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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
2. Before you take Cetirizine Hydrochloride
3. How to take Cetirizine Hydrochloride
4. Possible side effects
5. How to store Cetirizine Hydrochloride
6. Further information

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 counteracting 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
- itchy, red and watering eyes
- irritated, runny or blocked nose

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)
- skin allergies such as rash, itching and urticaria (hives)
- pet or house mite allergies

2. BEFORE YOU TAKE 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 piperazine derivatives (*see Section 6 and end of Section 2*).
- are breast-feeding, as cetirizine hydrochloride can pass into breast milk.
- have severe kidney failure (creatinine clearance less than 10 ml/min).

Take special care with Cetirizine Hydrochloride if:

- you have kidney problems. Your dose should be adjusted as recommended by a doctor.
- you have problems passing urine (like spinal cord problems or prostate or bladder problems), ask your doctor for advice.
- you are pregnant.
- you suffer from epilepsy or are at risk of convulsions.
- you have hereditary intolerance to some sugars.
- your 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 breast-feeding.
- Only take this medicine during pregnancy if advised to do so by your doctor.

Driving and using machines
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:

- sorbitol (E420): 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 alcohol-like symptoms.
- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

3. HOW TO TAKE CETIRIZINE HYDROCHLORIDE
Always take this 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, the 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 kidney problems, your dose should be adjusted as recommended by a doctor. 23LF01600PW




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If you take more Cetirizine Hydrochloride than you should:
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 a dose, 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.

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:

- 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 might start later.

The following side effects have also been reported.

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

- Somnolence (sleepiness)
- Diarrhoea, nausea, dry mouth
- Fatigue
- Pharyngitis, rhinitis (in children)
- Dizziness, headache

Uncommon side effects (may affect up to 1 in 100 people)

- Agitation
- Abdominal pain
- Asthenia (extreme fatigue), malaise
- Paresthesia (abnormal feelings of the skin)
- Pruritus (itchy skin), rash

Rare side effects (may affect up to 1 in 1000 people)

- Allergic reactions, some severe (very rare)
- Convulsions
- Liver function abnormal
- Oedema (swelling)
- Depression, hallucination, aggression, confusion, insomnia
- Tachycardia (heart beating too fast)
- Urticaria (hives)
- Weight increased

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

- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope, 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 cannot be estimated from the available data)

- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia, 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
- Joint pain
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

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. The expiry date refers to the last day of that month. Use within 6 months after opening. 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.

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), glycerol, propylene glycol, sodium acetate, acetic acid, saccharin sodium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), 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, 75 ml, 80 ml, 100 ml, 150 ml and 200 ml amber glass bottles, and includes a combined 5 ml / 2.5 ml measuring spoon.

Marketing Authorisation Holder and Manufacturer
Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland.

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