

Zeldox(R)

(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 medicine 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 is also not recommended for the following as there is not enough information on the effects of Zeldox in these groups:

- * children under 18 years of age
- * treating bipolar disorder in people over 65 years of age.

Before you take Zeldox

When you must not take it

Do not take Zeldox if you have an allergy to:

- * 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 if the packaging is torn or shows signs of tampering.

If this is the case, take it to your pharmacist.

Do not take Zeldox if the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Before you start to take it

If you have some medical conditions, you may not be able to use 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
- * if you are 65 years of age or over and have a condition known as 'dementia-related psychosis'.

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.

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

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

Zeldox is not recommended while you are breastfeeding. It is not known if 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
- * 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.

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

Your doctor or pharmacist has 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 40mg capsule taken twice daily with food.

Your doctor may increase your dose up to a maximum of one 80mg capsule twice daily with food. To help you increase your dose, your doctor may give you a specially designed pack, known as a 'Titration Pack'.

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

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

Bipolar disorder

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

Your doctor may adjust your dose up to a maximum of one 80mg capsule

twice daily with food. This dose may be reached on the second day from the start of your treatment.

When to take it

Swallow the capsules whole with a full glass of water.

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 find it hard to remember how to take the 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.

Immediately telephone your doctor or Poisons Information Centre (telephone number 13 11 26) for advice 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.

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.

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

Be careful driving or operating machinery until you know how Zeldox affects you.

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.

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.

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)
- * 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.

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.

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

Tell your doctor immediately 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.

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 you doctor immediately or go to Accident and Emergency at your nearest hospital:

- * convulsions, fits 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.

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 this medicine where young children cannot reach it.

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

Keep Zeldox in a cool, dry place where the temperature stays below 30 degrees 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 the capsules in their pack until it is time to take them.

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

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

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

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

All strengths come in blister packs of 60 capsules.

Your doctor may prescribe a 'Titration Pack' containing 6 capsules (2 x 40mg, 2 x 60mg, 2 x 80mg) which may be initially used either when you start on Zeldox or when you swap to Zeldox from another medicine used to treat your condition. This can help you achieve the correct dose of Zeldox for your treatment.

Ingredients

Active ingredients

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

Other ingredients

- * lactose
- * pregelatinised maize starch

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

Australian Registration Numbers

Zeldox 20mg - AUST R 65526

Zeldox 40mg - AUST R 65527

Zeldox 60mg - AUST R 65528

Zeldox 80mg - AUST R 65529

Zeldox 40mg, 60mg, 80mg titration pack - AUST R 134150

For more information

Zeldox is supplied in Australia by:
Pfizer Australia Pty Limited
38-42 Wharf Road
West Ryde NSW 2114
Tel No: 1800 675 229

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