

Package leaflet: information for the user

Cetimax 10 mg film-coated tablets cetirizine dihydrochloride

Read all of this leaflet carefully before you start using 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 signs of illness are the same as yours.
- 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.

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

1. What Cetimax is and what it is used for

Cetirizine dihydrochloride is the active substance of Cetimax. Cetimax belongs to the group of medicines called antihistamines for systemic use, which are used against allergy (hypersensitivity).

In adults and children aged 6 year and above, Cetimax is used

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. What you need to know before you take Cetimax

Do not take Cetimax

- if you are allergic to cetirizine dihydrochloride 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 a severe kidney disease

Warnings and precautions

Talk to your doctor or pharmacist before using Cetimax if;

- you have impaired renal function. If necessary, your dose will be adjusted. The new dose will be determined by your doctor.
- you have problems passing urine (like spinal cord problems or prostate or bladder problems).

- you have epilepsy or are prone to convulsions.
- you are going to have an allergy skin test made. Cetimax use should be stopped three days before tests are performed.

Children

Do not give this medicine to children below the age of 6 because the tablet formulation does not allow the necessary dose adjustments.

Other medicines and Cetimax

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.

Cetimax with food, drink and alcohol

The absorption of cetirizine is hardly affected by 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. In sensitive patients, the concurrent use of alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance, although Cetimax does not increase the effect of alcohol. As with all antihistamines, it is recommended to avoid concurrent consumption of 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 or pharmacist for advice before taking this medicine.

The use of Cetimax should be avoided in pregnant women. Accidental use of the drug is not believed to cause any harmful effects on the foetus. Nevertheless, the medicine should only be administered if necessary and after medical advice.

The active substance cetirizine passes into breast milk. Therefore, you should not take Cetimax during breast-feeding unless your doctor has told you to do so.

Driving and using machines

Clinical studies reveal no evidence of impaired attention, alertness and driving capabilities after taking Cetimax at the recommended dose.

If you intend 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.

3. How to take Cetimax

How and when should you take Cetimax

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

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

The tablets should be swallowed with a glass of liquid.
The tablet can be divided into two equal doses.

Adults and adolescents above 12 years old:

The recommended dose is: 10 mg (1 tablet) once daily.

Use in children between 6 and 12 years old:

The recommended dose is: 5 mg (half tablet) twice daily.

Patients with moderate to severe renal impairment

Patients with moderate renal impairment are recommended to take 5 mg once daily.

If you feel that the effect of Cetimax is too weak or too strong, please consult your doctor.

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 Cetimax than you should

If you have taken more Cetimax 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 pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and difficulty to urinate have been reported.

If you forget to take Cetimax

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

If you stop taking Cetimax

If you have any further questions on the use of this product, 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 Cetimax and contact a doctor or go to the nearest emergency department immediately if you experience any of the following symptoms: 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 a very serious allergic reaction (angioedema) or anaphylactic shock. The reactions are very rare (may affect up to 1 in 10,000 users).

Other possible side effects are:

Common (may affect up to 1 in 10 users):

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

Uncommon (may affect up to 1 in 100 users):

- abdominal pain
- asthenia (extreme fatigue), malaise (feeling of being generally unwell)
- paresthesia (abnormal feelings of the skin)
- agitation
- Pruritus (itchy skin), rash

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

- 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 (hives)

Very rare (may affect up to 1 in 10,000 users):

- thrombocytopenia (low levels of blood platelets)
- accommodation disorder (difficulty focusing), blurred vision, oculogyration (eyes having uncontrolled circular movements)
- syncope, tremor, dysgeusia (altered taste), dystonia (abnormal prolonged muscular contractions), dyskinesia (involuntary movements)
- tics (habit spasm)
- abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)
- fixed drug eruption

Frequency not known (cannot be estimated from the available data):

- increased appetite
- suicidal ideation
- amnesia, memory impairment
- vertigo (sensation of rotation or movement)
- urinary retention (inability to completely empty the urinary bladder)

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cetimax

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

Store below 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer used. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cetimax contains

- The active substance is cetirizine dihydrochloride. One film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are microcrystalline cellulose, pregelatinised starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, polydextrose, hypromellose, titanium dioxide (E 171), macrogol.

What Cetimax looks like and contents of the pack

Appearance:

A white, round, convex one-side scored tablet with logo "5". Diameter is 7 mm.

Pack sizes:

7, 10, 14, 20, 30, 50 and 100 tablets (Al/Al blister with carton).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Cetimax (DK, FI, HU, NO, SE)
Cetrix (EE, LV, LT, PL)
Cetixin (CZ, DE, SI, SK)

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