PATIENT INFORMATION LEAFLET
Cetirizine Hydrochloride 5 mg/5 ml Oral Solution
Cetirizine hydrochloride

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription, however, you still need to take your medicine carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Ask your pharmacist if you need more information or advice.

You must contact a doctor if your symptoms worsen or do not improve after a few days.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT CETIRIZINE HYDROCHLORIDE IS AND WHAT IT IS USED FOR

Cetirizine Hydrochloride 5 mg/5 ml Oral Solution ("Cetirizine Hydrochloride") belongs to a group of medicines called antihistamines. It works by countering the effects of histamine which is produced naturally by your body’s defence system, but may be over-produced in allergic reactions.

Cetirizine Hydrochloride is used to relieve the symptoms of hayfever (seasonal rhinitis) in adults and children over the age of 2 years, which include:

- sneezing
- itching, runny or blocked nose
- itchy, red and watering eyes
- skin allergies such as rash, itching and urticaria (hives)

It is used to relieve the symptoms of other allergies in adults and older children (over the age of 6 years), including:

- runny and itchy nose (non-seasonal rhinitis)
- post or nose milk allergies

2. BEFORE YOU TASTE CETIRIZINE HYDROCHLORIDE

DO NOT TAKE CETIRIZINE HYDROCHLORIDE IF you:

• are allergic to cetirizine hydrochloride, hydroxyzine or any of the other ingredients of Cetirizine Hydrochloride, or to any pipeamine derivatives (see Section 6 and end of Section 2).
• are breastfeeding, as cetirizine hydrochloride can pass into breast milk.
• have severe liver failure (previously clearance less than 10 ml/min).

Take special care with Cetirizine Hydrochloride if:

• you have liver problems. Your dose should be adjusted as recommended by a doctor.
• you have problems passing urine (like kidney or heart problems).
• you have epilepsy or are at risk of convulsions.
• you have hereditary intolerance to some sugars.
• you have symptoms persist, you should get advice from your doctor or pharmacist.

• you are due to have an allergy test, as this medicine may affect your allergy test result.

Taking other medicines

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

Especially tell your doctor if you are taking: 

- theophylline (which is taken for some heart conditions or breathing disorders like asthma or bronchitis).
- central nervous system depressants e.g. barbiturates which are used as sedatives or anaesthetics.

Taking Cetirizine Hydrochloride with food and drink

Food does not affect absorption of Cetirizine Hydrochloride. You must avoid alcohol consumption while you are taking this medicine, as with all antihistamine medicines.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

Do not take Cetirizine Hydrochloride if you are breastfeeding.

Only take this medicine during pregnancy if advised to do so by your doctor.

Driving and using machinery

Cetirizine Hydrochloride does not usually cause drowsiness at the recommended dose. However, individuals react differently, so do not drive or operate machinery until you know how it affects you.

Important information about some of the ingredients of Cetirizine Hydrochloride

Cetirizine hydrochloride contains:

- sodium (≤420 mg)
- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- propylene glycol, which may cause alcoholic-like symptoms.
- methylparaben and propylparaben (E218 and E216) which may cause allergic reactions (possibly delayed).
- propylene glycol, which may cause alcohol-like symptoms.

3. HOW TO TAKE CETIRIZINE HYDROCHLORIDE

Please take the medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Cetirizine Hydrochloride is to be taken only by mouth, and is not to be taken by children aged under 2 years. The measuring spoon provided is double-ended. The larger spoon holds 5 ml of your medicine, and the smaller spoon holds 2.5 ml. Each 5 ml spoonful of solution contains 5 mg cetirizine hydrochloride. The usual dose is:

Adults, elderly and children aged 12 years and above:

- two 5 ml spoonfuls once daily (to a maximum of 10 mg daily).

Children aged 6 to 11 years:

- either two 5 ml spoonfuls once daily, or one 5 ml spoonful twice daily (to a maximum of 10 mg daily).

Children aged 2 to 5 years:

- either one 5 ml spoonful once daily, or one 2.5 ml spoonful twice daily (to a maximum of 5 mg daily).

If you have taking problems, your dose should be adjusted as recommended by a doctor. 23L701600PW

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cetirizine Hydrochloride can cause side effects, although not everybody gets them.

The following side effect are rare or very rare, but you must stop taking the medicine and speak to your doctor immediately if you notice these symptoms:

Rash with blisters containing pus
Joint pain
Pruritus (intense itching) and/or urticaria upon discontinuation
Urinary retention (inability to completely empty the urinary bladder)
Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

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

Increased appetite
Suicidal ideation (recurring thoughts of or preoccupation with suicide)

Anorexia, memory impairment
Vertigo (sensation of rotation or movement)
Urinary retention (inability to completely empty the urinary bladder)
Pruritus (itching) and/or urticaria upon desensitisation

Palpitations
Rest with bolsters containing vas

Hypertension (increase of the level)

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

Keep out of the sight and reach of children, and do not store above 25°C. Do not use Cetirizine Hydrochloride after the expiry date which is stated on the label. If you or your child may have taken too much of this medicine, talk to a doctor or pharmacist immediately. You or the child may feel drowsy or dizzy. In children, agitation or restlessness may occur before drowsiness.

If you forget to take Cetirizine Hydrochloride

If you forget to take Cetirizine Hydrochloride, take it as soon as you remember, but wait at least 24 hours before taking the next dose.

If you stop taking Cetirizine Hydrochloride

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Cetirizine Hydrochloride.

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

6. FURTHER INFORMATION

What Cetirizine Hydrochloride contains

The active ingredient is cetirizine hydrochloride: 5 mg in each 5 ml of solution.

The other ingredients are: liquid sorbitol (E420), glycerine, propylene glycol, sodium acetate, acetic acid, saccharin sodium, methyl and propylparaben (E218, E219), banana flavour and purified water.

What Cetirizine Hydrochloride looks like and contents of the pack

Cetirizine Hydrochloride 5 mg/5 ml Oral Solution is a clear or almost clear colourless solution, with the taste and smell of banana. It is available in pack sizes of 60 ml, 120 ml, 150 ml and 200 ml amber glass bottles, and includes a combined 5.3 ml measuring spoon.

Marketing Authorization Holder and Manufacturer

Pinewood Laboratories Ltd., Dallymearcy, Clermont, Co. Tipperary, Ireland.

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