

**Cetirizine dihydrochloride Cas No. 83881-51-1**

Cetirizine dihydrochloride is an antihistamine widely used in the relief of hayfever and other allergies, the usual dosage is a single tablet containing 10 mg taken once a day by persons over the age of twelve - some sources advise cetirizine dihydrochloride is safe for children over the age of six. Cetirizine dihydrochloride should not be taken by pregnant or breast-feeding women, and can cause drowsiness, dizziness, agitation, stomach upset and intestinal pain

Active Pharmaceuticals Ingredients Manufacturers



Taj Pharma PDF

# Taj Pharmaceuticals Ltd.

## Cetirizine dihydrochloride

### CAS No. : 83881-51-1

**Chemical Formulas**

Cetirizine dihydrochloride FORMULA  $C_{21}H_{23}ClN_2O_3 \cdot 2HCl$

CAS NO. 83881-51-1 (Base)

FORMULA  $C_{21}H_{23}ClN_2O_3 \cdot 2HCl$

MOL WT. 461.82

SYNONYMS (1S,2S)-2-Methylamino-1-phenyl-1-propanol dichloride;

**PHYSICAL AND CHEMICAL PROPERTIES**

PHYSICAL STATE white to off-white crystalline powder

MELTING POINT

BOILING POINT

SPECIFIC GRAVITY

SOLUBILITY IN WATER Soluble (Insoluble in acetone )

Cetirizine dihydrochloride is an antihistamine widely used in the relief of hayfever and other allergies, the usual dosage is a single tablet containing 10 mg taken once a day by persons over the age of twelve - some sources advise cetirizine dihydrochloride is safe for children over the age of six. Cetirizine dihydrochloride should not be taken by pregnant or breast-feeding women, and can cause drowsiness, dizziness, agitation, stomach upset and intestinal pain

Effects of cetirizine dihydrochloride on human lymphocytes in vitro: micronucleus induction. Evaluation of clastogenic and aneugenic potential using CREST and FISH assays.

This medicine contains the active ingredient cetirizine, which is a type of medicine called a non-sedating antihistamine. It works by preventing the actions of histamine.

All this results in the symptoms of an allergic reaction. In hayfever, histamine causes inflammation of the nose, eyes, skin or airways and results in itchy watery eyes, a runny nose, sneezing and nasal congestion.

The released histamine then binds to its receptors (H1 receptors), causing a chain reaction that results in allergic symptoms. It causes an increase in blood flow to the area of the allergy, and the release of other chemicals that add to the allergic response.

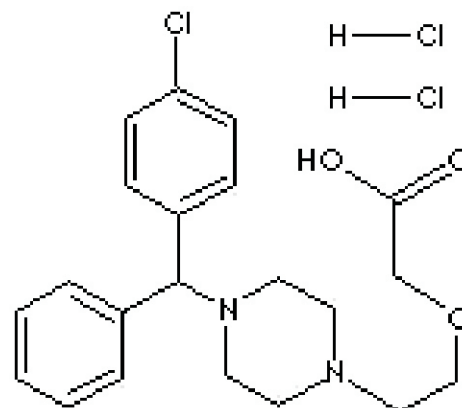
**USES**

Cetirizine dihydrochloride

CAS NO. 83881-51-1

**What Is Cetirizine Used For?**

Cetirizine is used to treat several allergy symptoms, including runny nose, sneezing, and itchy throat. This eMedTV article takes a closer look at what cetirizine is used for, including information on how it works and whether it is used in children.



Taj Pharmaceuticals Ltd  
**Cetirizine Dihydrochloride**  
CAS 83881-52-1

Cetirizine Hydrochloride is an antihistamine. Antihistamines prevent sneezing, runny nose, itching and watering of the eyes, and other allergic symptoms. Cetirizine Hydrochloride is used to treat allergies, hives (urticaria), and other allergic inflammatory conditions.

Cetirizine belongs to a group of medications known as non-sedating antihistamines, which means that it is less likely to cause drowsiness. However, some people still experience drowsiness when taking it. Cetirizine is approved to treat the following allergy symptoms

Runny nose  
Itchy or watery eyes  
Itchy nose or throat  
Sneezing.

It is also approved to treat itching due to hives, which may or may not be caused by allergies

If you are self-treating with this medication, it is important to read the manufacturer's package instructions carefully so you know when to consult your doctor or pharmacist. (See also Precautions section.)

This medication is an antihistamine that treats symptoms such as itching, runny nose, watery eyes, and sneezing from "hay fever" and other allergies. It is also used to relieve itching from hives.

Cetirizine does not prevent hives or prevent/treat a serious allergic reaction (e.g., anaphylaxis). Therefore, if your doctor has prescribed epinephrine to treat allergic reactions, always carry your epinephrine injector with you. Do not use cetirizine in place of your epinephrine.

### Dosage

**Cetirizine Dosage for Adults & Children 12 yrs and Older:** The usual starting Cetirizine dose is 5 or 10 milligrams once a day, depending on the severity of your symptoms. If you have a kidney or liver condition, the doctor will probably prescribe 5 milligrams daily.

**Cetirizine Dosage for Children 6 to 11 years:** The usual starting dose of Cetirizine is 5 or 10 milligrams (1 or 2 teaspoonfuls of syrup) once a day. If your child has a kidney or liver condition, the doctor will probably prescribe the lower Cetirizine dose.

**Cetirizine Dosage for Children 2 to 5 years:** The usual starting Cetirizine dose is 2.5 milligrams (half a teaspoonful) once a day. Cetirizine dosage may be increased to a maximum of 5 milligrams (1 teaspoonful) once daily or 2.5 milligrams (half a teaspoonful) every 12 hours. If the child has a kidney or liver condition, Cetirizine should not be given.

Any medication taken in excess can have serious consequences. In adults, the primary symptom of a Cetirizine overdose is extreme sleepiness. In children, restlessness and irritability may precede drowsiness. If you suspect an overdose of Cetirizine, seek medical treatment immediately.

**If you miss a dose of Cetirizine:** If you are taking Cetirizine on a regular schedule, take the forgotten dose of Cetirizine as soon as you remember. If it is almost time for your next Cetirizine dose, skip the one you missed and go back to your regular schedule. Do not take 2 doses of Cetirizine at once.

**Storage instructions for Cetirizine:** Store tablets and syrup at room temperature.



The recommended dose of cetirizine for most adults and children age six and over is cetirizine 10 mg once daily. For mild symptoms, cetirizine 5 mg once daily may be sufficient. Check with your healthcare provider if you have liver or kidney disease, as a lower dose may be recommended.

The label of cetirizine recommends that people age 65 and older check with their healthcare providers before taking the drug in order to determine the best dose. It is common for liver and kidney function to decline with age, and a lower cetirizine dosage may be recommended.

### **Cetirizine Dihydrochloride Side Effects**

Side effects of Cetirizine cannot be anticipated. If any develop or change in intensity, tell your doctor as soon as possible. Only your doctor can determine if it is safe for you to continue taking Cetirizine.

More common side effects of Cetirizine in adults may include: Drowsiness, dry mouth, fatigue.

Less common side effects of Cetirizine in adults may include: Dizziness, sore throat.

More common side effects of Cetirizine in children aged 6 to 11 may include: Abdominal pain, coughing, diarrhea, headache, nosebleed, sleepiness, sore throat, wheezing.

Less common side effects of Cetirizine in children aged 6 to 11 may include: Nausea, vomiting.

If your doctor has prescribed this medication, he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

Side effects cannot be anticipated. If any develop or change in intensity, tell your doctor as soon as possible. Only your doctor can determine if it is safe for you to continue taking Zyrtec.

\* Side effects in adults may include:

Drowsiness, dry mouth, fatigue

\* Side effects in children aged 6 to 11 may include:

Abdominal pain, coughing, diarrhea, headache, nosebleed, sleepiness, sore throat, wheezing

Although side effects from cetirizine are not common, they can occur. Tell your doctor if any of these symptoms are severe or do not go away:

### **Cetirizine Dihydrochloride Pharmacology**

Cetirizine, a human metabolite of hydroxyzine, is an antihistamine; its principal effects are mediated via selective inhibition of peripheral H1 receptors. The antihistaminic activity of cetirizine has been clearly documented in a variety of animal and human models. In vivo and ex vivo animal models have shown negligible anticholinergic and antiserotonergic activity.

### **Pharmacokinetics**

#### **Absorption**

Cetirizine was rapidly absorbed with a time to maximum concentration (Tmax) of approximately 1 hour following oral administration of tablets, chewable tablets or syrup in adults. Comparable bioavailability was found between the tablet and syrup dosage forms. Comparable bioavailability was also found between the ZYRTEC tablet and the ZYRTEC chewable tablet taken with or without water.

When healthy volunteers were administered multiple doses of cetirizine (10 mg tablets once daily for 10 days), a mean peak plasma concentration (C<sub>max</sub>) of 311 ng/mL was observed. No accumulation was observed.

A sympathomimetic amine that has a decongestant effect on the nasal mucosa. Its peripheral effects are similar to those of ephedrine and its central effects are similar to, but less intense than, those of amphetamines. {01} Covering tens of thousands of individual drug products, monographs include: drug interactions; adverse reactions; toxicity; therapeutic perspective; specific dosage and administration information; preparations, chemistry, and stability; pharmacology and pharmacokinetics; contraindications; and more.

Contains information from medical literature and expert advice from medical scientists, physicians, pharmacists, pharmacologists, and other professionally qualified physicians that goes beyond FDA-approved labeling.

Cetirizine, a human metabolite of hydroxyzine, is an antihistamine; its principal effects are mediated via selective inhibition of peripheral H<sub>1</sub> receptors. The antihistaminic activity of cetirizine has been clearly documented in a variety of animal and human models. In vivo and ex vivo animal models have shown negligible anticholinergic and antiserotonergic activity. In clinical studies, however, dry mouth was more common with cetirizine than with placebo.



Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

Information: The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers. Also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
Taj Pharmaceuticals Limited,  
Mumbai (India).

MPSTJ278

Last revised: 29 August 2009