

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 more 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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- 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.
- In this leaflet **CETIMIN 10 mg film-coated tablets** will be called **CETIMIN 10 mg Tablets**

CETIMIN 10 mg tablets

Cetirizine

What is in this leaflet:

1. What **CETIMIN 10 mg Tablets** are and what they are used for
2. What you need to know before you take **CETIMIN 10 mg Tablets**
3. How to take **CETIMIN 10 mg Tablets**
4. Possible side effects
5. How to store **CETIMIN 10 mg Tablets**
6. Contents of the pack and other information

1. What CETIMIN 10 mg Tablets are and what they are used for

Cetirozone hydrochloride is the active ingredient of **CETIMIN 10 mg Tablets**.

CETIMIN 10 mg Tablets is an antiallergic medication.

In adults and children aged 6 year and above, **CETIMIN 10 mg Tablets** are indicated

- for the relief of 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, itchy, red and watery eyes.

- for the relief of swelling, redness and itchiness of the skin (symptoms of chronic idiopathic urticaria, which is also known as chronic nettle rash).

2. What you need to know before you take CETIMIN 10 mg Tablets

Do not take CETIMIN 10 mg Tablets

- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min).

- if you are known to be allergic (hypersensitive) to the active substance of **CETIMIN 10 mg Tablets** or any of the other ingredients of these tablets (these are listed below, in section 6 "Further information").

- if you are known to be allergic (hypersensitive) to hydroxyzine (closely related active substances of other medicines).

- if you are known to be allergic (hypersensitive) to drugs from the piperazine family, for example buclizine, cyclizine, meclozine, levocetirizine.

Warnings and precautions

Talk to your doctor or pharmacist before taking **CETIMIN 10 mg Tablets**.

If you have kidney problems, please ask your doctor for advice; if necessary, you may have to take a lower dose. The new dose will be determined by your doctor.

If you have predisposition factors of urinary retention (eg: spinal cord lesion, prostatic hyperplasia) as **CETIMIN** increases the risk of urinary retention, please ask your doctor for advice.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

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 CETIMIN 10 mg Tablets

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

Due to the profile of **CETIMIN**, no interactions with other drugs

are expected.

Taking **CETIMIN 10 mg Tablets** with food and drink. Food does not noticeably affect the absorption of **CETIMIN**. No interactions having a noticeable impact have been observed between alcohol (at the blood level of 0.5 per mille (g/l) corresponding to one glass of wine) and **CETIMIN** used at the recommended doses. However, as it is the case with all antihistamines, it is recommended to avoid consumption of alcohol while taking this medicine.

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 for advice before taking this medicine. **CETIMIN 10mg Tablets** 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.

CETIMIN passes into breast milk. Side effects associated with **CETIMIN** may be seen in breastfed infants. Therefore, you should not take **CETIMIN 10 mg Tablets** during breast-feeding unless you have contacted a doctor.

Allergy skin test

If you are going to have an allergy skin test stop taking **CETIMIN 10 mg Tablets** for three days before the test.

This medicine may affect your allergy test results.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking **CETIMIN 10 mg Tablets** at the recommended dose.

You should closely observe your response to the drug after you have taken **CETIMIN 10 mg Tablets** if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

CETIMIN 10 mg Tablets contains lactose

CETIMIN 10 mg Tablets contain lactose; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. How to take CETIMIN 10 mg Tablets

Always take **CETIMIN 10 mg Tablets** exactly as your doctor has told you. Check with your doctor if you are not sure.

Tablets need to be swallowed with a glass of liquid.

Children aged 6 to 12 years

The recommended dose is 5 mg twice daily as half a tablet twice a day.

Adults and children aged 12 years and over:

The recommended dose is 10 mg once daily as one tablet. Patients with moderate to severe renal impairment:

Patients with moderate renal impairment are recommended to take 5 mg once daily as a half tablet.

If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.

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 **CETIMIN 10 mg Tablets** 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 **CETIMIN 10 mg Tablets** than you should if you think you have taken an overdose of **CETIMIN 10 mg Tablets**, 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 (widening) of the pupil, itching, restlessness, sedation, somnolence, stupor (lowered consciousness), abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take CETIMIN 10 mg Tablets

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

If you stop taking CETIMIN 10 mg Tablets

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking CETIMIN 10 mg Tablets. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, CETIMIN 10 mg Tablets can cause side effects, although not everybody gets them.

In very rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets and see your doctor immediately.

If you develop one of the very rare side effects described below, please inform your doctor straight away.

At the first signs of a severe allergic (hypersensitivity) reaction (symptoms include: rash, itchiness and fever, difficulty breathing, swelling of the neck, throat, tongue, face, eyelids or lips) stop taking the tablets and contact your doctor immediately.

This reaction may start soon after you first take the medicine or it might start later.

Your doctor will then assess the severity and decide on any further measures that may be necessary.

The following side effects have also been reported.

Common side effects (may affect up to 1 in 10 patients)

- Fatigue, somnolence (sleepiness)
- Dizziness, headache,
- Dry mouth, nausea (feeling sick), diarrhoea (children only)
- Pharyngitis (sore throat), rhinitis (swelling and irritation inside the nose (children only))

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

- Pruritus (itching), rash
- Abdominal pain
- Agitation
- Asthenia (feeling of weakness), malaise (feeling of being generally unwell)
- Paraesthesia (abnormal feelings of the skin), tingling in the hands and feet

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

- Tachycardia (heart beating fast)
- Oedema (generalised swelling due to water retention)
- Liver function abnormal
- Convulsions
- Weight increased

- Aggression, confusion, depression, hallucination (hearing or seeing things), insomnia (difficulty sleeping)
- Urticaria (swelling, redness and itchiness of the skin)

Very rare side effects (may affect up to 1 in 10,000 patients)

- Thrombocytopenia (low level of blood platelets), which increases risk of bleeding or bruising
- Accommodation disorder (impaired ability of the eye to focus), blurred vision, oculogyration (eyes moving in an uncontrolled circular manner)
- Syncope (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Tics (sudden abnormal repetitive muscle movement)
- Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin)
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

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

- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia (loss of memory), 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
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

Reporting of suspected adverse reactions

If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CETIMIN

Keep out of the sight and reach of children.

Do not use CETIMIN 10 mg Tablets after the expiry date which is stated on the box and blister.

This medicine does not require any special storage conditions.

What CETIMIN 10 mg Tablets contain

· The active substance of CETIMIN 10 mg Tablets is CETIMIN hydrochloride. One film coated tablet contains 10 mg CETIMIN hydrochloride.

· **The other ingredients are:** lactose monohydrate, microcrystalline cellulose, pregelatinized starch, magnesium stearate

Film: Opadry white, purified water

What CETIMIN 10 mg Tablets look like and contents of the pack?

White, film-coated, slightly biconvex tablets.

Box of 10 tablets of 10 mg cetirizine in blister pack.

Marketing Authorization Holder and Manufacturer:

ZADA Pharmaceuticals Ltd.

Donji Bistarac without number

75 300 Lukavac

Bosnia and Herzegovina

Date and number of first authorisation/renewal of the authorization

CETIMIN 10 mg, film-coated tablets: 18.04.2018.

This leaflet was last revised in June 2019.