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PACKAGE LEAFLET INFORMATION FOR THE USER Cetirizine Hydrochloride 10mg Tablets

Read all 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 your doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Cetirizine Hydrochloride Tablets are and what they are 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 are and what they are used for

The active ingredient (which makes this medicine work) is called cetirizine hydrochloride, which belongs to a family of medicines called antihistamines. Cetirizine Hydrochloride 10mg Tablets are used for the relief of symptoms of hayfever and other allergic conditions (e.g. sneezing, runny or itchy nose) or for skin rashes (chronic nettle rash, idiopathic urticaria) in adults and children over 6 years of age.

2. What you need to know before you take Cetirizine Hydrochloride Tablets

Do not take Cetirizine Hydrochloride Tablets

- if you are **allergic** to cetirizine hydrochloride, or any of the ingredients of this medicine (listed in section 6), to hydroxyzine or to any 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

- If you have **liver or kidney problems**, 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.
- 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 and Cetirizine Hydrochloride Tablets

The use of this medicine is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation.

Other medicines and Cetirizine Hydrochloride Tablets

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

Cetirizine Hydrochloride Tablets with food and drink and alcohol

Food does not affect absorption of Cetirizine Hydrochloride Tablets. No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 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.

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 if you are **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, contact your doctor before taking these tablets.

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 should be swallowed with water.

Adults, elderly patients and children 12 years and over: 1 tablet daily.

Children aged 6 to 12 years: Half a tablet twice daily.

Children under 6 years: Not recommended.

Patients with renal impairment: Patients with moderate renal impairment are recommended to take 5 mg once daily. If you have **severe kidney problems** (or **liver and kidney problems together**) 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.

Duration of treatment

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

If you take more than you should

If you accidentally take too much medicine, contact your doctor or nearest casualty department at once.

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.

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4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. **The following side effects are very rare but you must stop taking the tablets and speak to your doctor immediately if you notice them:**

- Allergic reactions including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat)
- Convulsions (fits)
- Thoughts about committing suicide.

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

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

- Somnolence, (sleepiness)
- Dizziness, headache
- Diarrhoea, nausea, dry mouth
- Fatigue
- Pharyngitis, cold-like symptoms of the nose (children only).

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

- Feeling agitated
- Paresthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise (feeling generally unwell).

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

- Depression, hallucination (hearing or seeing things), aggression, confusion, sleeplessness
- Tachycardia (heart beating too fast)
- Abnormal liver function test results (your doctor will know what to do)
- Urticaria (hives)
- Oedema (generalised swelling due to water retention)
- Weight increased.

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

- Low levels of blood platelets causing unusual bleeding or bruising
- 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)
- Fixed drug eruption
- Abnormal elimination of urine (bedwetting, pain and/or difficulty passing water).

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

- Increased appetite
- Memory loss and forgetfulness
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Arthralgia (joint pain)
- Acute generalised exanthematous pustulosis (rash with blisters containing pus).
- Nightmares.

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: www.mhra.gov.uk/yellowcard 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 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 carton. 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 Hydrochloride Tablets contain

Each tablet contains 10mg of cetirizine hydrochloride (the active ingredient). They also contain: lactose, microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate, talc, hypromellose, titanium dioxide (E171), macrogol 4000 and sodium citrate.

What Cetirizine Hydrochloride Tablets look like and contents of the pack

The tablets are white circular bi-convex, film-coated tablets marked C on one side and a breakline on the other.

Available in cartons containing 7, 14, 21, 28, 30 and 60 tablets.

Marketing authorisation holder and manufacturer

Dr. Reddy's Laboratories (UK) Ltd
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