

Ziprasidone Hcl Cas No. : 138982-67-9

This medication is used to treat certain mental/mood disorders (schizophrenia or manic/mixed episodes associated with bipolar disorder). It may be used after other medications have not been effective.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Ziprasidone Hcl

CAS No. : 138982-67-9

Molecular Formula C<sub>21</sub>H<sub>21</sub>ClN<sub>4</sub>OS.HCl;C<sub>21</sub>H<sub>22</sub>Cl<sub>2</sub>N<sub>4</sub>OS

Molecular Weight 449.40

CAS Registry Number 138982-67-9

**Chemical data**Formula C<sub>21</sub>H<sub>21</sub>ClN<sub>4</sub>OS

Mol. mass 412.936

**Pharmacokinetic data**

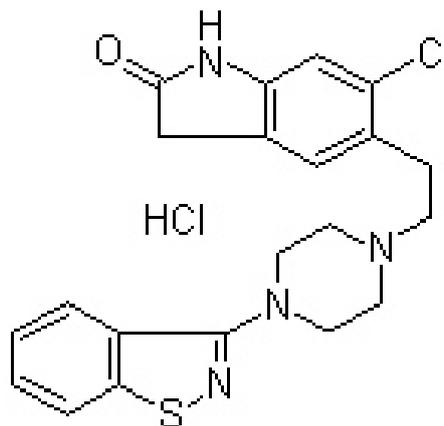
Bioavailability 100% (intramuscular)

60% (orally)

Metabolism hepatic (aldehyde reductase)

Half life 2 - 5 hours

Excretion Urine and feces

**DOSAGE**

Ziprasidone comes as a capsule to take by mouth. It is usually taken twice a day with food. Take ziprasidone at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ziprasidone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor may start you on a low dose of ziprasidone and gradually increase your dose. Ziprasidone may help control your symptoms but will not cure your condition. Continue to take ziprasidone even if you feel well. Do not stop taking ziprasidone without talking to your doctor.

Ziprasidone Hcl Capsules should be administered at an initial daily dose of 20 mg BID with food. In some patients, daily dosage may subsequently be adjusted on the basis of individual clinical status up to 80 mg BID. Dosage adjustments, if indicated, should generally occur at intervals of not less than 2 days, as steady-state is achieved within 1 to 3 days. In order to ensure use of the lowest effective dose, ordinarily patients should be observed for improvement for several weeks before upward dosage adjustment.

**SIDE EFFECTS**

Ziprasidone may cause side effects.

- \* drowsiness
- \* headache
- \* restlessness
- \* anxiety
- \* constipation
- \* diarrhea
- \* loss of appetite
- \* muscle pain
- \* runny nose, sneezing
- \* cough
- \* weight gain



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**Some side effects can be serious**

- \* unusual movements of your face or body that you cannot control
- \* fast, irregular, or pounding heartbeat
- \* rash or hives
- \* fever
- \* muscle stiffness
- \* confusion
- \* sweating
- \* painful erection of the penis that lasts for hours

**PRECAUTIONS**

Before taking ziprasidone, tell your doctor if you use or have ever used street drugs or have overused prescription medications or if you have recently had a heart attack or have trouble swallowing. Also tell your doctor if you have or have ever had heart or liver disease, breast cancer, heart failure, an irregular heartbeat, a stroke or mini-stroke, or seizures, or if you or anyone in your family has or has ever had diabetes. Also tell your doctor if you have ever had to stop taking a medication for mental illness because of severe side effects.

tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking ziprasidone, call your doctor. Do not breast-feed while taking ziprasidone.

you should know that ziprasidone may make you drowsy. Do not drive a car or operate machinery until you know how this medication affects you.

you should know that alcohol can add to the drowsiness caused by this medication. Do not drink alcohol while taking ziprasidone.

you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. If you have schizophrenia, you are more likely to develop diabetes than people who do not have schizophrenia, and taking ziprasidone or similar medications may increase this risk. Tell your doctor immediately if you have any of the following symptoms while you are taking ziprasidone: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar that is not treated can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.

you should know that ziprasidone may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. This is more common when you first start taking ziprasidone. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.

you should know that ziprasidone may make it harder for your body to cool down when it gets very hot. Tell your doctor if you plan to do vigorous exercise or be exposed to extreme heat.



## DRUG DESCRIPTION

Ziprasidone Hcl Capsules contain a monohydrochloride, monohydrate salt of ziprasidone. Chemically, ziprasidone hydrochloride monohydrate is 5-[2-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]ethyl]-6-chloro-1,3-dihydro-2H-indol-2-one, monohydrochloride, monohydrate. The empirical formula is  $C_{21}H_{21}ClN_4OS \cdot HCl \cdot H_2O$  and its molecular weight is 467.42. Ziprasidone hydrochloride monohydrate is a white to slightly pink powder.

Ziprasidone Hcl is available as Capsules for oral administration and is most effective when taken with food. It has been approved for treatment of schizophrenia.

Ziprasidone Hcl is a serotonin dopamine antagonist that works to treat the positive, negative, and depressive symptoms associated with schizophrenia. Positive symptoms include visual and auditory hallucinations and delusions. Negative symptoms, which are harder to treat, include blunted affect, social withdrawal, and lack of motivation.

Schizophrenia is a chronic illness that requires lifelong treatment.

The efficacy of Capsules (hydrochloride) as a treatment for schizophrenia was established in four short-term, four to six week trials and one long-term 52 week trial. All were placebo-controlled studies in inpatients, most of whom met DSM III-R criteria for schizophrenia. Each trial evaluated two or three fixed doses of , ranging from 20 to 100 mg,

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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  
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Mumbai (India).

MPSTJ278

Last revised: 29 August 2009

