

<p>PACKAGE LEAFLET: INFORMATION FOR THE USER Cetirizine 1 mg/ml Oral Solution (cetirizine dihydrochloride)</p> <p>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</p> <ul style="list-style-type: none">Keep this leaflet. You may need to read it again.If you have any further questions, ask your doctor or pharmacist.This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.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. <p>WHAT IS IN THIS LEAFLET:</p> <ol style="list-style-type: none">What Cetirizine is and what it is used forWhat you need to know before you take CetirizineHow to take CetirizinePossible side effectsHow to store CetirizineContents of the pack and other information <p>1. WHAT CETIRIZINE IS AND WHAT IT IS USED FOR</p> <p>Cetirizine dihydrochloride, the active ingredient of the solution is an antihistamine. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions.</p>	<p>Cetirizine is used to treat adults and children aged 2 and over 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).</p> <p>Antihistamines like Cetirizine 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.</p> <p>2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CETIRIZINE</p> <p>DO NOT take Cetirizine if:</p> <ul style="list-style-type: none">You are allergic to cetirizine dihydrochlorideYou are allergic to any of the other ingredients of this medicine (listed in section 6)You have severe kidney failure (creatinine clearance less than 10 ml/min). <p>If any of the above applies to you talk to your pharmacist.</p> <p>You should not take Cetirizine 1mg/ml Oral Solution:</p> <ul style="list-style-type: none">if you have rare hereditary problems of fructose intolerance. <p>Warnings and precautions</p> <p>Talk to your doctor or pharmacist before taking Cetirizine</p> <ul style="list-style-type: none">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 are a patient with predisposition factors of urinary retention (e.g. spinal cord disease or injury, enlarged prostate gland) as cetirizine may increase the risk of urinary retention. <ul style="list-style-type: none">If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice. <p>If you are taking this medicine over a long period of time it may lead to an increased risk of caries (tooth decay) due to mouth dryness. Oral hygiene is therefore very important.</p> <p>The recommended dose should not be exceeded and if symptoms persist then the doctor or pharmacist should be consulted.</p> <p>Other medicines and Cetirizine</p> <p>Tell your doctor if you are taking, have recently taken or might take any of the following medications:</p> <ul style="list-style-type: none">antidepressants (e.g. fluoxetine, citalopram, venlafaxine)statinoriv (to treat HIV);betahistine (used to treat Ménière's Disease)any other medicines that you have bought without a prescription. <p>Allergy Testing</p> <p>If you are due to have an allergy test, ask your doctor if you should stop taking Cetirizine for 3 days before testing. This medicine may affect your allergy test results.</p> <p>Cetirizine with food and alcohol</p> <p>No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 g/l corresponding to one glass of wine) and cetirizine used at the recommended doses. However, there are 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 with alcohol.</p> <p>Pregnancy and breast-feeding</p>		<p>Pregnancy</p> <p>Ask your doctor or pharmacist for advice before taking any medicine. As with other drugs, use of Cetirizine 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 medicine should only be administered if necessary and after medical advice.</p> <p>Breast-feeding</p> <p>Cetirizine is present in breast milk.</p> <p>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</p> <p>Driving and using machines</p> <p>Although rare, there have been reports of drowsiness. If you feel drowsy do not drive or operate machinery. You should not take more than the recommended dose as this may affect your ability to perform these tasks.</p> <p>Cetirizine contains sorbitol, methyl parahydroxybenzoate and propyl parahydroxybenzoate</p> <p>If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause an allergic reaction (possibly delayed).</p> <p>3. HOW TO TAKE CETIRIZINE</p> <p>Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The normal doses for Cetirizine are given below. Sometimes doctors prescribe different doses to those mentioned below, if</p>	<p>this applies to you discuss it with your doctor if you have not already done so.</p> <p>The recommended dose is:</p> <p>Adults and adolescents over 12 years of age: 10 mg once daily as 10 ml oral solution (2 full spoons).</p> <p>Children between 6 and 12 years: 5 mg twice daily as 5 ml (one full spoonful).</p> <p>Children between 2 and 4 years for seasonal rhinitis (hay fever): 2.5 mg twice daily as 2.5 ml oral solution (a half spoonful).</p> <p>When dispensing the product, a measuring spoon (which is available from the pharmacist) should be used and not a standard teaspoon.</p> <p>Children under 2 years: Not recommended.</p> <p>Elderly people: As for adults.</p> <p>Patients with moderate to severe kidney impairment: Patients with moderate kidney impairment are recommended to take 5 mg or 5 ml once daily.</p> <p>If you feel that the effect of Cetirizine is too weak or too strong, please consult your doctor.</p> <p>Duration of treatment:</p> <p>The duration of treatment depends on the type, duration and course of your complaints. Please ask your pharmacist for advice.</p> <p>If you take more Cetirizine than you should</p> <p>However if you or someone else has taken too much medicine or an overdose contact your doctor or your hospital accident and emergency department immediately.</p> <p>After an overdose, the side effects described below may occur with increased intensity:</p> <ul style="list-style-type: none">confusiondiarrhoea
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<ul style="list-style-type: none">dizzinessheadachedilated pupilsrestlessnessfeeling of being vague (not with it)tremor (shaking) <ul style="list-style-type: none">fatiguefeeling unwellitchy skinsleepiness (sometimes for longer periods)fast heartbeatnot making as much urine as normal. <p>If you forget to take Cetirizine</p> <p>If you forget to take your usual dose take the dose as soon as you remember. Do not take a double dose to make up for the missed dose. Take your next dose at the normal time.</p> <p>4. POSSIBLE SIDE EFFECTS</p> <p>Like all medicines, this medicine can cause side effects, although not everybody gets them.</p> <p>Some very rare side effects could be serious:</p> <p>If any of the following happens, stop taking this medicine and tell your doctor immediately or go to the accident and emergency department at your nearest hospital:</p> <ul style="list-style-type: none">Allergic reactions, including severe allergic reaction (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. <p>Other side effects:</p>	<p>Common side effects (may affect up to 1 in 10 people):</p> <ul style="list-style-type: none">Tiredness, feeling sleepyHeadacheNauseaCold-like symptoms of the nose (children only). <ul style="list-style-type: none">Dry mouthDiarrhoea (children only)DizzinessSore throat <p>Uncommon side effects (may affect up to 1 in 100 people):</p> <ul style="list-style-type: none">Itching and rashFeeling weak or generally unwellFeeling agitated <ul style="list-style-type: none">DiarrhoeaTingling in the hands and feetPain in the abdomen. <p>Rare side effects (may affect up to 1 in 1,000 people):</p> <ul style="list-style-type: none">Fast heart beatAbnormal liver function test results (your doctor will know what to do)Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness <ul style="list-style-type: none">Oedema (generalised swelling due to water retention)ConvulsionsIncreased weightUrticaria (hives). <p>Very rare side effects (may affect up to 1 in 10,000 people):</p> <ul style="list-style-type: none">Blurred vision, difficulty focussingRotation of the eyesBed wetting, pain and/or difficulty passing waterTremor, tics	<ul style="list-style-type: none">FaintingUnusual bleeding or bruisingA recurring rash.Bad taste in the mouth <ul style="list-style-type: none">Involuntary movements and/or jerking of the limbsMuscle spasms in the neck and shouldersSwelling of the skin particularly around the face <p>Not Known (frequency cannot be estimated from the available data):</p> <ul style="list-style-type: none">Increased appetiteUrinary retentionLoss of balance <p>Some cases of memory loss and/or impairment have also been reported.</p> <p>In very rare cases people have thought about committing suicide and if you feel this way then stop taking the oral solution and see your doctor.</p> <p>Reporting of suspected adverse reactions</p> <p>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: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.</p> <p>5. HOW TO STORE CETIRIZINE</p> <p>Keep this medicine out of the sight and reach of children.</p> <p>Do not use Cetirizine after the expiry date shown on the label. The expiry date refers to the last day of that month. If you notice any defects in the solution such as floating particles, take the medicine to your pharmacist for advice before taking it.</p>	<p>Do not store above 25°C. Store in the original package. Use within 3 months.</p> <p>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.</p> <p>6. CONTENTS OF THE PACK AND OTHER INFORMATION</p> <p>What Cetirizine contains:</p> <p>Each 1ml of solution contains 1 mg of the active ingredient cetirizine dihydrochloride.</p> <p>The solution also contains: liquid sorbitol (non-crystallising), glycerol, propylene glycol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium acetate, glacial acetic acid, saccharin sodium, mixed fruit flavour ID 21533 (which contains vanillin, orange oil, ethyl vanillin, amyl acetate, amyl butyrate, amyl propionate, ethyl butyrate, ethyl propionate, citral, ethyl heptylate, linalool, terpenol, lemon oil, geraniol, butyric acid and propylene glycol), raspberry flavour 249 (which contains raspberry aldehyde, amyl acetate, amyl butyrate, ethyl acetate, ethyl butyrate, hexan-3-yl butyrate, alpha ionone, geraniol, clove oil, cinnamon oil, orange oil, geranium oil and propylene glycol) and purified water. Cetirizine Oral Solution is sugar free.</p> <p>What Cetirizine looks like and contents of the pack:</p> <p>Cetirizine 1mg/ml Oral Solution is a clear solution available in bottles of 200ml.</p> <p>Marketing Authorisation Holder and Manufacturer:</p> <p>The product licence holder and manufacturer of this medicine is Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR.</p> <p>This leaflet was last revised in 05/2014.</p>	<p>Cetirizine 1 mg/ml Oral Solution (Cetirizine Dihydrochloride) Sugar Free 200 ml SANDOZ</p> <p>Oral use. Use as directed by your doctor. Read the package leaflet before use. Do not store above 25°C. Store in the original package. Once opened do not store above 25°C and use within 3 months. Cetirizine does not normally cause drowsiness. However, some individuals can react differently, so if affected, do not drive or operate machinery. Avoid alcoholic drink and do not exceed the recommended dose. Keep out of the sight and reach of children. Each 1 ml contains 1 mg of cetirizine dihydrochloride. Also includes glycerol, propylene glycol, sorbitol (E240), methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216).</p> <p>PL 04416/0410</p> <p>Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK. SZ000001L000</p> <p>POM</p> <p>5 015915 909077</p>
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