

ZELDOX[®] CAPSULE

Ziprasidone hydrochloride monohydrate (40 mg, 60 mg)

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What ZELDOX is used for

Schizophrenia:

ZELDOX is used for the management of a mental disorder known as schizophrenia and other psychotic disorders, and for maintenance of clinical improvement and prevention of relapse during continuation therapy.

Bipolar mania:

ZELDOX is also used for the treatment of manic or mixed episodes associated with bipolar disorder with or without psychotic features.

Bipolar I disorder:

ZELDOX is used for the short-term treatment of manic or mixed episodes associated with bipolar I disorder.

ZELDOX is also used along with lithium or valproate for the maintenance treatment of bipolar I disorder.

How ZELDOX works

ZELDOX capsules belong to a group of medicines called antipsychotics. It works by changing the activity of certain natural substances in the brain.

Before you use ZELDOX

- When you must not use it

- if you are allergic (hypersensitive) to ZELDOX or any of the other ingredients of ZELDOX capsules. Signs of an allergic reaction include rash, itching, swelling in the face or lips, difficulty in breathing.
- if you have recently had a heart attack.
- if you have heart rhythm problems and are taking certain medicines for it (Class IA and III antiarrhythmic

drugs).

- if you have uncompensated heart failure.
- if you have long QT interval syndrome.

Pregnancy and lactation

You should not take ZELDOX capsules during pregnancy unless you are told otherwise by your doctor because there is a risk that this medicine may harm your baby. ZELDOX should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the baby.

The following symptoms may occur in newborn babies of mothers who have used ZELDOX in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding.

In some cases, babies experience these symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own.

ZELDOX may be excreted in breast milk, hence you should not breast-feed if you are taking ZELDOX capsules. If you are planning to breast-feed, talk to your doctor before taking this medicine.

If you are a woman of child-bearing potential, always use effective contraception. Tell your doctor immediately if you become pregnant or are planning to become pregnant whilst taking ZELDOX capsules. Talk to your doctor for the contraceptive methods which may be appropriate for you.

- Before you start to use it

- Check with your doctor before you use this medicine:
- if you or someone else in your family has a history of blood clots of deep veins, as medicines like these have been associated with formation of blood clots;
 - if you suffer or have suffered from seizures;
 - if you are elderly (over 65 years old) and suffer from dementia as there is

- a risk of death and side effects related to brain and its blood vessels;
- if you are at risk of having a stroke;
- if you have a low resting heart-rate;
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate;
- if you or someone else in your family has a history of diabetes mellitus (high blood glucose levels);
- if you are taking or have recently taken any prescription medicines;
- if you have 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;
- if you are taking alcohol or other drugs acting on central nervous system;
- if you are lactose intolerant;

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Do not take ZELDOX if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics. These medicines affect the heart rhythm by prolonging the QT interval.

Please tell your doctor or pharmacist if you are taking or have recently taken medicines for the treatment of:

- depression, e.g. herbal medicines or natural remedies containing St. John's Wort; skin and fungal infections, e.g. ketoconazole;
- bacterial infections (antibiotics), e.g. rifampin;
- mood swings (ranging from depressive mood to euphoria), agitation and irritation these are known as mood stabilising medicines, e.g. carbamazepine.

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How to use ZELDOX

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

ZELDOX capsules are for oral use.

Use in Adults:

The amount of ZELDOX capsules needed varies from person to person. Most people need 40 mg twice a day to be taken with food. The daily dose may be adjusted by your doctor to a maximum of 80 mg twice a day.

Use in Children:

Safety and effectiveness in children under 18 years have not been established.

Use in Patients with Liver Problems:

If you have liver problems you may need to take a lower dose of ZELDOX capsules. Your doctor will work out the correct dose for you.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking ZELDOX for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have taken too many ZELDOX capsules, you may experience drowsiness, shaking, anxiety and abnormalities of movement including involuntary movements, muscular stiffness and rigidity, slowness of movements, shaking, general weakness and tiredness.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking ZELDOX.

Tell your doctor immediately if you become pregnant while taking this medication.

It is particularly important to tell your doctor if you:

- have signs and symptoms of Neuroleptic Malignant Syndrome that may include fever, faster breathing, sweating, muscle stiffness, shaking and reduced consciousness;
- have signs and symptoms of tardive dyskinesia (involuntary/unusual movements, especially in your face or tongue);
- have persistent abnormal and painful erection of the penis;
- have abnormal breast milk production;
- have high prolactin levels;
- have diabetes or have risk factors or symptoms of diabetes. Your blood sugar should be monitored. Symptoms include excessive thirst, urination, increased appetite and weakness;
- have severe skin reactions such as rash with blisters which could

include ulcers in the mouth, skin shedding, fever and target-like spots on the skin that could be symptoms of Stevens-Johnson syndrome. These skin reactions could potentially be life-threatening;

- have any condition which may lead to falls such as sleepiness, low blood pressure while standing and difficulty in movement. Your doctor may conduct a fall risk assessment before starting the treatment with ZELDOX.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give ZELDOX to anyone else, even if they have the same symptoms or condition as you.

You should not drink alcohol during treatment with this medicine, as this may increase the risk of side effects.

- Things to be careful of

Driving and using machines

Taking ZELDOX capsules may make you feel drowsy. If you experience this symptom, you should not drive or use tools or machinery until the drowsiness disappears.

Medicinal Products Containing Lactose

ZELDOX capsules contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZELDOX capsules.

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Side effects

Like all medicines, ZELDOX can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Following are the adverse drug reactions reported from clinical trials:

Very Common (affects more than 1 in 10 users)

- sleepiness
- headache
- drowsiness

Common (affects 1 to 10 users in 100)

- anxiety
- restlessness and a compelling need to be in constant motion
- dizziness
- abnormal muscle movements including tremor, shuffling and uncontrolled involuntary movements
- muscular stiffness and rigidity
- constipation
- dry mouth
- indigestion
- increased salivation
- nausea
- vomiting
- general weakness
- abnormal vision
- male sexual dysfunction

Following are the side effects reported during post-marketing experience:

- difficulty falling asleep
- sleepiness (sedation)
- wild or violent behavior extrapyramidal disorder (a group of clinical disorders marked by abnormal involuntary movements, alterations in muscle tone, and postural disturbances)
- agitation
- symptoms of tardive dyskinesia (involuntary, repetitive body movements)
- fast heartbeat
- rash
- tiredness
- increase or decrease in weight

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of ZELDOX**- Storage**

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**- What it looks like**

ZELDOX is available as capsules for oral administration:

40 mg – No. 4 blue capsules, marked “Pfizer” and “ZDX 40”

60 mg – No. 3 white capsules, marked “Pfizer” and “ZDX 60”

- Ingredients

- Active ingredient
Ziprasidone hydrochloride monohydrate
- Inactive ingredients
Lactose monohydrate, pregelatinised maize starch, magnesium stearate, gelatin, titanium dioxide, indigotin

- MAL numbers

ZELDOX Capsule 40mg
MAL20032623ACRZ
ZELDOX Capsule 60mg
MAL20032624ACRZ

Manufacturer

Pfizer Ireland Pharmaceuticals,
Little Connell,
Newbridge, Country Kildare,
Ireland

Product Registration Holder

Viatrix Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.

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