

Zeldox IM[®]

(zell-docks-i-m)

ziprasidone (zi-pra-si-don)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zeldox IM.

It does not contain all the available information.

It does not take the place of talking to your doctor or nurse.

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

If you have any concerns about using this medicine, ask your doctor or nurse.

Keep this leaflet with the medicine.

You may need to read it again.

What Zeldox IM is used for

What Zeldox IM is for

Zeldox IM is used to treat severe agitation or aggression in people with schizophrenia or similar illnesses.

Your doctor may have prescribed Zeldox IM for another reason.

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

After you have been given Zeldox IM, your symptoms should get better. Your doctor may then switch you to Zeldox capsules or another oral medicine to help manage your symptoms in the long term.

How Zeldox IM works

Zeldox IM belongs to a group of medicines called antipsychotics. It contains the ingredient ziprasidone.

Ziprasidone is thought to work by correcting the imbalance of some chemicals in the brain. This, in turn, reduces the agitation or aggression caused by the illness.

Using Zeldox IM

Zeldox IM is an injection. It is available only in a hospital with a doctor's prescription.

Only a doctor or nurse can give the injection.

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

Zeldox IM is not recommended for use in children under 18 years of age. There is not enough information on its effects in this age group.

Before you are given Zeldox IM

When it must not be used

You must not be given Zeldox IM 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 IM 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.

You should not be given Zeldox IM if you have had any of the following medical conditions. Your doctor or nurse need to know if you have ever had:

- a recent heart attack
- heart failure that is not well-controlled

- abnormal rhythm of the heart or any other condition requiring other drugs to control your heart rhythm.

Before you are given it

Your doctor and nurse need to know if you have any allergies to:

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

Your doctor and nurse need to know about all your medical conditions, especially if you have ever had any of 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
- high sugar levels in your blood
- a condition that may give you low blood pressure
- kidney problems
- a history of seizures (fits)
- liver problems

- 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 suffers 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.

Your doctor and nurse need to know 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.

Your doctor and nurse need to know if:

- you are pregnant
- you are breastfeeding.

Like most antipsychotic medicines, Zeldox IM is not recommended for use during pregnancy or during breastfeeding. It is thought that low levels of Zeldox passes into breast milk.

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

Taking other medicines

Some medicines may be affected by Zeldox IM 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.

Your doctor and nurse need to know if you are taking any other medicines, including:

- all prescription medicines

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

Your doctor and nurse need to know if you are taking medicines for any of the following medical conditions:

- Parkinson's disease
- Schizophrenia or other psychoses
- fast or irregular heart rhythms
- sedatives to help you sleep
- anxiety
- depression or mood swings
- pain - especially any narcotic
- epilepsy or mood disorder - especially carbamazepine
- fungal infections - especially ketoconazole

- rifampicin an antibiotic used for the treatment of tuberculosis.

Your doctor or nurse has more information on medicines to be careful with or to avoid while using Zeldox IM.

How Zeldox IM is given

Your doctor will decide how much Zeldox IM you need.

A doctor or nurse will inject Zeldox IM into a muscle.

Your doctor may use Zeldox IM for up to three days.

If you receive too much (overdose)

As your doctor will supervise how much Zeldox IM you are given, you are unlikely to have an overdose.

If you are given too much Zeldox IM, you may feel slightly drowsy and your speech may be slurred.

You may also experience high and low blood pressure, diarrhoea and a fast heart rate. Your lungs might fail to breathe properly which can result in a build-up of carbon dioxide in the body.

If you think you have been given too much Zeldox IM:

- tell your doctor or nurse immediately, or

- telephone the Poisons Information Centre on 131 126.

Side effects

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.

It is important to tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with Zeldox IM.

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

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

Tell your doctor if...

The following list shows common side effects of Zeldox IM. Some of these side effects may affect up to 1 in 10 people, whereas others are less common.

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

- weakness or loss of strength
- palpitations or a fast heart rate
- dizziness on standing up, especially when getting up from a sitting or lying position
- pain or irritation where the injection is given
- headache
- constipation
- diarrhoea
- dry mouth
- feeling sick (nausea)
- vomiting
- loss of appetite
- difficulties breathing
- difficulties speaking
- excessive sweating
- flushing
- muscle stiffness
- involuntary muscle spasms

- blurred vision
- male sexual dysfunction.

Tell your doctor or nurse 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 immediately if...

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

Do not be alarmed as you may not experience any of them.

Tell your doctor or nurse 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 given Zeldox IM or taking other antipsychotic 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.

Get emergency attention if...

The following list contains very serious side effects. These symptoms can also sometimes happen after you stop Zeldox IM treatment. 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, 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 (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

Experience symptoms of a condition called Neuroleptic Malignant Syndrome (NMS) which include:

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

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.

Product description

What it looks like

Zeldox IM is supplied to the hospital as a sterile powder for injection, with an ampoule of Water for Injections.

The hospital will mix the Zeldox IM and Water for Injections to produce a solution containing ziprasidone 20 mg/mL.

Ingredients

Zeldox IM contains the active ingredient ziprasidone.

The inactive ingredients are:

- sulfobutyl betadex sodium (SBECD)
- Water for Injections.

Supplier

Zeldox IM 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 number

AUST R 154458.

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