

Cetrine 10 mg Film-coated Tablets

cetirizine dihydrochloride

ROWEX[®]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1 What Cetrine is and what it is used for

The active ingredient of Cetrine is cetirizine dihydrochloride. Cetrine is an anti-allergy medicine. It helps control your allergic reaction and its symptoms.

In adults and children aged 6 years and above: Cetrine relieves symptoms associated with, for example, hay fever, allergy to dust mites (allergic rhinitis) such as:

- sneezing,
- runny or itchy nose,
- itchy palate,
- itchy, red or tearing eyes.

Cetrine is also used to relieve symptoms such as itching and hives (associated with chronic urticaria of unknown cause).

2 What you need to know before you take Cetrine

Do not take Cetrine:

- if you are allergic to cetirizine or any of the other ingredients of this medicine (listed in section 6), to hydroxyzine or piperazine derivatives (closely related active substances of other medicines)
- if you have severe kidney problems.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Cetrine:
- if you have **kidney problems**. Your treatment may need to be adjusted.
- if you have predisposition factors of urinary retention (e.g. spinal cord lesions or prostatic hyperplasia)
- 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 for several days before testing. This medicine may affect your allergy test results.

Children and adolescents

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 Cetrine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Cetrine with food, drink and alcohol

Please be careful if you drink alcohol during use of this medicine, as it may increase the effects of alcohol. Food does not affect the absorption of Cetrine.

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 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.

Breast-feeding: You should avoid using this medicine if you are breastfeeding an infant, as cetirizine hydrochloride is excreted in human milk.

Driving and using machines

At the recommended dose, Cetrine is not expected to

cause you to be drowsy or less alert. However, if you are a sensitive patient, simultaneous use of alcohol and other nervous depressant agents may additionally affect your ability to drive and use machines.

Cetrine 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 Cetrine

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

Adults and adolescents aged 12 years and over:

The usual dose is one tablet once a day.

Children aged between 6-12 years:

The usual dose is half a tablet twice a day (morning and evening).

These tablets are not intended for children under the age of 6 years.

Patients with kidney problems: if you have moderate kidney problems your doctor may reduce your dose to half a tablet once a day. If you have severe kidney problems your doctor may reduce your dose to half a tablet every 2 days.

Swallow the tablets with a glass of water. The tablet can be divided into equal doses. You may take this medicine with or without food.

Duration of treatment:

The duration of the treatment may vary depending on the symptoms.

If you take more Cetrine than you should

The following symptoms may occur after an overdose of Cetrine:

Confusion, diarrhoea, dizziness, fatigue, headache, weakness, dilatation of the pupils, itching, restlessness, sedation, drowsiness, unresponsiveness, fast heart rhythm, involuntary trembling and inability to pass water.

If you have accidentally taken more of this medicine than you should please contact your doctor or pharmacist immediately.

If you forget to take Cetrine

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

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.

Some very rare side effects could be serious:

If any of the following happens, stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions such as sudden difficulty in breathing, speaking and swallowing, swelling of the lips, face and neck, extreme dizziness or collapse, itchy, raised skin rash
- unusual bruising or bleeding caused by low blood platelets.

Other possible side effects:

Tell your doctor if any of the following side effects bother you:

Common: may affect up to 1 in 10 people
headache, dizziness, dry mouth, fatigue, feeling sick, diarrhoea, drowsiness, sore throat, runny nose.

Uncommon: may affect up to 1 in 100 people
stomach upset, extreme fatigue, feeling weak, tingling or numbness in the hands and feet, agitation, itchiness, rash.

Rare: may affect up to 1 in 1,000 people
rapid heart beat, swelling, allergic reactions, changes in liver function, weight increase, convulsions, aggression, confusion, depression, hallucination, difficulty in sleeping, red and/or blotchy skin rash.

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Very rare: may affect up to 1 in 10,000 people
difficulty focusing, blurred vision, unusual eye
movements, fainting, tremor, altered taste, tics, pain
and/or difficulty passing water, fixed drug eruption.

Not known: frequency cannot be estimated from the
available data
increased appetite, impairment or loss of memory,
vertigo, urinary retention, joint pain, nightmare,
hepatitis, rash with blisters containing pus.

After stopping treatment with Cetrine, pruritis (intense
itching) and/or urticaria (hives) have been reported.

In very rare cases people have thought about
committing 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,
pharmacist or nurse. 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

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 carton after EXP. The expiry date refers to
the last day of that month.

Do not store above 25°C.

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 Further information

What Cetrine contains:

- the active substance is cetirizine dihydrochloride.
Each film-coated tablet contains 10 mg cetirizine
dihydrochloride.
- The other ingredients are: lactose monohydrate,
microcrystalline cellulose, colloidal anhydrous silica,
magnesium stearate, hypromellose, titanium dioxide
(E171) and macrogol 4000.

What Cetrine looks like and contents of the pack:

Cetrine are white, oblong film-coated tablets with a
score line on one side.

The tablets can be divided into equal halves.

PVC/Aluminium blister: 30 film-coated tablets

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland

Manufacturers:

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

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork.

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