RXfarma

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Legal Status

Package Leaflet: Information For The User

Cetirizine Dihydrochloride 1mg/ml Oral Solution

Cetirizine Dihydrochloride

Read all of this leaflet carefully before you use this medicine, because it contains important information for you. Keep this leaflet: you might need it again.

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 Cetirizine Dihydrochloride is and what it is used for

Cetirizine Dihydrochloride is the active ingredient in Cetirizine Dihydrochloride Oral Solution. Cetirizine Solution is an antiallergic medication.

In adults and children aged 2 years and above, Cetirizine Dihydrochloride Oral Solution is 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 giving Cetirizine Dihydrochloride to your child

Do not take Cetirizine Dihydrochloride

- if you have a severe kidney disease requiring dialysis;
- if you are allergic to Cetirizine Dihydrochloride or any of the other ingredients of this medicine (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cetirizine Dihydrochloride.

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 g/l corresponding to one glass of wine) and Cetirizine Dihydrochloride used at the recommended doses.

However, there are no data available on the safety when higher doses of Cetirizine Dihydrochloride and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid taking Cetirizine Dihydrochloride with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Cetirizine Dihydrochloride for several days before testing.

This medicine may affect your allergy test results.

Other medicines and Cetirizine Dihydrochloride

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

Cetirizine Dihydrochloride with food and drink

Food does not affect absorption of Cetirizine Dihydrochloride.

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 Dihydrochloride 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 Dihydrochloride passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetirizine Dihydrochloride 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 Dihydrochloride at the recommended dose. You should closely observe your response to the drug after you have taken Cetirizine Dihydrochloride if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Cetirizine Dihydrochloride contains sorbitol.

This medicine contains 54.73 (%w/w) sorbitol (E 420) which is equivalent to 220.5 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Cetirizine Dihydrochloride Oral Solution contains methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216) that may cause allergic reactions (possibly delayed).

This medicine contains 8.69 (% w/w) propylene glycol in each 1 ml which is equivalent to 50.00 mg/ml.

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

3. How to take Cetirizine Dihydrochloride

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 solution can be swallowed as such.

The solution can be swallowed as such.

Adults and adolescents above 12 years old:
The recommended dose is 10 mg once daily as 10 ml oral solution (two full measuring spoons of 5ml)

Use in children between 6 and 12 years old:
The recommended dose is 5 mg twice daily as 5 ml (one full measuring spoon of 5 ml) twice daily.

Use in children between 2 and 6 years old
The recommended dose is 2.5 mg twice daily as 2.5 ml oral solution (one full measuring spoon of 2.5 ml) twice daily

Patients with 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.

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back side

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 Dihydrochloride 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. Please ask your doctor or pharmacist for advice.

If you take more Cetirizine Dihydrochloride than you should

If you think you have taken an overdose of Cetirizine Dihydrochloride 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, malaise (feeling unwell), dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty in emptying the bladder) have been reported.

If you forget to take Cetirizine Dihydrochloride

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

If you stop taking Cetirizine Dihydrochloride

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

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 (sore throat), rhinitis (runny, stuffy nose) (in children)
- Diarrhoea, nausea, dry mouth
- Fatigue

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

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

Rare side effects (may affect up to 1 in 1,000 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 (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyric crisis (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption (drug allergy)
- 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
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare Amnesia (memory loss), 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
- Arthralgia (joint pain), myalgia (muscular pain)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- Hepatitis (inflammation of the liver)

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: Yellow Card Scheme Website: 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 Dihydrochloride

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 box and bottle. The expiry date refers to the last day of that month.

Do not use after 3 months of first opening the bottle.

This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What Cetirizine Dihydrochloride contains

- The active substance is Cetirizine Dihydrochloride. 10 ml (two spoonfuls of 5 ml) contains 10 mg of Cetirizine Dihydrochloride.
- The other ingredients are sorbitol (E 420), glycerol (E 422), propylene glycol (E 1520), saccharin sodium (E 954), methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), banana flavor 505449B, sodium acetate (E 262), glacial acetic acid, purified water.
- 10 ml Cetirizine Dihydrochloride (two spoonfuls of 5 ml) contain: 2.205 g glucose equivalents (sorbitol).

What Cetirizine Dihydrochloride looks like and contents of the pack

Clear and colorless liquid with slightly sweet taste and a banana flavor.

Pack with a bottle containing volumes of 70 or 200ml solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR United Kingdom

Manufacturer:

RX Farma Limited, Unit 3 Colonial Way, Watford, Hertfordshire, WD24 4YR, United Kingdom

This leaflet was last revised in **November 2024**

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