

## **Package Leaflet: Information for the Patient**

### **Anti-Hist Allergy 1mg/ml Oral Solution**

Cetirizine dihydrochloride

**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 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 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 Anti-Hist Allergy oral solution is and what it is used for
2. What you need to know before you take Anti-Hist Allergy oral solution
3. How to take Anti-Hist Allergy oral solution
4. Possible side effects
5. How to store Anti-Hist Allergy oral solution
6. Contents of the pack and other information.

#### **1. What Anti-Hist Allergy oral 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.

Anti-Hist Allergy 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 Anti-Hist Allergy 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.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### **2. What you need to know before you take Anti-Hist Allergy oral solution**

##### **Do not take Anti-Hist Allergy oral solution if:**

- You are allergic to cetirizine dihydrochloride 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).
- You have severe kidney failure (severe renal failure with creatinine clearance less than 10 ml/min).
- You are breast-feeding

If any of the above applies to you talk to your pharmacist.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Anti-Hist Allergy oral solution if:

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 Anti-Hist Allergy oral solution with alcohol.

### **Children**

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

### **Other medicines and Anti-Hist Allergy oral 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.

### **Anti-Hist Allergy oral solution with food and drink**

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.

Anti-Hist Allergy oral 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 Anti-Hist Allergy oral solution during breast-feeding unless you have contacted a doctor.

### **Allergy testing**

If you are due to have an allergy test, ask your doctor if you should stop taking Anti-Hist Allergy oral solution for several days before testing. This medicine may affect your allergy test results.

### **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 Anti-Hist Allergy oral solution if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

### **Anti-Hist Allergy oral 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).

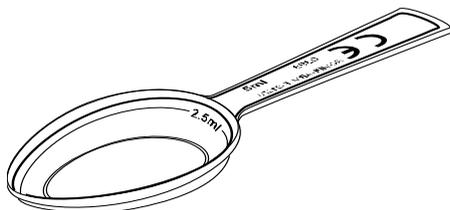
- This medicine contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

### 3. How to take Anti-Hist Allergy oral 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.

The dose should be measured using the spoon enclosed with this pack. The spoon has a measure at each end, and lets you choose either the 2.5 ml (half-measuring spoon) or 5 ml quantity (one full measuring spoon).



Do not take/give more Anti-Hist Allergy oral solution than the quantities shown below. 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 (a half-measuring spoon) twice daily.

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

5 mg twice daily as 5 ml (one full measuring spoon) twice daily.

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

10 mg once daily as 10 ml oral solution (2 full measuring spoons) once daily.

#### **Use in children**

Anti-Hist Allergy oral 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 Anti-Hist Allergy oral 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 Anti-Hist Allergy oral solution than you should**

If you accidentally take 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 Anti-Hist Allergy oral solution**

If you forget to take a dose, you should take one as soon as you remember, but wait at least 24 hours before taking the next dose.

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 or pharmacist.

**If you stop taking Anti-Hist Allergy oral solution**

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Anti-Hist Allergy oral 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.

**The following side effect is very rare, but you must stop taking the medicine and speak to your doctor straight away if you notice these symptoms:**

- A severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips.  
This reaction 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)

- |                            |                                                 |
|----------------------------|-------------------------------------------------|
| Tiredness, feeling sleepy, | Pain in the abdomen,                            |
| Headache,                  | Dizziness,                                      |
| Dry mouth,                 | Sore throat,                                    |
| Nausea,                    | Cold-like symptoms of the nose (children only). |
| Diarrhoea (children only), |                                                 |

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

Itching and rash, Tingling in the hands and feet,  
Diarrhoea, Feeling agitated.  
Feeling weak or generally unwell,  
Abdominal pain

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

- Fast heart beat,
- Oedema (generalised swelling due to water retention),
- Abnormal liver function test results (your doctor will know what to do),
- Convulsions,
- Increased weight,
- Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness.

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

- Low levels of blood platelets,
- Blurred vision, difficulty focusing,
- Rotation of the eyes,
- Bad taste in the mouth,
- Fainting,
- Bed wetting, pain and/or difficulty passing water,
- Unusual bleeding or bruising,
- Tremor, tics,
- Involuntary movements and/or jerking of the limbs,
- Muscle spasms in the neck and shoulders,
- fixed drug eruption (appearance of red or blistered skin in the same place after taking this medicine).

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

- Increased appetite,
- Vertigo,
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Inflammation of liver (hepatitis)
- Urinary retention (inability to completely empty the urinary bladder)
- Forgetfulness, memory impairment
- Joint pain
- acute generalized exanthematous pustulosis (a red, scaly rash with bumps under the skin and blisters).

Some cases of memory loss and/or impairment have also been reported.

In very rare cases people have thought about committing suicide and if you feel this way then stop taking the oral solution and see your doctor.

**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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Anti-Hist Allergy oral solution**

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

Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of the month.

Do not use after 6 months of first opening the bottle.

This medicinal product does not require any special storage conditions.

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. Contents of the pack and other information**

### **What Anti-Hist Allergy oral solution contains**

The active substance is cetirizine dihydrochloride. Each ml of solution contains 1 mg cetirizine dihydrochloride.

The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sorbitol solution at 70% (non-crystallising) (E420), glycerol, trisodium citrate (sodium citrate), citric acid, propylene glycol, monoammonium glycyrrhizinate, purified water, pineapple No.1 (012080) flavour and Juicy Orange (SC406296) flavour.

### **What Anti-Hist Allergy oral solution looks like**

Anti-Hist Allergy oral solution is a clear, colourless, flavoured solution.

Anti-Hist Allergy 1 mg/ml oral solution is packed in a 200 ml amber glass bottle and polyethylene terephthalate bottle with child resistant cap and 2.5 ml/5 ml transparent plastic measuring spoon with CE marking.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, County Tipperary, Ireland

#### **Manufacturer**

Cipla (EU) Limited,  
Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE,  
UK

Cipla Europe NV,  
De Keyserlei 58-60, Box-19, 2018 Antwerp, Belgium

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Portugal:	Cetirizina Cipla, 1 mg/ml, solução oral
Ireland:	Anti-Hist Allergy 1 mg/ml Oral Solution
Spain:	Cetirizina Cipla 1 mg/ml solución oral EFG

This leaflet was last revised in November 2019.