

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Pollenase

ALLERGY RELIEF 10MG FILM-COATED TABLETS

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine, referred to as Cetirizine dihydrochloride Tablets, because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- This medicine is available without prescription. However, you still need to take it carefully to get the best results.
- 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 Cetirizine dihydrochloride Tablets are and what they are used for
2. What you need to know before you take Cetirizine dihydrochloride Tablets
3. How to take Cetirizine dihydrochloride Tablets
4. Possible side effects
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1. What Cetirizine dihydrochloride Tablets are and what they are used for

The full name of this medicine is Pollenase Allergy Relief 10mg film-coated tablets but within this leaflet it will be referred to as Cetirizine dihydrochloride Tablets.

Cetirizine dihydrochloride, the active ingredient of the tablets is an antihistamine. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions. Cetirizine dihydrochloride 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).

Antihistamines like Cetirizine dihydrochloride Tablets 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 Cetirizine dihydrochloride Tablets

Do not take Cetirizine dihydrochloride Tablets if:

- you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6);
- you are breast-feeding;
- you have severe kidney failure (creatinine clearance less than 10 ml/min);
- you have problems of urinary retention;
- you have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

If any of the above applies to you talk to your pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cetirizine dihydrochloride Tablets if:

- you have problems with your kidneys;
- you have predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine increases the risk of urinary retention;
- you suffer from epilepsy or are at risk of convulsions;
- you want to use for children less than 6 years of age.

Cetirizine dihydrochloride Tablets with food, drink and alcohol

Avoid alcoholic drink while you are 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 or pharmacist for advice before taking this medicine.

Allergy Testing

If you are due to have an allergy test, ask your doctor if you should stop taking Cetirizine dihydrochloride Tablets for several days before testing. This medicine may affect your allergy test results.

Driving and using machines

Some people have reported that they feel drowsy or dizzy while they are taking Cetirizine dihydrochloride Tablets. If you are affected DO NOT drive or use machines.

Cetirizine dihydrochloride Tablets contain lactose

This medicine 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 Cetirizine dihydrochloride Tablets

Remember. Take the tablet with a glass of water. DO NOT take more than one tablet each day. If you do not feel better within a few days, consult your doctor.

Children aged 6 to 12:

Take half a tablet twice a day.

Adults and children aged 12 years and over:

Take 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. Cetirizine dihydrochloride Tablets are not suitable for children under 6.

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If you take more Cetirizine dihydrochloride Tablets than you should

If you accidentally take too many tablets go and see your doctor straightaway.

If you forget to take Cetirizine dihydrochloride Tablets

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 pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effect is very rare, but you must stop taking the tablets and speak to your doctor straight away if you notice these symptoms:

- A severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips. This reaction may start soon after you first take the medicine, or it might start later.

The following side effects have also been reported.

Common side effects (affects less than 1 in 10 people)

- Tiredness, feeling sleepy
- Headache
- Dry mouth
- Nausea
- Diarrhoea (children only)
- Pain in the abdomen
- Dizziness
- Sore throat
- Cold-like symptoms of the nose (children only).

Uncommon side effects (affects less than 1 in 100 people)

- Itching and rash
- Diarrhoea
- Feeling weak or generally unwell
- Tingling in the hands and feet
- Feeling agitated.

Rare side effects (affects less than 1 in 1000 people)

- Fast heart beat
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results (your doctor will know what to do)
- Convulsions
- Increased weight
- Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness
- Urticaria (hives).

Very rare side effects (affects less than 1 in 10,000 people)

- Blurred vision, difficulty focussing
- Rotation of the eyes
- Unusual bleeding or bruising
- Bad taste in the mouth
- Tremor, tics
- Involuntary movements and/or jerking of the limbs
- Muscle spasms in the neck and shoulders

- Swelling of the skin particularly around the face
- Fainting
- A recurring rash
- Bed wetting, pain and/or difficulty passing water.

Not known side effects

- Increased appetite
- Vertigo
- Urinary retention

Some cases of memory loss and/or impairment have also been reported.

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.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cetirizine dihydrochloride Tablets

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

DO NOT use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Cetirizine dihydrochloride Tablets contain

- The active substance is cetirizine dihydrochloride.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, hydroxypropylmethylcellulose (E464), polydextrose, titanium dioxide (E171), and macrogol/polyethylene glycol 4000.

What Cetirizine dihydrochloride Tablets look like and contents of the pack

The tablets are white to off-white capsule-shaped film-coated tablets, each with one plain face and with a break line on the other face.

Your medicine is supplied in clear colourless PVC/PVdC-Aluminium blisters packs of 7, 14, or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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