Pharmacode

Numark Allergy Relief 10 mg Film-Coated Tablets Cetirizine Hydrochloride

PATIENT INFORMATION LEAFLET

The name of this medicine is Numark Allergy Relief 10 mg Film-Coated Tablets Cetirizine Hydrochloride, which will be referred to as Cetirizine Hydrochloride Tablets throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine 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.
- 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, pharmacist or nurse. 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 3 days.

What is in this leaflet

1. What Cetirizine Hydrochloride Tablets are and what they are used for

The active ingredient in your tablets is Cetirizine hydrochloride, which belongs to a group of medicines called antihistamines. These are used to relieve the symptoms of seasonal allergic rhinitis (e.g. hayfever), perennial allergic rhinitis (e.g. year roundallergies often due to house dust mites or animal allergies) and urticaria (itchy, red, swollen skin). These symptoms include itchy skin rashes; sneezing; itchy, runny or blocked nose; red, itchy and watering eyes.

2. What you need to know before you take Cetirizine Hydrochloride Tablets

Do not take Cetirizine Hydrochloride Tablets if you:
- **are allergic** to cetirizine hydrochloride, hydroxyzine, piperazine derivatives or any of the **other ingredients** in Cetirizine Hydrochloride Tablets (these are listed in section 6)
- have a **severe kidney disease** (severe renal failure with creatinine clearance below 10 ml/min).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Cetirizine Hydrochloride Tablets. If you are a patient with renal 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 have problems passing urine (like spinal cord problems or prostate or bladder problems), 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.

No clinically significant interactions susceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per ml corresponding to one glass of wine) and cetirizine used at the recommended doses. However, there is 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 Hydrochloride Tablets with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Cetirizine Hydrochloride Tablets for several days before testing. This medicine may affect your allergy test results.

Children
Do not give this medicine to children below the age of 6 years because the tablet formulation does not allow necessary dose adjustment.

Other medicines and Cetirizine Hydrochloride Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, as they may decrease or increase the effect of Cetirizine Hydrochloride Tablets and vice versa.
- medication for anxiety or stress (CNS depressants).

Taking your medicine with food and drink
Cetirizine Hydrochloride Tablets can be taken with or without food.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant or breast-feeding, think you might be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. As with other drugs, the use of Cetirizine Hydrochloride 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 administration of the medicine should be discontinued.

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetirizine Hydrochloride Tablets during breast-feeding unless you have contacted a doctor.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Cetirizine Hydrochloride Tablets at the recommended dose.

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

Cetirizine Hydrochloride Tablets 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 Hydrochloride Tablets

Always take Cetirizine Hydrochloride Tablets exactly as your doctor or pharmacist has told you to do so.
You should check with your doctor or pharmacist if you are not sure.

Dosage
The usual dosage is:
Adults, elderly and children over 12 years: Take one tablet (10 mg) once daily.
Children aged 6 - 12 years: Take half a tablet (5 mg) twice daily (morning and evening).
Children weighing less than 30 kg: Half a tablet (5 mg) should be taken once daily.
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 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 the effect of Cetirizine is too weak or too strong, please contact 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 drowsiness occurs, your tablet can be taken in the evening.
Method of administration: For oral use.

If you take more Cetirizine Hydrochloride Tablets than you should
If you have accidentally taken more than the recommended dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately.** Remember to take the pack and any remaining tablets with you.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, malaise (feeling unwell), ailing, dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty in completely emptying the bladder) have been reported.

If you forget to take Cetirizine Hydrochloride Tablets
If you have forgotten to take your tablet, take it as soon as you remember and then wait 24 hours before taking your next dose. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects are rare or very rare, but you must stop taking the medicine and speak to your doctor straight away if you notice them:
- Allergic reactions, including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat).

These reactions may start soon after you first take the medicine, or it might start later.
- Suicidal ideation (recurring thoughts of or preoccupation with suicide).

Common side effects (may affect up to 1 in 10 patients)
- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis (sore throat), rhinitis (runny, stuffy nose) (in children)
- Diarrhoea, nausea, dry mouth
- Fatigue.

Uncommon side effects (may affect up to 1 in 100 patients)
- Agitation
- Paresthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise (feeling unwell).

Rare side effects (may affect up to 1 in 1,000 patients)
- Allergic reactions, some severe (very rare)
- Depression, hallucination, aggression, confusion, insomnia
- Convulsions (fits)
- Tachycardia (heart beating too fast)
- Liver function abnormal
- Urticaria (hives)
- Oedema (swelling)
- Weight increased.

Very rare side effects (may affect up to 1 in 10,000 patients)
- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- 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
- Amnesia (memory loss), 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
- Arthralgia (Joint pain)
- Nightmares
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- Hepatitis (inflammation of the liver)
- Myalgia (muscular pain).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cetirizine Hydrochloride 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 medicinal product 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 further information

What Cetirizine Hydrochloride Tablets contain:
The active ingredient is Cetirizine hydrochloride. Each tablet contains 10 mg of Cetirizine hydrochloride.
The other ingredients are: lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, maize starch, talc, magnesium stearate, titanium dioxide (E171), hypromellose, macrogol, sodium citrate.

What Cetirizine Hydrochloride Tablets look like and the contents of the pack
White coloured, circular, biconvex film coated tablet. Marked with 'A' on one side and a breakline on the other.
Your medicine is available in packs containing 60 tablets.

Marketing Authorisation Holder and Manufacturer:
Relonchem Limited,
Cheshire House, Gorsey Lane,
Widnes, Cheshire,
WA8 0RP, UK.

Distributed by: Numark, Rivington Road, Runcorn, WA7 3DJ, UK.

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