Package leaflet: Information for the patient

Zirtene 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.
- 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 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 Zirtene is and what it is used for

Cetirizine dihydrochloride is the active ingredient of Zirtene.
Zirtene is an anti-allergy medication.

In adults and children aged 6 years and above, Zirtene 10 mg film-coated tablets are indicated:
- for the relief of nasal and ocular symptoms of hay fever (seasonal allergic rhinitis) and allergies such as dust or pet allergies (perennial allergic rhinitis), such as sneezing, itchy, runny and blocked nose, red and watery eyes.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. What you need to know before you take Zirtene

Do not take Zirtene
- if you have a severe kidney disease and are undergoing dialysis due to severe kidney failure (creatine 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 piperazine derivatives (closely related active ingredients of other medicines).

Warnings and precautions
Talk to your doctor or pharmacist before taking Zirtene:
- if you have kidney (renal insufficiency) problems. You may need to take a lower dose. The new dose will be determined by your doctor.
- if you have problems passing urine (e.g. spinal cord problems or prostate or bladder problems).

- if you have epilepsy or are at risk of convulsions.

If you need a skin (allergy) test, tell the doctor you are taking these tablets, as antihistamines can effect skin test results. You will need to stop treatment at least three days before the test.

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 Zirtene
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 medicines are expected.

Zirtene with food and drink
Food does not affect absorption of Zirtene.

Zirtene with alcohol
No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 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 Zirtene with 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.

Zirtene should be avoided in pregnant women. Accidental use of this medicine by a pregnant woman should not cause any harmful effects on the foetus. Nevertheless, this medicine should only be administered if necessary and after medical advice.

Cetirizine passes into breast milk. Therefore, you should not take Zirtene if you are 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 Zirtene at the recommended dose.
If you feel tired, less able to concentrate or think clearly, or feel unwell after you have taken Zirtene you should not drive, take part in activities that could be dangerous or operate machinery. You should not exceed the recommended dose.

Zirtene 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 Zirtene

Always take this medicine exactly 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 score line is only there to help you break the tablet if you have difficulty in swallowing it whole.

Adults and adolescents above 12 years old:
The recommended dose is 10 mg once daily as 1 tablet.

Children between 6 and 12 years old:
The recommended dose is 5 mg twice daily. Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Patients with 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 you child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.
For these dosing regimens; a different formulation should be used.

If you feel that the effect of Zirtene 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 Zirtene than you should
If you think you have taken an overdose of Zirtene 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, sleepiness, loss of consciousness, abnormal rapid heart rate, tremors and not being able to pass urine have been reported.

If you forget to take Zirtene
Do not take a double dose to make up for a forgotten dose.

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

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.

If you notice any of the following stop taking Zirtene and contact your doctor immediately or go to the nearest hospital emergency department:

Rare (may affect up to 1 in 1,000 people)
- Convulsions (fits)

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

- Swelling of the face, throat, tongue or mouth, difficulty breathing, rash, itching as these may be signs of a serious allergic reaction (anaphylactic shock).
- Uncontrolled movements of the eyes (oculogyration)

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

- Thoughts of harming or killing yourself (suicidal ideation)
- Trouble emptying your bladder when passing urine (urinary retention)

Other side effects are:

Common (may affect up to 1 in 10 people)

- somnolence (sleepiness)
- dizziness, headache
- pharyngitis (sore throat)
- fatigue (feeling tired)
- dry mouth, feeling sick

Uncommon (may affect up to 1 in 100 people)

- agitation
- paraesthesia (numbness or tingling of the skin)
- abdominal pain
- pruritus (itching)
- asthenia (feeling weak)
- diarrhoea
- malaise (generally feeling unwell)
- rash

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

- hypersensitivity
- depression
- tachycardia (fast heart beat)
- liver function abnormal (this will be seen in a blood test)
- urticaria (hives)
- oedema (swelling)
- weight gain
- aggression
- confusion
- hallucinations (seeing, hearing or feeling things that are not there)
- insomnia (problems with sleeping)

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

- thrombocytopenia (low levels of blood platelets) which increases the risk of bleeding or bruising
- tics (uncontrolled repeated twitching movements)
- syncope (fainting)
- dyskinesia (involuntary movements)
- dystonia (abnormal, repeated twisting movements of the muscles that may be painful)
- tremor

- dysgeusia (altered taste)
- blurred vision
- eye accommodation disorder (inability of the eye to automatically change focus)
- Loss of control of passing urine (bed wetting, pain when passing urine)
- fixed drug eruption (appearance of red or blistered skin in the same place after taking this medicine)

Not known (frequency cannot be estimated from the available data)
- increased appetite
- amnesia
- memory problems
- vertigo (spinning sensation)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Joint pain
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

Additional side effect seen in children aged 6 months to 12 years

Common (may affect 1 in 10 people)
- rhinitis

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. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zirtene

Keep out of the sight and reach of children.

Do not use Zirtene 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.

High density polyethylene containers (HDPE): store below 25°C.
PVdC coated PVC blister: this medicine does not require any special storage conditions.

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 Zirtene contains
- The active substance is cetirizine dihydrochloride. Each film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are lactose monohydrate (see section 2 “Zirtene contains lactose”), pregelatinised maize starch, povidone, magnesium stearate.

The coating includes hypromellose, macrogol and titanium dioxide (E171).

What Zirtene looks like and contents of the pack
White, capsule shaped film-coated tablets with a score line and marked ‘CZ 10’ on one side and ‘G’ on the other. Zirtene is supplied in plastic containers with screw caps containing 30, 100 or 250 tablets or blister packs containing 7, 10, 14, 15, 20, 30, 50, 60, 90, or 100 tablets or 100 (10x10x1) or 50 (50x1) unit-dose tablets.
Not all pack sizes may be marketed

Marketing Authorisation Holder
Viatris Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland.

Manufacturers

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This leaflet was last revised in 02/2024.