

Package leaflet: Information for the user

CETEC 10mg FILM-COATED TABLETS (Cetirizine hydrochloride)

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 a few days.

What is in this leaflet:

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

1. What Cetec tablets are and what they are used for

The name of your medicine is Cetec 10mg film-coated tablets, referred as Cetec tablets in this leaflet. The active ingredient, Cetirizine hydrochloride belongs to a group of medicines called antihistamines. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions.

Cetec tablets are used to treat people who have hay fever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin). Cetec tablets also relieve the unpleasant symptoms and discomfort associated with these conditions, such as sneezing, irritated, runny and blocked up nose, itchy, red and watering eyes and skin rashes.

2. What you need to know before you take Cetec tablets

Do not take if you:

- have severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min)
- are allergic to cetirizine hydrochloride or any of the other ingredients (listed in section 6) or to hydroxyzine or to piperazine derivatives (closely related active substances of other medicines)

Warnings and precautions

Talk to your doctor or pharmacist before taking Cetec tablets 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.
 - you have problems passing urine (like spinal cord problems or prostate or bladder problems), please ask your doctor for advice.
 - 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 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 taking Cetec with alcohol.

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

Children

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 Cetec tablets

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

Cetec tablets with food and drink

Food does not affect absorption of Cetec.

Pregnancy, breast-feeding and fertility

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.

Cetec 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 not take Cetec 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 Cetec at the recommended dose.

You should closely observe your response to the drug after you have taken Cetec if you are intending to drive, engage in potentially hazardous activities or operate

machinery. You should not exceed the recommended dose.

Cetec tablets contain 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 Cetec tablets

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 tablets need to be swallowed with a glass of liquid. The tablet can be divided into equal doses. Do not take more than one tablet each day.

The recommended doses are as follows:

Adults and children aged 12 years and over:

The recommended dose is 10 mg once daily as one tablet daily. If the tablets make you feel drowsy or dizzy, taking half a tablet twice a day may be better than taking one tablet once a day.

Other form (s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Children aged 6 to 12:

The recommended dose is 5 mg twice daily as half a tablet. Other form (s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Not recommended for children under 6 years.

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.

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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 Cetec 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 Cetec tablets than you should

If you think you have taken an overdose of Cetec 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 Cetec tablet

Do not take a double dose to make up for a forgotten dose. If you forget to take a tablet, you should take one as soon as you remember, but wait at least 24 hours before taking your next tablet.

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 tablets 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).

Suicidal ideation (recurring thoughts of or preoccupation with suicide).

Rash with blisters containing pus.

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 people)

- Somnolence (sleepiness)
- Headache, dizziness
- Pharyngitis, rhinitis (in children)
- Diarrhoea, nausea, dry mouth
- Fatigue

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

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

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

- 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 people)

- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)

- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)
- Fixed drug eruption
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

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

- Increased appetite
- Nightmare
- Amnesia, 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
- Joint pain
- 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 the Yellow card scheme at 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 Cetec tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do not use the tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- 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 Cetec tablets contain

- Each tablet contains 10mg of the active ingredient cetirizine hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, pregelatinised starch, purified talc, magnesium stearate, hypromellose, titanium dioxide (E171) and macrogol.

What Cetec tablets look like and the contents of the pack

- Cetec tablets are white to off white capsule shaped film coated tablets with a scoreline and 'B' and 'L' debossed on either side of the scoreline and '10' debossed on the other side.
- Cetec tablets are available in packs of 7, 14 and 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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