

Zeldox[®]

(zell-docks)

ziprasidone hydrochloride (zi-pra-si-don hi-dro-klor-ride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zeldox.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zeldox against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Zeldox is used for

What Zeldox is for

Zeldox is used to treat schizophrenia and bipolar disorder.

Your doctor may have prescribed Zeldox for another reason.

Ask your doctor or pharmacist if you have any questions about Zeldox or why Zeldox has been prescribed for you.

Schizophrenia

Schizophrenia is a mental illness. It varies from person to person, but can involve:

- hallucinations: the person sees, hears, feels, smells or tastes something that is not actually

there; most commonly a person may hear voices

- delusions: a delusion is a false belief held by a person which is not held by others of the same cultural background
- disturbed or disorganised thinking
- poor memory and concentration
- loss of emotion and expression
- loss of motivation and energy
- difficulty interacting with others, leading to social isolation.

Bipolar disorder

Bipolar disorder is a mental illness where a person cycles through:

- 'manic' phases - with symptoms such as over-activity, irritability/ elation and limited need for sleep
- 'depressive' phases - with symptoms such as depressed mood, anxiety, difficulty making decisions, concentrating and hopelessness.

How Zeldox works

Zeldox belongs to a group of medicines called atypical antipsychotics/neuroleptics. It contains the ingredient ziprasidone.

Schizophrenia

Researchers do not know exactly what causes schizophrenia, but they do know that many people with it have high levels of some brain chemicals - including dopamine and serotonin.

Zeldox is thought to work by helping to correct the imbalance of these chemicals, in turn, reducing the symptoms of schizophrenia.

Research has found Zeldox can help reduce:

- hallucinations
- delusions
- confused thoughts
- social withdrawal
- lack of motivation.

Zeldox does not cure schizophrenia, but it can help manage the symptoms and help prevent further episodes.

Taking antipsychotic/neuroleptic medicines like Zeldox can also allow you to try psychological therapies when recommended by your doctor. These may further help you manage your schizophrenia.

Bipolar disorder

Research has shown that there is a chemical imbalance in the brain in patients with bipolar disorder.

Zeldox does not cure bipolar disorder. It is used as a short-term treatment for the manic phases. Zeldox is not used to treat the depressive phases of bipolar disorder.

Controlling the manic phase of bipolar disorder with medicine can also allow you to try psychological therapies when recommended by your doctor.

Taking Zeldox

Zeldox is available only with a doctor's prescription.

Zeldox is not recommended for the treatment of elderly patients with dementia-related psychosis.

Zeldox should be used with caution in elderly patients with risk factors for stroke.

Zeldox is also not recommended for children under 18 years of age as there is not enough information on the effects of Zeldox in this group.

Before you take Zeldox

When you must not take it

Do not take Zeldox if you have an allergy to:

- any medicine containing ziprasidone
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Zeldox may include:

- hives, itching or skin rash
- shortness of breath, wheezing
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing.

Do not take Zeldox if you have or have had any of the following medical conditions:

- a recent heart attack
- heart failure that is not well-controlled
- abnormal rhythm of the heart
- any other condition requiring drugs to control your heart rhythm.

Do not take Zeldox after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

If you have some medical conditions, you may not be able to take Zeldox, or your doctor may need to adjust your medicines.

Tell your doctor or pharmacist if you have any allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- irregular heart rate
- a condition requiring other drugs to control the heart rhythm
- any heart or blood vessel problems
- low blood levels of potassium or magnesium
- a condition that may give you low blood pressure
- a history of seizures (fits)
- liver problems
- blood sugar level problems e.g., diabetes
- headache
- nausea
- vomiting
- blurred vision
- muscle weakness
- if you are 65 years of age or over and have a condition known as 'dementia-related psychosis'
- if you have ever suffered or suffer from a condition called deep vein thrombosis (DVT). DVT is the formation of blood clots in one of the deep veins within the body, e.g., the leg or pelvis. The symptoms of DVT are pain and swelling in your legs. Sometimes the blood clot may break away from its original location and travel to the lungs. This condition is called pulmonary embolism (PE). Symptoms of PE may include sharp chest pain, shortness of breath or you may cough up blood.
- breathing stops and starts while sleeping.

Tell your doctor or pharmacist if you have ever had any of the following reactions to this type of medicine:

- Neuroleptic Malignant Syndrome (NMS) - symptoms include sudden fever, fast breathing, blood pressure changes, sweating, confusion, muscle stiffness and drowsiness or sleepiness
- Tardive Dyskinesia (TD) - unusual movements (mainly of the face and tongue), or uncontrollable twitching or jerking of the arms and legs.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most atypical antipsychotic/neuroleptic medicines, Zeldox is not recommended for use during pregnancy.

For women of child-bearing age an appropriate method of contraception is recommended.

If you become or plan to become pregnant while taking Zeldox your doctor will discuss the benefits and risks of taking it.

Babies exposed to antipsychotic drugs (including Zeldox) during the third trimester of pregnancy are at risk of experiencing agitation, abnormal muscle tone, tremor, somnolence, breathing problems, difficulty in feeding and/or withdrawal symptoms after being born.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Zeldox is not recommended while you are breast-feeding. It is thought that low levels of Zeldox passes into breast milk.

Taking other medicines

Some medicines may be affected by Zeldox or may affect how well it works. Your doctor may need to give you different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines you buy over the counter from a pharmacy or supermarket
- all complementary and alternative therapies
- any supplements or herbal remedies you buy from a health food shop
- a type of herbal medicine to treat depression called St John's Wort (*Hypericum perforatum*).
- any illicit drugs.

Tell your doctor or pharmacist if you are taking medicines for any of the following conditions:

- Parkinson's disease
- fast or irregular heart rhythms
- insomnia (unable to fall asleep or stay asleep)
- anxiety
- depression or mood swings
- pain - especially any narcotic pain killers
- epilepsy or mood disorders - especially carbamazepine
- fungal infections - especially ketoconazole
- rifampicin an antibiotic used for the treatment of tuberculosis.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking Zeldox.

How to take Zeldox

Follow all directions given to you by your doctor and pharmacist carefully.

These may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

How much Zeldox you need to take will depend upon your condition.

Schizophrenia

The usual starting dose is one 40 mg capsule taken twice daily with food.

Your doctor may increase your dose up to a maximum of one 80 mg capsule twice daily with food.

Allow at least 48 hours between changes to your dose unless otherwise instructed by your doctor.

You may reach the maximum dose of one 80 mg capsule twice daily with food on the third day from the start of your treatment.

Bipolar disorder

The usual starting dose is one 40 mg capsule twice daily with food.

Your doctor may adjust your dose up to a maximum of one 80 mg capsule twice daily with food. This dose may be reached on the second day from the start of your treatment.

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take your capsule(s) with food, so in the morning with breakfast and in the evening with your evening meal.

You need to take Zeldox with food because it helps your body absorb the medicine much better. If you do not take with food, the medicine may have less effect.

How long to take it

Keep taking Zeldox for as long as your doctor recommends, even if you feel better.

If you keep taking Zeldox as recommended, there is less chance of your symptoms returning.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not double a dose to make up for the dose you have missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your capsules, ask your doctor or pharmacist for help.

If you take too much (overdose)

If you take too much Zeldox, you may feel slightly drowsy and show signs of tremor and uncontrollable movements of the tongue, jaw, arms and legs. High and low blood pressure, diarrhoea, a fast heart rate may also be experienced. Your lungs might fail to breathe properly which can result in a build-up of carbon dioxide in the body.

Immediately telephone your doctor, or Poisons Information Centre 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Zeldox.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Tell your doctor or pharmacist immediately if you become pregnant while taking Zeldox.

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Zeldox.

Tell any other doctors, dentists and pharmacist who are treating you that you are taking Zeldox.

Keep all of your doctor's appointments so that your doctor can check your progress.

Your doctor will check your progress and may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

Talk to your doctor or mental health professional if you have thoughts or talk about death, suicide or self-harm.

These may be signs of changes or worsening in your mental illness.

Things you must not do

Do not stop taking Zeldox or change the dosage, even if you feel better, without checking with your doctor.

Do not use Zeldox to treat any other complaint unless your doctor tells you to.

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

Things to be careful of

If you feel drowsy or sleepy while taking Zeldox, do not drive or operate machinery, or do things that could be dangerous if you are not alert.

Medicines like Zeldox may cause drowsiness and sleepiness in some people. Make sure you know how you react to Zeldox before you drive a car, operate machinery or do anything else that could be dangerous if you are not alert.

Zeldox may also cause falls resulting in fractures or other injuries in some people.

Be careful when drinking alcohol while taking Zeldox.

Combining Zeldox and alcohol can make you more sleepy, dizzy or

light-headed. Your doctor may suggest you avoid alcohol while you are being treated with Zeldox.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Zeldox.

This medicine has been prescribed to help you, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed below may also occur in some people.

Tell your doctor if...

Tell your doctor or pharmacist if you notice any of the following physical problems and they worry you.

These are common side effects of Zeldox:

- headache
- feeling sick (nausea)
- vomiting
- sleepiness
- difficulty sleeping
- dizziness on standing up, especially when getting up from a sitting or lying position
- dry mouth
- too much saliva
- indigestion
- constipation
- diarrhoea

- restlessness
- muscle stiffness
- blurred vision
- palpitations
- weakness or loss of strength
- male sexual dysfunction.

In schizophrenia studies of 4-6 weeks duration, the incidence of weight gain in people taking Zeldox was low and comparable to those who took a placebo or inactive medicine.

Tell your doctor or pharmacist if you notice any of the following mental or emotional problems and they worry you:

- drowsiness or sleepiness
- trouble sleeping
- restlessness or difficulty sitting still
- dizziness, blackouts or feeling faint
- anxiety or agitation
- loss of control of your bladder
- unusual secretion of breast milk.

Tell your doctor or pharmacist if you have a persistent painful erection of the penis without sexual arousal.

Tell your doctor as soon as possible if...

The following list includes serious side effects which may require medical attention.

Tell your doctor immediately if you notice:

- any worm-like movements of the tongue
- any other uncontrolled movements of the tongue, mouth, cheeks or jaw
- any uncontrolled movements spreading to the arms and legs
- sleepwalking
- eating during sleepwalking
- breathing stops and starts while sleeping. Symptoms can be loud or frequent snoring, silent pauses in breathing, choking or gasping sounds.

These are symptoms of a condition called Tardive Dyskinesia. Tardive Dyskinesia is more likely in people who have been taking Zeldox or other antipsychotics/neuroleptics medications for a long time. If detected early, it is usually reversible. Your doctor will decide whether to lower your dose or stop the medicine completely.

Go to hospital if...

The following list contains very serious side effects. These symptoms can also sometimes happen after you stop taking Zeldox. You may need urgent medical attention or hospitalisation.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- convulsions, fit or seizures
- trembling and shaking of the hands and fingers
- shuffling walk and stiffness of the arms and legs
- sudden uncontrollable muscle spasms in the eyes, head, neck and body
- sudden signs of allergy - including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing (symptoms resembling a condition called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- pain and swelling in the large veins of your legs or hip
- sharp chest pain, shortness of breath or and coughing up blood.

Stop taking Zeldox and contact your doctor immediately or go to Accident and Emergency if you get all of the following at once:

- high fever
- fast breathing
- stiff muscles
- confusion, drowsiness or sleepiness

These are symptoms of a condition called Neuroleptic Malignant Syndrome (NMS).

After taking Zeldox

Storage

Keep the capsules in their pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep Zeldox in a cool, dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Zeldox, or the capsules have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

Zeldox 20 mg - blue/white capsules marked ZDX 20 and Pfizer.

Zeldox 40 mg - blue capsules marked ZDX 40 and Pfizer.

Zeldox 60 mg - white capsules marked ZDX 60 and Pfizer.

Zeldox 80 mg - blue/white capsules marked ZDX 80 and Pfizer.

All strengths come in blister packs of 60 capsules.

Ingredients

Active ingredients

Zeldox capsules contain the active ingredient ziprasidone. Each capsule contains either 20 mg, 40 mg, 60 mg or 80 mg of ziprasidone.

Other ingredients

- lactose monohydrate
- pregelatinised maize starch
- magnesium stearate
- gelatin
- titanium dioxide (E171)
- indigo carmine CI73015 (E132; 20, 40 and 80 mg capsules only)
- black ink.

Supplier

Zeldox is supplied in Australia by:

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

Australian registration numbers

Zeldox 20 mg - AUST R 65526

Zeldox 40 mg - AUST R 65527

Zeldox 60 mg - AUST R 65528

Zeldox 80 mg - AUST R 65529.

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