

**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
4. Possible side effects
5. How to store Cetirizine Solution
6. Contents of the pack and other information

**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 to cetirizine hydrochloride, hydroxyzine, piperazine derivatives** or any of the **other ingredients** of this medicine ( listed in section 6)
- **If you have a severe kidney disease** (severe renal failure with creatine clearance below 10/ml/min) or are undergoing dialysis

**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 are a patient with liver problems or renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

### **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

It may still be alright for you to take Cetirizine Tablets and your doctor will be able to decide what is suitable for you. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### Allergy Testing

Cetirizine Tablets can affect the results of allergy skin tests. If you require an allergy test, you should stop taking Cetirizine Tablets 3 days before you have the tests.

### **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 alcohol. 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 parahydroxy benzoate and propyl parahydroxy benzoate.**

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 you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicine contains less than 1 mmol sodium, (23 mg) per 10ml that is to say essentially 'sodium-free'.

Glycerol may cause headache, stomach upset and diarrhoea.

Methyl parahydroxybenzoate and Propyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

### **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
- diarrhoea, dry mouth, nausea (feeling sick)
- dizziness, headache
- sore or inflamed throat,
- swelling and irritation of the lining of the nose ((runny nose) (in children))

**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)
- hypersensitivity reactions (including anaphylactic shock)
- feelings of aggression, confusion and depression
- hallucinations, difficulty in sleeping
- convulsions (fits), movement disorders
- Involuntary eye movements
- rapid heart beat
- oedema (swelling)
- 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)**

- 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 (thrombocytopenia)

#### **Side effects of unknown frequency**

- forgetfulness, memory impairment
- increased appetite
- difficulty passing water
- a feeling of dizziness (vertigo).
- Myalgia (muscular pain)
- 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.
- Nightmares
- Joint pain
- Hepatitis (inflammation of the liver)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Rash with blisters containing pus
- Severe skin reactions characterised by fever and numerous small, superficial pustules, arising within large areas of redness
- Difficulty breathing (dyspnoea)
- Accommodation disorder (eye disorder), blurred vision, abnormal pupil dilatation, eye pain, visual impairment, abnormal intolerance to visual perception of light
- Erectile dysfunction

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](http://www.mhra.gov.uk/yellowcard) or search MHRA Yellow Card on the Google Play and Apple App store. 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 1 ml 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:**

Kent Pharmaceuticals Limited, Westminster Industrial Estate, Repton Road, Measham, DE12 7DT, England.

**Manufacturer responsible for batch release:**

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

This leaflet was last revised in January 2026