

# Cetirizine Hydrochloride 10 mg Tablets

Cetirizine hydrochloride

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

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

Cetirizine dihydrochloride is the active ingredient of Cetirizine. Cetirizine is an antiallergic medication.

In adults and children aged 6 years and above, Cetirizine 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 CETIRIZINE****Do not take Cetirizine:**

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

**Warnings and precautions:**

Talk to your doctor or pharmacist before taking Cetirizine Hydrochloride.

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

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

If you plan having an allergy skin test made. The use of Cetirizin Sandoz should be interrupted at least 3 days prior to skin tests.

No interactions susceptible to have a noticeable impact 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 normal doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

**Other medicines and Cetirizine**

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.

**Cetirizine with food and drink**

Food does not affect noticeably the 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.

As with other drugs, use of Cetirizine 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 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 Cetirizine 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.

**Cetirizine contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. HOW TO TAKE CETIRIZINE****How and when should you take Cetirizine?**

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.

Tablets need to be swallowed with a glass of liquid.

**The recommended dose is:**

Adults and adolescents above 12 years old  
10 mg once daily as 1 tablet

Children between 6 and 12 years old  
5 mg twice daily as a half tablet twice daily

*Continued on the next page >>*

#### 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 Cetirizine 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 Cetirizine than you should**

If you think you have taken an overdose of Cetirizine 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 Cetirizine**

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

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

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 Cetirizine Sandoz and seek for medical attention without delay if you experience symptoms like:**

- swelling in your mouth, face and/or throat
- difficulties in breathing (chest tightness or wheezing)
- sudden drop in your blood pressure with subsequent fainting or shock.

The symptoms can be signs of hypersensitivity reactions, anaphylactic shock and angioedema. These reactions are rare (may affect up to 1 in 1,000 people).

The following outline contains further side effects listed by their frequency:

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

- fatigue
- dry mouth, nausea
- dizziness, headache
- somnolence
- pharyngitis (sore throat), rhinitis (swelling and irritation inside the nose)

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

- abdominal pain
- asthenia (extreme fatigue), malaise (feeling of being generally unwell)
- paresthesia (abnormal feelings of the skin)
- restlessness
- itching, rash
- diarrhea

#### *Rare: (may affect up to 1 in 1,000 people):*

- tachycardia (heart beating too fast)
- oedema (swelling)
- liver function abnormal
- weight increased
- convulsions, movement disorders
- aggression, confusion, depression, hallucination, insomnia
- urticaria

#### *Very rare: (may affect up to 1 in 10,000 people):*

- thrombocytopenia (low blood platelets count manifested by bleeding or bruising more easily

than normal)

- accommodation disorder, blurred vision, oculogyric crisis (eyes having uncontrolled circular movements)
- syncope, tremor, dysgeusia (altered taste)
- tics
- abnormal elimination of urine
- fixed drug eruption

*Frequency not known: (cannot be estimated from the available data):*

- memory loss, memory impairment
- increased appetite
- vertigo (sensation of rotation or movement)
- urinary retention (inability to completely empty the urinary bladder)
- suicidal ideation (recurring thoughts of or preoccupation with suicide)

If you feel this way, 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: [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

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

Do not use Cetirizine after the expiry date which is stated on the on the carton after EXP. The expiry date refers to the last day of that month.

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 Cetirizine contains**

Each tablet contains 10 mg of cetirizine hydrochloride

- The active substance is cetirizine hydrochloride.
- The other ingredients are  
Tablet core : cellulose microcrystalline, lactose monohydrate , magnesium stearate, colloidal anhydrous silica,  
Tablet coat: hypromellose, lactose monohydrate , titanium dioxide (E171) and macrogol 4000.

#### **What Cetirizine looks like and contents of the pack**

Cetirizine Hydrochloride 10 mg Tablets are white, oblong film-coated tablets, scored on one side. PVC blister with aluminium foil lidding: 7, 10, 14, 20, 21, 28, 30, 50, 60, 98 and 100 and 50 (50x1) unit-dose.

Not all pack sizes may be marketed.

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

##### **Marketing Authorisation Holder**

Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR

##### **Manufacturer**

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany

**This leaflet was last revised in 11/2014**

SZ00000LT000