

PART III: CONSUMER INFORMATION

PrZELDOX®

ziprasidone capsules

This leaflet is part III of a three-part "Product Monograph" published when ZELDOX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ZELDOX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

ZELDOX belongs to a group of medicines called atypical antipsychotic drugs. ZELDOX is used to treat symptoms of schizophrenia and related psychotic disorders, and symptoms of acute manic or mixed episodes associated with bipolar disorder.

Some of the most common symptoms of schizophrenia are:

- hearing voices, seeing things, or sensing things that are not there (hallucinations)
- mistaken beliefs (delusions)
- feeling paranoid or not trusting others and feeling very suspicious
- avoiding family or friends and wanting to be alone
- becoming depressed or anxious.

Some of the most common symptoms of bipolar disorder are:

- feeling invincible or all powerful
- inflated self-esteem,
- racing thoughts, easily lose your train of thought
- overreaction to what you see or hear
- misunderstanding of events,
- speeded-up activity,
- talking very quickly, too loudly, or more than usual,
- decreased need for sleep
- poor judgment

ZELDOX is not a cure for your condition, but it can help manage your symptoms as you continue your treatment, and reduce the risk of relapse.

Your physician may have prescribed ZELDOX for another reason. Ask your physician if you have any questions about why ZELDOX has been prescribed for you.

What it does:

Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). Illnesses that affect the brain, such as schizophrenia, may be due to certain chemicals in the brain being out of balance. These imbalances may cause some of the symptoms you may be experiencing. Doctors and scientists are not sure what causes these imbalances to occur. Exactly how ZELDOX

works is unknown. However it seems to readjust the balance of the chemicals called dopamine and serotonin.

When it should not be used:

You should not take ZELDOX if you are allergic to its main ingredient, ziprasidone, or any of the ingredients listed in the "**What the important non-medicinal ingredients are**" section of this leaflet.

Do not take ZELDOX if

You have the following heart conditions:

- long QT syndrome (a specific heart rhythm problem)
- a recent heart attack
- severe heart failure
- certain irregularities of heart rhythm (discuss the specifics with your doctor).

The reason for this restriction is that one potential side effect of ZELDOX is that it may change the way the electrical current in your heart works, more than some other antipsychotic drugs do. 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. This risk can be increased if you already have certain abnormal heart conditions, or if you are taking certain other medicines that may also change the way the electrical current in the heart works.

Do not take ZELDOX if

You are taking medications that should not be taken in combination with ziprasidone, for example:

- heart medication, such as dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics,
- other anti-psychotics such as mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide
- other medications such as sparfloxacin, levomethadyl acetate, dolasetron mesylate, probucol or tacrolimus.

Tell your doctor about any other medicines that you take, including non-prescription medicines and natural/herbal remedies.

ZELDOX is not recommended for use in children under the age of 18 years.

What the medicinal ingredient is:

Ziprasidone hydrochloride.

What the nonmedicinal ingredients are:

Nonmedicinal ingredients include: lactose monohydrate, magnesium stearate, pregelatinized starch, and gelatin capsules.

What dosage forms it comes in:

Capsules containing 20, 40, 60 and 80 mg of ziprasidone.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Studies with various medicines of the group to which ZELDOX belongs, when used in the elderly patients with dementia, have been associated with an increased rate of death. ZELDOX is not indicated in elderly patients with dementia.

BEFORE you use ZELDOX talk to your doctor or pharmacist 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 or any 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 had any problems with your liver
- have had any problem with fainting or dizziness
- have ever had blackouts or seizures
- have diabetes or a family history of diabetes
- are pregnant, might be pregnant, or plan to get pregnant
- are breastfeeding
- are allergic to any medicines
- drink alcohol or use recreational drugs
- abuse drugs
- have ever had an allergic reaction to ziprasidone or any of the other ingredients of ZELDOX capsules
- 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
- 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), immobility due to air travel or other reason, or take oral contraceptives ("The Pill").

If you are a woman of child bearing potential and receiving ZELDOX you should use a reliable method of birth control.

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. Sometimes, the symptoms may resolve on their own. 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.

INTERACTIONS WITH THIS MEDICATION

Because some medicines can affect how ZELDOX works, and some medicines may increase the risk of heart rhythm problems (as described in the above section “ABOUT THIS MEDICATION”, 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.

The effects of alcohol could be made worse while taking ZELDOX. It is recommended that you do not drink alcohol while taking ZELDOX.

PROPER USE OF THIS MEDICATION

In order for ZELDOX to help you feel better, it is very important to take it every day, exactly as your doctor has prescribed. Your doctor has decided on the best dosage for you based on your individual needs. Your doctor may increase or decrease your dose depending on your response.

- ZELDOX capsules should be swallowed whole, with a glass of water.
- The capsules should be taken with a meal.
- It is best to 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 have taken more ZELDOX capsules than your doctor has recommended, contact your regional Poison Control Centre and talk to your doctor right away or go to your nearest hospital emergency department. Take the medication package with you.

Missed Dose:

If you miss a dose of ZELDOX by only a few hours, take it as soon as possible. If most of the day has passed since your missed dose, skip that dose and wait until your next scheduled dose. **Do not take 2 doses at once.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, ZELDOX may cause some side effects. The most common side effects of ZELDOX are:

- feeling unusually tired or sleepy
- nausea or upset stomach
- constipation
- dizziness
- restlessness
- abnormal movements
- diarrhea
- rash
- increased cough/runny nose.

Tell your doctor immediately if you experience muscle twitching or abnormal movements of the face or tongue.

It is important to tell your doctor or pharmacist if you have diarrhea, vomiting, 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”) after such illnesses, 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.

Your doctor should check your body weight before starting ZELDOX and continue to monitor it for as long as you are being treated.

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.

If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, you should seek immediate medical attention.

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 (for example with vigorous exercise or exposure to extreme heat) while taking ZELDOX.

Because some people experience sleepiness with ZELDOX, you should avoid driving a car or operating machinery until you know how ZELDOX affects you.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom/effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
	Only if severe	In all cases	
Common			
Skin rash on its own	√		
Muscle twitching or abnormal movement of your face or tongue		√	
Sudden weakness or numbness of the face, arms, or legs and speech or vision problems			√
Uncommon			
Feeling faint, or dizzy, or lose consciousness, or feel a change in the way your heart beats (palpitations)		√	
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 palpitations.		√	
Seizure (i.e., loss of consciousness with uncontrollable shaking, “fit”)			√
Allergic reaction (symptoms include skin rash, hives, swelling of throat and tongue, difficulty breathing)			√
Rare			
High fever with pronounced muscle stiffness, state of confusion, rapid or irregular heartbeat, profuse sweating			√
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 (symptoms include skin rash, fever, chest pain and abdominal pain)			√
Skin rash and fever with swollen glands			√
Severe skin reactions (symptoms can include rash with blisters, mouth ulcers, peeling skin, fever)			√

This is not a complete list of side effects. If you have any unexpected effects while taking ZELDOX, contact your doctor or pharmacist.

HOW TO STORE IT

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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals may be obtained by contacting the sponsor, Upjohn Canada ULC, at: 1-800-463-6001, or www.pfizer.ca

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People are there to help

There is always someone to help you. In addition to family and friends remember that doctors, nurses, pharmacists, social workers and other healthcare professionals are available if you have any problems or concerns. The Schizophrenia Society of Canada has local chapters that provide support for individuals and families living with mental illnesses: Schizophrenia Society of Canada, 4 Fort Street, Winnipeg, MB R3C1C4, Tel: 1-204-786-1616, Toll Free: 1-800-263-5545, Fax: 204-783-4898; e-mail: info@schizophrenia.ca; www.schizophrenia.ca. Contact your physician for more information.

Mood Disorders Society of Canada
110 North Front St, Unit A3, Suite 325
Belleville, ON K8P 0A6
Tel: 613-921-5565
Email: info@mdsc.ca

Website: <https://www.mdsc.ca> provides [info@mdsc.ca] advice regarding bipolar disorder, depression and other mood disorders together with helpful tips and information about where you can get help in your own province.

Contact your physician for more information.