

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrZELDOX®

Ziprasidone capsules

Read this carefully before you start taking **ZELDOX** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZELDOX**.

Serious Warnings and Precautions

ZELDOX can increase the risk of death when used in elderly people with dementia. The reasons for death varied but most were related to heart or circulatory problems or infections.

What is ZELDOX used for?

ZELDOX is used in adults to treat:

- schizophrenia and related psychotic disorders
- acute manic or mixed episodes associated with bipolar disorder

How does ZELDOX work?

ZELDOX belongs to a group of medicines called atypical antipsychotics. Exactly how ZELDOX works is unknown, however it seems to readjust the balance of the chemicals called dopamine and serotonin which are out of balance in people with schizophrenia or bipolar disorder. You should see an improvement in your symptoms within a few days of starting treatment with ZELDOX.

What are the ingredients in ZELDOX?

Medicinal ingredients: Ziprasidone hydrochloride monohydrate.

Non-medicinal ingredients: gelatin capsules, lactose monohydrate, magnesium stearate, and pregelatinized starch.

ZELDOX comes in the following dosage forms:

Capsules containing 20 mg, 40 mg, 60 mg and 80 mg of ziprasidone (as Ziprasidone hydrochloride monohydrate)

Do not use ZELDOX if:

- You are allergic to ziprasidone hydrochloride.
- You are allergic to any of the other ingredients in ZELDOX or to a component of the container.
- You have the following heart conditions:
 - have QT prolongation (abnormal electrical activity of the heart) including a

- condition called long QT syndrome (a specific heart rhythm problem)
- have had a recent heart attack
- have heart failure
- have certain irregularities of heart rhythm (discuss the specifics with your doctor)
- You are taking any of the following medicines:
 - heart medicines, such as dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics,
 - medicines which have been shown to have an effect on heart rhythm as indicated in their respective Patient Medication Information leaflet,
 - other anti-psychotic medicines such as mesoridazine, thioridazine, chlorpromazine, droperidol, pimozone,
 - other medications such as sparfloxacin (antibiotic medicine), levomethadyl acetate (opiate dependence medicine), dolasetron mesylate (nausea medicine), probucol (cholesterol lowering medicine) or tacrolimus (immunosuppressant medicine).
- ZELDOX is not recommended for use in children and adolescents under the age of 18 years.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZELDOX. Talk about any health conditions or problems you may have, including if you:

- 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 heart
- have a family history of heart disease
- are taking any medications for heart disease or blood pressure that makes you prone to low blood pressure
- have a history of stroke or “mini-stroke”
- have liver problems
- have had any problem with fainting or dizziness
- have ever had blackouts or seizures
- have diabetes or a family history of diabetes
- are allergic to any medicines
- drink alcohol or use recreational drugs
- abuse drugs or have abused drugs in the past
- exercise vigorously or work in hot or sunny places
- suffer from lactose intolerance because ZELDOX capsules contain lactose
- have low white blood cell counts
- have low levels of potassium or magnesium in your blood
- are dehydrated or overhydrated
- suffer from electrolyte imbalances (which can occur during diuretic therapy, severe episodes of diarrhea or vomiting, if you suffer from an eating disorder or alcoholism)

- have or have had breast cancer
- have risk factors for developing blood clots such as: a family history of blood clots, age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), not being able to move due to air travel or other reason, or take oral contraceptives ("The Pill"). All possible risk factors for developing blood clots should be identified before and while you are taking ZELDOX and eliminated when possible.
- have a condition that increases your risk of having a seizure (such as Alzheimer's dementia)

Other warnings you should know about:

Heart Rhythm Problems:

You should not take ZELDOX if you have QT prolongation (abnormal electrical activity of the heart) including a condition called long QT syndrome (a specific heart rhythm problem) or if you are taking certain medicines. See the "Do not use ZELDOX if" section above for more information. Tell your doctor if you already have heart conditions, or if you are taking certain other medicines that may also change the way the electrical current in the heart works. ZELDOX may change the way the electrical current in your heart works and in rare cases cause dangerous heart rhythm abnormalities.

It is important to tell your physician, pharmacist or other healthcare professional that you are taking ZELDOX before you start taking any other drugs, including over-the-counter medications and natural/herbal remedies.

If you experience any symptoms of possible **heart rhythm problems**, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, you should get immediate medical help.

Pregnancy:

Tell your doctor if you are pregnant, think you might be pregnant or are planning to become pregnant. You should not take ZELDOX if you are pregnant. You must use a reliable method of birth control while you are taking ZELDOX. Talk to your doctor about reliable methods of birth control.

Breastfeeding:

Tell your doctor if you are breastfeeding or planning to breastfeed. ZELDOX is released into breast milk. It is not known if this is safe for your baby. You should not breastfeed a baby if you are taking ZELDOX.

Effects on Newborns:

In some cases, babies born to a mother taking ZELDOX during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

Alcohol:

The effects of alcohol could be made worse while taking ZELDOX. You should not drink alcohol while taking ZELDOX.

Driving and using machines:

ZELDOX can impair your judgment, thinking and motor skills and make you sleepy or dizzy. This may impair your ability to drive or to use machines. Wait until you know how ZELDOX affects you before driving or using machines. Do not drive or use machines if ZELDOX impairs your ability to do so safely.

Electrolyte imbalance:

Tell your doctor or pharmacist if you have diarrhea, vomiting, if you suffer from an eating disorder or alcoholism or any other 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 (“electrolytes”). This is because an imbalance in electrolytes is a risk factor for heart problems, which may occur more frequently with ZELDOX than with other anti-psychotics. Disordered eating, alcoholism and water intoxication are also risk factors for imbalance in electrolytes.

Since medications of the same drug class as ZELDOX may interfere with the ability of the body to adjust to heat, it is best to avoid becoming overheated or dehydrated while taking ZELDOX. Avoid vigorous exercise or being exposed to extreme heat.

Laboratory tests:

Your doctor should check your body weight before starting ZELDOX and during treatment.

Your doctor should take blood tests before starting ZELDOX. They will monitor blood sugar, and the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

If you have high levels of prolactin (measured with a blood test) and a condition called hypogonadism you may be at increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

Falls:

Feeling sleepy, a fall in blood pressure when you stand up from sitting or lying down, movement problems have been reported with the use of antipsychotic drugs. This can lead to falls that may cause fractures or other fall-related injuries.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ZELDOX:

How to take ZELDOX:

- Take ZELDOX exactly as your doctor has told you to.
- Swallow ZELDOX capsules whole with a glass of water.
- Do not open, crush or chew the capsules.

- Always take ZELDOX with a meal.
- Take ZELDOX at the same time each day.
- Do not change your dose or stop taking your medicine without your doctor’s approval.
- Dosage directions should be followed carefully. Never take more than the prescribed dose.
- Remember to keep taking ZELDOX, even when you feel better, to avoid relapse of symptoms. ZELDOX should be taken for as long as you and your doctor believe it is helping you.
- Never give ZELDOX to anyone else as this medicine has been prescribed only for you.

Overdose:

If you think you, or a person you are caring for, have taken too much ZELDOX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms. Take the medication package with you.

Missed Dose:

If you miss a dose of ZELDOX, wait until your next scheduled dose. **Do not take 2 doses at once.**

What are possible side effects from using ZELDOX?

These are not all the possible side effects you may have when taking ZELDOX. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- feeling unusually tired or sleepy
- nausea or upset stomach
- restlessness
- diarrhea
- increased cough/runny nose

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Blood disorders: fever, chills, weakness, sore throat, sores in the mouth or throat, bleeding gums, bone pain, low blood pressure, fast heartbeat, and trouble breathing, muscle weakness, fatigue, difficulty swallowing, difficulty breathing,		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
protrusion of the tongue			
Falls due to feeling dizzy, or faint		✓	
COMMON			
Skin rash on its own	✓		
Dystonia (movement disorder): muscle spasms that you cannot control, neck spasms, tightness of the throat, difficulty swallowing, breathing problems, tongue sticking out			✓
Extrapyramidal symptoms (movement disorder): feeling restless, tense, involuntary muscle contractions, continuous spasms, rigidity, slowness of movement, tremor, jerky movements		✓	
Tardive dyskinesia (movement disorder): muscle twitching or abnormal movement of your face or tongue		✓	
Stroke (bleeding or blood clot in the brain): sudden weakness or numbness of the face, arms, or legs and speech or vision problems			✓
Weight gain	✓		
UNCOMMON			
Heart rhythm problems: dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures			✓
Blood clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
palpitations.			
Seizure: loss of consciousness with uncontrollable shaking, “fit”			✓
Allergic reaction: skin rash, hives, swelling of throat and tongue, difficulty breathing			✓
Hyperprolactinemia (elevated prolactin levels): irregular menstrual cycles, production and discharge of breast milk, abnormal hair growth, infertility		✓	
Serotonin toxicity (too much serotonin in the body): agitation, restlessness, confusion, rapid heart rate, dilated pupils, loss of muscle coordination, twitching muscles, rigidity, heavy sweating, diarrhea			✓
RARE			
Neuroleptic malignant syndrome (nervous system disorder): high fever with pronounced muscle stiffness, state of confusion, rapid or irregular heartbeat, profuse sweating			✓
Priapism: long lasting (greater than 4 hours in duration) and painful erection of the penis			✓
Feeling very hot and unable to cool down (generally as a result of several factor together, such as vigorous exercise, dehydration, warm conditions)		✓	
New or worsening constipation		✓	
Severe allergic reaction: skin rash, fever, chest pain and			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
abdominal pain.			
Skin rash and fever with swollen glands			✓
Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine			✓
VERY RARE			
Hyperglycemia (high blood sugar): extreme thirst, frequent urination, excessive hunger, weakness, nausea, vomiting, fruity-smelling breath		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep ZELDOX and all medicines out of the reach of children.

Store ZELDOX capsules at controlled room temperature (15°-30°C).

If your doctor tells you to stop taking ZELDOX or if your medicine has expired, return any leftover medicine to your pharmacist for proper discarding.

If you want more information about ZELDOX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.viatris.ca, or by calling 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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