

Package leaflet: Information for the user

Cetirizine dihydrochloride 10 mg film-coated tablets

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, pharmacist or nurse 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, pharmacist or nurse. 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 (antihistamine).

In adults and children aged 6 year 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).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Cetirizine

Do not take Cetirizine

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cetirizine if:

- you have kidney problems. You may need to take a lower dose. The new dose will be determined by your doctor.
- you have epilepsy or are at risk of convulsions (fits).

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, drink and alcohol

Cetirizine can be taken with or without food.

There is no evidence of interactions between alcohol (at a blood level of 0.5 per mille corresponding to one glass of wine) and Cetirizine at normal doses. However, as with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 medicines, 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 breastfeeding because cetirizine passes into breast milk.

Driving and using machines

In most people this product does not cause drowsiness. However, there are rare exceptions and you should take care when you use this product for the first time.

If this product makes you feel drowsy, do not drive or operate machinery.

3. How to take Cetirizine

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The tablets should be swallowed with a glass of liquid.

The recommended dose is:

Adults:

10 mg (1 tablet) once daily.

Use in children and adolescents

Children between 6 and 12 years old:

5 mg (half tablet) twice daily.

Adolescents above 12 years old:

10 mg (1 tablet) once daily.

Patients with moderate to severe kidney problems:

Patients with moderate kidney problems 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.

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Duration of treatment:

The duration of treatment depends on the type, duration and cause of your complaints and is determined by your doctor.

If you take more Cetirizine than you should

If you have taken more Cetirizine than you should, or if a child has taken medicine by accident, you should contact your doctor or the nearest hospital casualty department for advice.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, malaise, dilating of pupils, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and difficulty to urinate have been reported.

If you forget to take Cetirizine

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, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience first signs of hypersensitivity reaction, stop taking Cetirizine and seek for medical attention without delay. The signs of hypersensitivity reaction can be as follows: 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 following side effects have also been reported:

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- diarrhoea.
- 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, sometimes severe (very rare).
- liver function abnormal.
- 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), dystonia, dyskinesia (difficulty in moving).
- tics.

- abnormal elimination of urine.
- swelling, fixed drug eruption.
- anaphylactic shock.

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

- weight increased.
- amnesia, memory impairment.

Reporting of side effects

If you get any side effects, talk to your doctor or 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. Website: 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 this medicine after the expiry date which is stated on the carton and blister. 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. Contents of the pack and other information**What Cetirizine contains**

- The active substance of Cetirizine is Cetirizine dihydrochloride. Each film-coated tablet contains 10 mg Cetirizine dihydrochloride.
- The other ingredients are: croscarmellose sodium, microcrystalline cellulose, colloidal silica, (anhydrous), magnesium stearate, hypromellose and titanium dioxide (E171).

What Cetirizine looks like and contents of the pack

White to off white, oval shaped film-coated tablets with squared edges with '10' on one side and break line on other side.

Packs with 7, 14 or 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer*Marketing Authorisation Holder*

Somex Pharma
Ilford, Essex, IG3 8BS

Manufacturer

Somex Pharma
Ilford, Essex, IG3 8RA

This medicinal product is authorised in the Member States of the EEA under the following names:

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This leaflet was last revised in 06/2014

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