

Package leaflet: Information for the patient
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
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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.

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

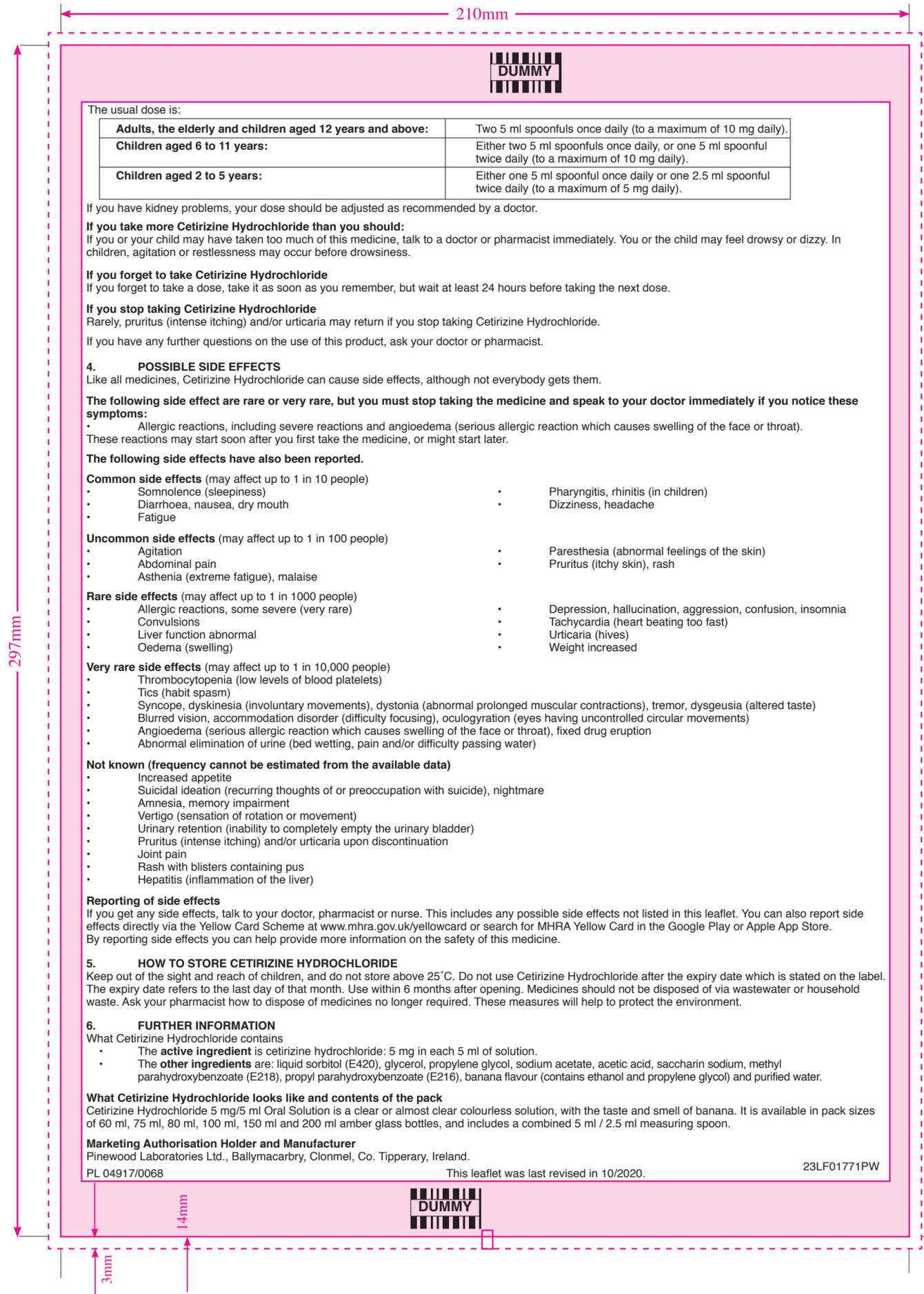
Driving and using machines
 Cetirizine Hydrochloride does not usually cause drowsiness at the recommended dose. However, individuals react differently, so do not drive or operate machinery until you know how it affects you.

Important information about some of the ingredients of Cetirizine Hydrochloride
 Cetirizine hydrochloride contains:

- sorbitol (E420): this medicine contains 4500 mg sorbitol per 10 ml dose which is equivalent to 450 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- propylene glycol: this medicine contains 501.52 mg propylene glycol per 10 ml dose which is equivalent to 50.15 mg/ml.
- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).
- sodium: this medicine contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially 'sodium-free'.
- ethanol: this medicine contains 0.0525 mg of alcohol (ethanol) in each 10 ml which is equivalent to 0.00065625 v/v%. The amount in 10 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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.

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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.

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)	• Pharyngitis, rhinitis (in children)
• Somnolence (sleepiness)	• Dizziness, headache
• Diarrhoea, nausea, dry mouth	
• Fatigue	
Uncommon side effects (may affect up to 1 in 100 people)	
• Agitation	• Paresthesia (abnormal feelings of the skin)
• Abdominal pain	• Pruritus (itchy skin), rash
• Asthenia (extreme fatigue), malaise	
Rare side effects (may affect up to 1 in 1000 people)	
• Allergic reactions, some severe (very rare)	• Depression, hallucination, aggression, confusion, insomnia
• Convulsions	• 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 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 (contains ethanol and propylene glycol) 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., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
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