

Package leaflet: Information for the user

Cetrine Allergy 1 mg/ml oral solution

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 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

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1. What Cetrine Allergy is and what it is used for

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

In adults and children aged 2 years and above, Cetrine Allergy 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 you take Cetrine Allergy

Do not take Cetrine Allergy

- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min)
- if you are allergic to cetirizine dihydrochloride, to 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 before taking Cetrine 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.

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

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 concurrent consumption of alcohol.

Other medicines and Cetrine 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.

Taking Cetrine Allergy with food and drink

Food does not affect 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.

Cetrine 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 medicine should only be administered if necessary and after medical advice.

Cetirizine passes into breast milk. Therefore, you should only take Cetrine Allergy during breast-feeding if your doctor thinks it is necessary.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Cetrine 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.

Cetrine Allergy contains sorbitol;

This medicine contains 315 mg sorbitol in each 1 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.

Cetrine Allergy contains propylene glycol (E1520): This medicine contains 49 mg propylene glycol in each 1 ml.

Cetrine Allergy contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216).

Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed).

Cetrine Allergy contains sodium: This medicine contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially 'sodium-free'.

3. How to take Cetrine Allergy

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.

Adults and adolescents above 12 years old

10 mg once daily as 10 ml oral solution (2 full measuring spoons).

Children between 6 and 12 years old

5 mg twice daily as 5 ml (one full measuring spoon) twice daily.

Children between 2 and 6 years old

2.5 mg twice daily as 2.5 ml oral solution (a half-measuring spoon) twice daily

Patients with moderate to severe 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.

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 Cetrine 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 Cetrine Allergy than you should

If you think you have taken an overdose of Cetrine 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 Cetrine Allergy

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

If you stop taking Cetrine Allergy

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Cetrine Allergy.

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 Cetrine Allergy and seek 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
- diarrhoea, 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

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

- tachycardia (heart beating too fast)
- oedema (swelling)
- allergic reactions, some severe (very rare)
- liver function abnormal
- weight increased
- convulsions
- 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, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions) 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), nightmare
- pruritus (intense itching) and urticaria upon discontinuation
- joint pain
- rash with blister 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Cetrine Allergy

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

Do not use Cetrine Allergy after the expiry date which is stated on the box and bottle. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Shelf-life after opening: 12 weeks.

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 Cetrine Allergy contains

The active substance of Cetrine Allergy is cetirizine dihydrochloride.

10 ml (equals to 2 measuring spoons) contain 10 mg of cetirizine dihydrochloride.

The other ingredients are: glycerol, propylene glycol (E1520), saccharin sodium (E954), sorbitol solution 70%, non-crystallizing, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium acetate, acetic acid, banana flavouring, purified water.

10 ml Cetirizine Allergy oral solution (=2 measuring spoons) contain: 3.15 g glucose equivalents (sorbitol).

What Cetrine Allergy looks like and contents of the pack

Clear, colourless liquid with banana flavour.

Cetrine Allergy oral solution is packed in 60 ml, 75 ml, 150 ml and 200 ml in amber glass bottle (type III) with polyethylene childproof screw top.

A 5 ml measuring spoon with lines at 1.25 ml and 2.5 ml is provided with the bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer

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

This leaflet was last revised in 06/2020.