

## **Package leaflet: Information for the user**

### **Cetirizine Hydrochloride 5 mg/ 5 ml Oral Solution**

Cetirizine hydrochloride

The name of this medicine is Cetirizine Hydrochloride 5mg/5ml Oral 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.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 or pharmacist. 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 or if you feel worse after 3 days.

#### **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**

Cetirizine, the active ingredient of the solution is an antihistamine. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions.

Cetirizine dihydrochloride oral solution is used to treat adults and paediatric patients aged 2 years and over who have hay fever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin).

Antihistamines like cetirizine dihydrochloride oral solution relieve the unpleasant symptoms and discomfort associated with these conditions, such as sneezing, irritated, runny and blocked up nose, itchy, red and watering eyes and skin rashes.

#### **2. What you need to know before you take Cetirizine Solution**

##### **Do not take Cetirizine Solution if you:**

- are allergic to cetirizine or any of the other ingredients of this medicine (listed in section 6) or to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines).

- have a severe kidney disease requiring dialysis.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Cetirizine Solution.

If you are a patient with 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.

If you have problems passing urine (like spinal cord problems or prostate or bladder problems), please ask your doctor for advice.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 per mille (g/l) corresponding to one glass of wine) and cetirizine used at the recommended doses. However, there are no data available on the safety when higher doses of cetirizine and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid taking Cetirizine Solution with alcohol.

**Allergy testing**

If you are due to have an allergy test, ask your doctor if you should stop taking Cetirizine Solution for several days before testing. This medicine may affect your allergy test results.

**Children**

Do not give this medicine to children below 2 years of age.

**Other medicines and Cetirizine Solution**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Due to the profile of cetirizine, no interactions with other drugs are expected.

**Cetirizine Solution with food and alcohol**

Avoid alcoholic drink while you are taking this medicine.

Food does not affect absorption of cetirizine.

**Pregnancy and breast-feeding**

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

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 medicine should only be administered if necessary and after medical advice.

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetirizine Solution during breast-feeding unless you have contacted a doctor.

### **Driving and using machines**

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

You should closely observe your response to the drug after you have taken Cetirizine Solution if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

### **Cetirizine Solution contains sorbitol, sodium, methyl parahydroxybenzoate and propyl parahydroxybenzoate.**

- This medicine contains 0.0005 mg sorbitol in each mL of solution which is equivalent to 0.0005 mg/ml.
- The oral solution contains the preservatives methyl parahydroxybenzoate, propyl parahydroxybenzoate that may cause allergic reactions (possibly delayed).
- This medicine contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

### **3. How to take Cetirizine Solution**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Remember the solution can be swallowed as such. Do not take more than 10 mL each day.

If you do not feel better within a few days, consult your doctor.

The recommended dose is:

#### **Children aged 2 to 6 years:**

2.5 mg twice daily as 2.5 mL oral solution twice daily.

#### **Children aged 6 to 12 years:**

5 mg twice daily as 5 mL oral solution twice daily.

#### **Adults and adolescents over 12 years of age:**

10 mg once daily as 10 mL oral solution.

#### **Use in children**

Cetirizine Solution is not suitable for children under 2 years of age.

#### **Renal impairment**

Patients with moderate renal impairment are recommended to take 5 mg once daily.

If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.

If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.

If you feel that the effect of Cetirizine Solution is too weak or too strong, please consult your doctor.

### **Method of administration**

For oral use.

### **Duration of treatment**

The duration of treatment depends on the type, duration and course of your complaints. Please ask your doctor or pharmacist for advice.

### **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**.

Your doctor will then decide what measures, if any, should be taken.

Remember to take any packaging with you.

After an overdose, the side effects described in section 4 below may occur with increased intensity.

The following side effects have been reported:

- confusion
- diarrhoea
- dizziness
- tiredness
- headache
- a vague feeling of discomfort
- dilating of pupils of the eyes
- itching
- restlessness
- sedation
- sleepiness
- stunned state in which it is difficult to get a response
- abnormal rapid heart rate
- tremors
- urinary retention

### **If you forget to take Cetirizine Solution**

Do not take double dose to make up for a forgotten dose.

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.

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

### **If you stop taking Cetirizine Solution**

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Cetirizine Solution.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the tablets and speak to your doctor straight away if you notice these symptoms:

- serious allergic reaction which causes difficulty in breathing or dizziness, swelling of the face or throat
- inflammation of liver (hepatitis)
- fits
- fixed drug eruption (appearance of red or blistered skin in the same place after taking this medicine)
- suicidal ideation
- acute generalized exanthematous pustulosis (a red, scaly rash with bumps under the skin and blisters)

These reactions may start soon after you first take the medicine, or it might start later.

The following side effects have also been reported:

**Common side effects** (may affect up to 1 in 10 people):

- fatigue
- dry mouth, nausea, diarrhoea
- dizziness, headache
- sleepiness
- sore throat, sneezing, a blocked, congested or itchy nose.

**Uncommon side effects** (may affect up to 1 in 100 people):

- paraesthesia (feeling of pins and needles)
- feelings of weakness and/or extreme tiredness (asthenia), feeling unwell (malaise)
- abdominal pain
- agitation
- itching, rash

**Rare side effects** (may affect up to 1 in 1,000 people)

- heart beating too fast
- oedema (swelling of the feet or ankles)
- changes in liver function tests, indicating the possibility of damage to the liver.
- weight increase
- aggression, confusion, depression, hallucination, insomnia
- hives

**Very rare side effects** (may affect up to 1 in 10,000 people)

- low levels of blood platelets
- difficulty with focussing the eyes, blurred vision, eyes having uncontrolled circular movements
- fainting, altered taste
- tics, shaking (tremor)
- loss of urinary control (enuresis)
- dyskinesia (involuntary movements)
- dystonia (abnormal prolonged muscular contractions)
- difficult, painful or involuntary urination

**Not known** (frequency cannot be estimated from the available data)

- increased appetite
- forgetfulness, memory impairment
- vertigo (sensation of rotation or movement)
- urinary retention (inability to completely empty the urinary bladder)
- nightmare
- joint pain
- myalgia (muscular pain)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Hepatitis (inflammation of the liver)

### **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: <https://yellowcard.mhra.gov.uk/> 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 Cetirizine Solution**

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. 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 medicine 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, flavoured solution.

Cetirizine Solution is available in a 200ml amber glass and polyethylene Terephthalate (PET) bottle.

### **Marketing Authorisation Holder:**

Cipla (EU) Limited,  
Dixcart House, Addlestone Road,

Bourne Business Park, Addlestone, Surrey,  
KT15 2LE, United Kingdom

**Manufacturer:**

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