

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

### **Anti-Hist Allergy 10mg Film-Coated Tablets**

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

#### **1. What Anti-Hist Allergy is and what it is used for**

Cetirizine dihydrochloride is the active ingredient of Anti-Hist Allergy. Anti-Hist Allergy is an antiallergic medication.

In adults and children aged 6 years and above, Anti-Hist Allergy is indicated

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

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

##### **Do not take Anti-Hist Allergy**

- if you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to hydroxyzine or piperazine derivatives (closely related active substances of other medicines).
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Anti-Hist Allergy

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 corresponding to one glass of wine) and cetirizine used at the recommended doses.

However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

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

#### **Use in children below 6 years old**

Do not give this medicine to children below the age of 6 years because the tablet formulation does not allow the necessary dose adjustments

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

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

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

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

Food does not affect noticeably the absorption of cetirizine.

#### **Pregnancy and breast-feeding**

Ask your doctor for advice before taking any medicine.

As with other drugs, use of Anti-Hist Allergy 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 Anti-Hist Allergy during breast feeding because cetirizine passes into breast milk.

#### **Driving and using machines**

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Anti-Hist Allergy 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.

#### **Anti-Hist Allergy contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

These guidelines apply unless your doctor has given you different instructions on how to use Anti-Hist Allergy. Please follow these instructions, otherwise Anti-Hist Allergy may not be fully effective. Tablets need to be swallowed with a glass of liquid.

#### **Adults and adolescents above 12 years old**

The recommended dose is 10 mg once daily as 1 tablet.

#### **Use in children between 6 and 12 years old**

The recommended dose is 5 mg twice daily as a half tablet twice daily.

### **Patients with moderate to severe renal impairment**

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

If you feel that the effect of Anti-Hist Allergy is too weak or too strong, please consult your doctor.

### **Duration of treatment**

The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

### **If you take more Anti-Hist Allergy than you should**

If you think you have taken an overdose of Anti-Hist Allergy please inform your doctor.

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

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

### **If you forget to take Anti-Hist Allergy**

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.

## **4. Possible side effects**

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

**The following side effects are rare or very rare, but you must stop taking the medicine and speak to your doctor straight away if you notice them:**

- Allergic reactions, including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat).

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

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

- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis, rhinitis (in children)
- Diarrhoea, nausea, dry mouth
- Fatigue

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

- Agitation
- Paraesthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise

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

- Allergic reactions, some severe (very rare)
- Depression, hallucination, aggression, confusion, insomnia
- Convulsions
- Tachycardia (heart beating too fast)
- Liver function abnormal
- Urticaria (hives)
- Oedema (swelling)
- Weight increased

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

- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

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

- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide)
- Amnesia, memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Joint pain
- Rash with blisters containing pus
- 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 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**

- 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 carton and blister after EXP. The expiry date refers to the last day of that month.
- This medicine 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 contains**

- The active substance is cetirizine dihydrochloride. Each film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate, talc, hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol 4000 and sodium citrate.

##### **What Anti-Hist Allergy looks like and contents of the pack**

Anti-Hist Allergy 10 mg Film-coated Tablets: White circular bi-convex, film-coated tablets marked A on one side and a breakline on the other. Anti-Hist Allergy 10 mg Film-coated Tablets are available in cartons containing 7, 10, 14, 21, 28, and 30 tablets.

Not all pack sizes may be marketed.

##### **Marketing authorisation holder and manufacturer**

Marketing authorisation holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Chanelle Medical, Loughrea, Co. Galway, Ireland

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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