

PACKAGE LEAFLET

Package leaflet: Information for the patient

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

1. What Cetirizin Viatris is and what it is used for

Cetirizine dihydrochloride is the active ingredient of Cetirizin Viatris. Cetirizin Viatris is an antiallergic medication.

In adults and children aged 6 years and above, Cetirizin Viatris 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).

2. What you need to know before you take Cetirizin Viatris

Do not take Cetirizin Viatris

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Cetirizin Viatris

- If you have kidney problems. You may need to take a lower dose. The new dose will be determined by your doctor.
- If you have problems passing urine (like spinal cord problems or prostate or bladder problems), ask your doctor for advice.
- If you have epilepsy or you are at risk of convulsions (fits).

Skin test

If you need a skin (allergy) test, tell the doctor you are taking these tablets as this medicine can affect skin test results. You will need to stop treatment 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 Cetirizin Viatris

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

Cetirizin Viatris with food, drink and alcohol

Food does not affect absorption of Cetirizin Viatris.

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 cetirizine Viatris 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.

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

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetirizin Viatris during breast-feeding.

Driving and using machines

There is no evidence of impaired attention, alertness and driving capabilities after taking Cetirizin Viatris at the recommended dose.

You should closely observe your response to the medicine after you have taken Cetirizin Viatris if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Cetirizin Viatris 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 Cetirizin Viatris

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

How and when should you take Cetirizin Viatris

These guidelines apply unless your doctor has given you different instructions on how to use Cetirizin Viatris.

Please follow these instructions, otherwise Cetirizin Viatris may not be fully effective. Tablets need to 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 once daily as one tablet.

Use in children between 6 and 12 years old:

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

Patients with kidney impairment

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

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

If your child suffers from kidney disease, please contact your doctor who may adjust the dose according to your child's needs.

If you feel that the effect of Cetirizin Viatris 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 or pharmacist.

If you take more Cetirizin Viatris than you should

If you think you have taken an overdose of Cetirizin Viatris 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, feeling generally unwell, dilating of pupil, itching, restlessness, sedation, sleepiness, stupor, abnormal rapid heart rate, tremors and inability to completely empty the bladder have been reported.

If you forget to take Cetirizin Viatris

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

If you stop taking Cetirizin Viatris

Rarely, pruritus (intense itching) and/or urticaria (hives) may return if you stop taking Cetirizin Viatris.

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.

Some side effects could be serious:**Very rare** (may affect up to 1 in 10,000 people)

- Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or throat, or other parts of the body, shortness of breath, wheezing or trouble breathing

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

- Thoughts of committing suicide
- Inability to completely empty the bladder

If any of the above occurs, you must stop taking this medicine and tell your doctor straight away.

Other possible side effects**Common** (may affect up to 1 in 10 people)

- Tiredness
- Dry mouth
- Feeling sick

- Dizziness
- Headache
- Sleepiness
- Sore throat and discomfort when swallowing

Uncommon (may affect up to 1 in 100 people)

- Weakness
- Generally feeling unwell
- Tingling or numbness of the hands or feet
- Agitation
- Itching
- Rash
- Stomach pain

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

- Fast heart beat
- Abnormal liver function tests
- Increase in weight
- Convulsions (fits)
- Aggression
- Confusion
- Depression
- Seeing, feeling or hearing things that are not there
- Inability to sleep
- Hypersensitivity (usually occurs with skin reaction like rash, itchy red skin)
- Hives
- Swelling, fluid retention (oedema)

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

- Bleeding or bruising more easily than normal
- Tics (habit spasm)
- Blurred vision, eyes having uncontrolled circular movements
- Accommodation disorder (difficulty focusing)
- Fainting
- Shaking
- Taste disturbance or loss of taste
- Uncontrolled body movements
- Involuntary muscle contractions
- Difficult, painful or involuntary urination

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

- Memory loss
- Memory impairment
- Increased appetite
- Vertigo (spinning sensation) Nightmare
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Arthralgia (joint pain), myalgia (muscular pain)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- Hepatitis (inflammation of the liver)

Side effects in children and adolescents

In children and adolescents, the following side effects occur more commonly and can affect up to 1 in

10 people:

- Runny or blocked nose
- Diarrhoea

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 [To be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cetirizin Viatris

Keep out of the sight and reach of children.

Do not use Cetirizin Viatris after the expiry date which is stated on the label and carton. 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.

Blister: This medicine does not require any special storage conditions.

Bottle: Store below 25°C.

6. Contents of the pack and other information

What Cetirizin Viatris contains

- The active substance of Cetirizin Viatris is cetirizine dihydrochloride. Each film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are lactose monohydrate (see section 2 “Cetirizin Viatris contain lactose”), pregelatinised maize starch, povidone, magnesium stearate, hypromellose (E464), macrogol, titanium dioxide (E171) and talc.

What Cetirizin Viatris looks like and contents of the pack

The tablets are white and capsule-shaped with ‘CZ 10’ on one side and ‘G’ on the other. All tablets have a breakline.

Packed in bottles of 30, 100 and 250 tablets and blister packs of 2, 7, 10, 14, 15, 20, 30, 50, 60, 90 and 100 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Mylan B.V.
Krijgsman 20,
Amstelveen, 1186DM,
Netherlands

Mylan Hungary Ltd.
Mylan utca 1.,
Komarom, 2900,
Hungary

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

Denmark: Cetirizin Viatriss

Italy: Cetirizina Mylan Generics 10 mg compresse rivestite con film

Netherlands: Cetirizine diHCl Viatris 10 mg filmomhulde tabletten

Norway: Cetirizin ViatrisViatris

Portugal: Cetirizina Mylan

Spain: Cetirizina Viatris 10 mg, comprimidos recubiertos con película EFG

Sweden: Cetirizin Viatris 10 mg filmdragerad tablett

United Kingdom: Cetirizine 10 mg Film-coated Tablets

This leaflet was last revised in 15 September 2025.