

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Aspar Hayfever and Allergy Relief  
Cetirizine hydrochloride 10 mg Tablets  
(One a day)  
Cetirizine hydrochloride**

**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 any get side effects, talk to your doctor or pharmacist. This includes side effects not listed in this leaflet, See section 4.
- You must contact a doctor if you do not feel better or if you feel better worse after 3 days.

**What is in this leaflet:**

1. What Cetirizine hydrochloride Tablets is and what it is used for
2. What you need to know before you take Cetirizine hydrochloride Tablets
3. How to take Cetirizine hydrochloride Tablets
4. Possible side effects
5. How to store Cetirizine hydrochloride Tablets
6. Contents of the pack and other information

**1. WHAT CETIRIZINE HYDROCHLORIDE TABLETS IS AND WHAT IT IS USED FOR**

Cetirizine hydrochloride is the active ingredient of Cetirizine hydrochloride Tablets.

Cetirizine hydrochloride Tablets are an anti allergy medication.

In adults and children aged 6 years and above, Cetirizine hydrochloride Tablets are indicated

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of urticaria.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CETIRIZINE HYDROCHLORIDE TABLETS**

**Do not take Cetirizine hydrochloride Tablets:**

- if you have severe kidney problems (severe renal failure with creatinine clearance below 10 ml/min);
- if you are allergic to Cetirizine hydrochloride, to any of the other ingredients (listed in section 6), to hydroxyzine or to piperazine derivatives (closely related active ingredients of other medicines).

**Warning and precautions**

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 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 hydrochloride tablets with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Cetirizine hydrochloride tablets for several days before testing. This medicine may affect your allergy test results.

**Children**

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 Cetirizine hydrochloride tablets**

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

**Cetirizine hydrochloride tablets with food and drink**

Food does not affect absorption of Cetirizine hydrochloride tablets.

**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 for advice before taking this medicine.

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

**Cetirizine hydrochloride Tablets contain lactose;** if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

**3. HOW TO TAKE CETIRIZINE HYDROCHLORIDE TABLETS**

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

The tablets need to be swallowed with a glass of liquid. The tablet can be divided into 2 equal doses.

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

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

**Use in Children between 6 to 12 years old:**

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

**Patients with renal impairment**

Patients with moderate renal impairment are recommended to take 5mg 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 hydrochloride tablets are 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. Please ask your doctor or pharmacist for advice.

**If you take more Cetirizine hydrochloride Tablets than you should**

If you think you have taken an overdose of Cetirizine hydrochloride tablets 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, dilated pupils, itching, restlessness, sedation, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

**If you forget to take Cetirizine hydrochloride Tablets**

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

**If you stop taking Cetirizine hydrochloride Tablets**

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

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 patients)

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

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

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

**Rare side effects** (may affect up to 1 in 1000 patients)

- 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 patients)

- 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 of side effects** (frequency cannot be estimated from the available data)

- Increased appetite
- 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

In very rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets 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 the Yellow Card Scheme, Website:

[www.mhra.gov.uk/yellowcard](http://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 HYDROCHLORIDE TABLETS**

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 blister and the carton. The expiry date refers to the last day of that month.

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 to protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION****What Cetirizine hydrochloride Tablets contains**

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

**What Cetirizine hydrochloride Tablets looks like and contents of the pack**

White, circular film-coated tablets, marked 'A' on one side with a break line on the other side.

Pack available in blister pack containing 7 tablets.

**Marketing Authorisation Holder**

Chanelle Medical,  
Loughrea, Co. Galway, Ireland.

**Manufacturer**

Chanelle Medical,  
Loughrea, Co. Galway, Ireland.

**Distributor**

The distributor is  
Aspar Pharmaceuticals., Ltd.

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