

CETYROL FILM COATED TABLETS

Consumer Medication Information Leaflet (RiMUP)

Cetirizine dihydrochloride (10mg)

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What is Cetyrol used for

In adults and children aged 6 years and above, Cetyrol is used for the relief of symptoms associated with seasonal and perennial (symptoms that are present throughout the year) allergies including sneezing; itchy nose and throat; stuffy and runny nose; and tearing, red, or itchy eyes. It is also used for the relief of symptoms associated with allergic skin conditions e.g., chronic idiopathic urticaria (hives with no known cause that last for an extended period of time) such as itchy skin and hives.

How Cetyrol works

Cetirizine dihydrochloride is the active ingredient of Cetyrol, an anti-allergic medication. Cetirizine works by blocking the actions of one of the body's natural chemicals known as histamine. Histamine is responsible for many of the symptoms caused by allergies.

Before you use Cetyrol

- When you must not use it
 - if you are known to be hypersensitive to the active substance of Cetirizine dihydrochloride, to any of its excipients (other constituents), to hydroxyzine or to piperazine derivatives (closely related active substances of other medicines).
 - if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
 - if you have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

As with other medicines, use of Cetyrol 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 administration of the medicine should be discontinued.

Cetyrol passes into breast milk. Therefore, you should only take Cetyrol during breast-feeding if your doctor thinks it is necessary

- Before you start to use it

If you are a patient with kidney insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

If you plan having an allergy skin test made, the use of Cetyrol should be interrupted at least 3 days prior to skin tests.

No interactions have been observed between alcohol and cetirizine used at the normal doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Taking other medicines

Please inform your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription.

Taking CETYROL with food and drink

Food does not affect noticeably the absorption of cetirizine.

How to use Cetyrol

- How much to use

Adults and adolescents above 6 years old
10 mg once daily as one tablet.

Patients with renal insufficiency

Your doctor will adjust your dose depending on the degree or renal impairment.

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

- When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

It is important to take your medicine every day. Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you forget to use it

It is important to take your medicine every day. However, if you forget to take one or more doses, take another as soon as you remember and then go on as prescribed. Do not take a double dose.

- If you use too much (overdose)

If you take too many tablets, contact your nearest hospital casualty department or tell your doctor immediately. After an overdose, the side effects described such as somnolence may occur with increased intensity.

While you are using it

- Things you must do
 - Take your medicine exactly as your doctor has told you.
 - Tell all the doctors, dentists and pharmacists treating you that you are taking CETYROL.
 - Tell your doctor immediately if you become pregnant while taking this medication.
- Things you must not do
 - Do not stop taking the medicine unless advised by your doctor.
 - Do not take any new medicines without consulting your doctor.
 - Do not give CETYROL to anyone else, even if they have the same symptoms or condition as you.

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Things to be careful of

Driving and using machines

The occurrence of somnolence has been reported in some patients taking Cetirizine. Due caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose and you should closely observe your response to the drug.

Side effects

Like all medicines, CETYROL can cause side effects, although not everyone gets them.

Following side effects have been reported in post marketing experience.

In rare cases, mild transient adverse reactions such as fatigue, headache, dizziness, agitation and gastrointestinal complaints have been reported.

In individual patients, hypersensitivity reactions, usually reversible hepatic dysfunctions (hepatitis, increase in transaminases) and thrombocytopenia have been observed. The occurrence of palpitations and syncope as well as weight gain have been reported in isolated cases.

If you develop one of the side effects described above, please inform your doctor. At the first signs of a hypersensitivity reaction, stop taking Cetyrol. Your doctor will then assess the severity and decide on any further measures that may be necessary.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers →

Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Cetyrol

Storage

Keep out of the reach and sight of children.

Do not use Cetyrol after the expiry date which is stated on the box and blister.

Do not store above 30°C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

White, oblong, scored on one side.

Ingredients

Active substance

The active substance of Cetyrol is cetirizine dihydrochloride
One film-coated tablet contains 10 mg cetirizine dihydrochloride.

Inactive ingredients

The other ingredients are: lactose monohydrate, cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate, hypromellose, macrogol 4000, titanium dioxide.

MAL Number

MAL09072797AZ

Manufacturer and Product Registration Holder

Manufacturer

Salutas Pharma GmbH,
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Product Registration Holder

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