets them. If you get any of the following symptoms after taking this medicine you **should contact your doctor or pharmacist immediately**:

- **any sudden wheeziness, difficulty in breathing**
- **dizziness**
- **Sudden signs of an allergic reaction such as developing a rash, swelling of the eyelids, face, lips or throat**
- **Loss of consciousness.**
- **Convulsions or fits.**
- **Bruising or bleeding more easily than normal**
- **Weight loss**
- **A worsening cough**
- **Fatigue**

The following side effects have also been reported:

Common side effects (seen in less than 1 in 10 patients but in more than 1 in 100 patients):

- drowsiness, fatigue
- dry mouth, nausea (feeling sick), diarrhoea
- dizziness, headache
- sore or inflamed throat,
- swelling and irritation of the lining of the nose (runny nose)
- restlessness
- abdominal pain

Uncommon side effects (seen in less than 1 in 100 patients but in more than 1 per 1000 patients):

- agitation
- burning, prickling sensation (feeling of pins and needles)
- stomach ache
- rash, itching
- feelings of weakness and/or extreme tiredness, feeling unwell

Rare side effects (seen in less than 1 in 1000 patients)

- allergic reactions, some severe (very rare)
- feelings of aggression, confusion and depression
- hallucinations, difficulty in sleeping
- convulsions (fits), movement disorders
- Involuntary eye movements
- muscle spasm and tics
- rapid heart beat
- oedema (swelling of the feet or ankles)
- hives (urticaria)
- unusual weight gain
- changes in liver function tests, indicating the possibility of damage to the liver

Very rare side effects (seen in less than 1 in 10,000 patients)

- serious allergic reaction which causes difficulty in breathing or dizziness
- tics, shaking
- distorted sense of taste
- fainting
- involuntary movements or muscle contractions
- blurred vision, difficulty in focusing, eyes having uncontrolled circular movements (oculogyration)
- swelling of the face, lips or throat
- severe blistering skin rash
- difficult and/or painful urination
- loss of urinary control
- an increased tendency to bruise or bleed easily

Side effects of unknown frequency

- forgetfulness, memory impairment
- increased appetite,
- difficulty passing water or
- a feeling of dizziness (vertigo).
- In very rare cases people have had suicidal thoughts when taking this medicine. If you experience these stop taking the medicine and see your doctor.

Long term treatment with Cetirizine Solution can lead to a dry mouth, it is therefore important that adequate oral hygiene is maintained.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CETIRIZINE SOLUTION

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

Do not take this medicine after the expiry date stated on the label. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions. Use within 6 months of opening.

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 Cetirizine Solution contains:

The active ingredient is cetirizine hydrochloride. Each 1ml of solution contains 1mg of cetirizine hydrochloride.

The other ingredients are: methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sorbitol solution (70%), glycerol, sodium citrate, citric acid, propylene glycol, monoammonium glycyrrhizinate, purified water, pineapple Singapore flavour, sweet orange no.1.

What Cetirizine Solution looks like and the contents of the pack:

Cetirizine Solution is a clear, colourless solution in an amber glass bottle.

Your medicine is available in a 200ml bottle.

Marketing Authorisation Holder:

Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough, NN8 6GT

Manufacturer responsible for batch release:

Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough, NN8 6GT

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