

PATIENT SUMMARY OF INFORMATION ABOUT

Ziprasidone (zi pras' i done hye'' droe klor' ide) Capsules USP

Rx only

Information for patients taking ziprasidone capsules or their caregivers

This summary contains important information about ziprasidone capsules. It is not meant to take the place of your doctor's instructions. Read this information carefully before you take ziprasidone capsules. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about ziprasidone capsules.

What Is Ziprasidone?

Ziprasidone is a type of prescription medicine called a psychotropic, also known as an atypical antipsychotic. Ziprasidone can be used to treat symptoms of schizophrenia and acute manic or mixed episodes associated with bipolar disorder. Ziprasidone can also be used as maintenance treatment of bipolar disorder when added to lithium or valproate.

Who Should Take Ziprasidone Capsules?

Only your doctor can know if ziprasidone capsules are right for you. Ziprasidone capsules may be prescribed for you if you are an adult with schizophrenia or bipolar disorder.

Symptoms of schizophrenia may include:

- hearing voices, seeing things, or sensing things that are not there (hallucinations)
- beliefs that are not true (delusions)
- unusual suspiciousness (paranoia)
- becoming withdrawn from family and friends

Symptoms of manic or mixed episodes of bipolar disorder may include:

- extremely high or irritable mood
- increased energy, activity, and restlessness
- racing thoughts or talking very fast
- easily distracted
- little need for sleep

If you show a response to ziprasidone capsules, your symptoms may improve. If you continue to take ziprasidone capsules there is less chance of your symptoms returning. Do not stop taking the capsules even when you feel better without first discussing it with your doctor.

It is also important to remember that ziprasidone capsules should be taken with food.

What is the most important safety information I should know about ziprasidone?

Ziprasidone is not approved for the treatment of patients with dementia-related psychosis. Elderly patients with a diagnosis of psychosis related to dementia treated with antipsychotics are at an increased risk of death when compared to patients who are treated with placebo (a sugar pill).

Ziprasidone is an effective drug to treat the symptoms of schizophrenia and the manic or mixed episodes of bipolar disorder. However, one potential side effect is that it may change the way the electrical current in your heart works more than some other drugs. The change is small and it is not known whether this will be harmful, but some other drugs that cause this kind of change have in rare cases caused dangerous heart rhythm abnormalities. Because of this, ziprasidone should be used only after your doctor has considered this risk for ziprasidone against the risks and benefits of other medications available for treating schizophrenia or bipolar manic and mixed episodes.

Your risk of dangerous changes in heart rhythm can be increased if you are taking certain other medicines and if you already have certain abnormal heart conditions. Therefore, it is important to tell your doctor about any other medicines that you take, including non-prescription medicines, supplements, and herbal medicines. You must also tell your doctor about any heart problems you have or have had.

Who should NOT take Ziprasidone Capsules?

Elderly patients with a diagnosis of psychosis related to dementia. Ziprasidone capsules are not approved for the treatment of these patients.

Anything that can increase the chance of a heart rhythm abnormality should be avoided. Therefore, do not take ziprasidone capsules if:

- You have certain heart diseases, for example, long QT syndrome, a recent heart attack, severe heart failure, or certain irregularities of heart rhythm (discuss the specifics with your doctor)
- You are currently taking medications that should not be taken in combination with ziprasidone, for example, dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol or tacrolimus.

What To Tell Your Doctor Before You Start Ziprasidone Capsules

Only your doctor can decide if ziprasidone capsules are right for you. Before you start ziprasidone capsules, be sure to tell your doctor if you:

- have had any problem with the way your heart beats or any heart related illness or disease
- any family history of heart disease, including recent heart attack
- have had any problem with fainting or dizziness
- are taking or have recently taken any prescription medicines
- are taking any over-the-counter medicines you can buy without a prescription, including natural/herbal remedies
- have had any problems with your liver
- are pregnant, might be pregnant, or plan to get pregnant
- are breastfeeding or plan to breastfeed.
- are allergic to any medicines

- have ever had an allergic reaction to ziprasidone or any of the other ingredients of ziprasidone capsules. Ask your doctor or pharmacist for a list of these ingredients
- have low levels of potassium or magnesium in your blood

Your doctor may want you to get additional laboratory tests to see if ziprasidone capsule is an appropriate treatment for you.

Ziprasidone and Other Medicines

There are some medications that may be unsafe to use when taking ziprasidone, and there are some medicines that can affect how well ziprasidone works. While you are on ziprasidone, check with your doctor before starting any new prescription or over-the-counter medications, including natural/herbal remedies.

How To Take Ziprasidone Capsules

- Take ziprasidone capsules only as directed by your doctor.
- Swallow ziprasidone capsules whole. Do not chew, crush, or open the capsules.
- Take ziprasidone capsules with food.
- It is best to take ziprasidone capsules at the same time each day.
- Ziprasidone capsules may take a few weeks to work. It is important to be patient.
- Do not change your dose or stop taking your medicine without your doctor's approval.
- Remember to keep taking your capsules, even when you feel better.

Possible Side Effects

Because these problems could mean you're having a heart rhythm abnormality, contact your doctor ***IMMEDIATELY*** if you:

- Faint or lose consciousness
- Feel a change in the way that your heart beats (palpitations)

Common side effects of ziprasidone include the following and should also be discussed with your doctor if they occur:

Adults:

- Feeling unusually tired or sleepy
- Nausea or upset stomach
- Constipation
- Dizziness
- Restlessness
- Abnormal muscle movements, including tremor, shuffling, and uncontrolled involuntary movements
- Diarrhea
- Rash
- Increased cough / runny nose

If you develop any side effects that concern you, talk with your doctor. It is particularly important to tell your doctor if you have diarrhea, vomiting, or another illness that can cause you to lose fluids. Your doctor may want to check your blood to make sure that you have the right amount of important salts after such illnesses.

For a list of all side effects that have been reported, ask your doctor or pharmacist for the ziprasidone capsules Professional Package Insert.

What To Do For An Overdose

In case of an overdose, call your doctor or poison control center right away or go to the nearest emergency room.

Other Important Safety Information

A serious condition called neuroleptic malignant syndrome (NMS) can occur with all antipsychotic medications including ziprasidone. Signs of NMS include very high fever, rigid muscles, shaking, confusion, sweating, or increased heart rate and blood pressure. NMS is a rare but serious side effect that could be fatal. Therefore, tell your doctor if you experience any of these signs.

Delayed-onset drug reaction called drug reaction with eosinophilia and systemic symptoms (DRESS) can occur with ziprasidone. Signs of DRESS may include rash, fever, and swollen lymph nodes. Other severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome can occur with ziprasidone. Signs of Stevens-Johnson syndrome may include rash with blisters which could include ulcers in mouth, skin shedding, fever and target-like spots in the skin. DRESS and other SCAR are sometimes fatal; therefore, tell your doctor immediately if you experience any of these signs.

Adverse reactions related to high blood sugar (hyperglycemia), sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with ziprasidone, and it is not known if ziprasidone is associated with these reactions. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia.

Dizziness caused by a drop in your blood pressure may occur with ziprasidone, especially when you first start taking this medication or when the dose is increased. If this happens, be careful not to stand up too quickly, and talk to your doctor about the problem.

Before taking ziprasidone capsules, tell your doctor if you

- are pregnant or plan on becoming pregnant.
- If you become pregnant while receiving ziprasidone, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>
- are breastfeeding or plan to breastfeed. Ziprasidone can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive ziprasidone capsules.

Because ziprasidone can cause sleepiness, be careful when operating machinery or driving a motor vehicle.

Since medications of the same drug class as ziprasidone may interfere with the ability of the body to adjust to heat, it is best to avoid situations involving high temperature or humidity.

It is best to avoid consuming alcoholic beverages while taking ziprasidone capsules. Call your doctor *immediately* if you take more than the amount of ziprasidone capsules prescribed by your doctor.

Ziprasidone capsules have not been shown to be safe or effective in the treatment of children and teenagers under the age of 18 years old.

Keep ziprasidone capsules and all medicines out of the reach of children.

How To Store Ziprasidone Capsules

Store ziprasidone capsules at room temperature (59° to 86°F or 15° to 30°C).

For More Information About Ziprasidone Capsules

This sheet is only a summary. Ziprasidone capsules are prescription medicine and only your doctor can decide if it is right for you. If you have any questions or want more information about ziprasidone capsules, talk with your doctor or pharmacist, address medical related queries to www.lupinpharmaceuticals.com or call 1-800-399-2561.

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