

ZELDOX IM[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or nurse.

1. Why am I using ZELDOX IM?

ZELDOX IM contains the active ingredient ziprasidone mesilate. ZELDOX IM is used to treat severe agitation or aggression in people with schizophrenia or similar illnesses.

For more information, see Section [1. Why am I using ZELDOX IM?](#) in the full CMI.

2. What should I know before I am given ZELDOX IM?

Do not use if you have ever had an allergic reaction to ziprasidone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given ZELDOX IM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZELDOX IM and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. 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.

More instructions can be found in Section [4. How ZELDOX IM is given?](#) in the full CMI.

5. What should I know while I am given ZELDOX IM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist or pharmacist you visit that you are using ZELDOX IM.
Driving or using machines	<ul style="list-style-type: none">• ZELDOX IM may cause drowsiness in some people. If affected, do

	not drive a vehicle or operate machinery.
Drinking alcohol	<ul style="list-style-type: none"> • Avoid alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • ZELDOX IM is stored by your doctor or nurse. • Store below 30 °C. Protect from light.

For more information, see Section [5. What should I know while I am given ZELDOX IM?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor or nurse if you notice any of these less serious side effects and they worry you: weakness or loss of strength; headache; constipation; diarrhoea; dry mouth; vomiting; excessive sweating; flushing; involuntary muscle spasms; blurred vision; drowsiness or sleepiness; trouble sleeping; restlessness or difficulty sitting still.

Call your doctor or nurse straight away if you notice any of these serious side effects: 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.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects:

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; pain and swelling in the large veins of your legs or hip; sharp chest pain, shortness of breath or/and coughing up blood.

This is not a complete list of all possible side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZELDOX IM®

Active ingredient: *ziprasidone mesilate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZELDOX IM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZELDOX IM.**

Where to find information in this leaflet:

- [1. Why am I using ZELDOX IM?](#)
- [2. What should I know before I am given ZELDOX IM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How ZELDOX IM is given?](#)
- [5. What should I know while I am given ZELDOX IM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZELDOX IM?

ZELDOX IM contains the active ingredient ziprasidone mesilate. ZELDOX IM belongs to a group of medicines called antipsychotics. 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.

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.

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.

2. What should I know before I am given ZELDOX IM?

Warnings

You should not be given ZELDOX IM if:

- you are allergic 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.

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
- have ever had any of the following medical conditions. Your doctor and nurse need to know about all your medical conditions.
 - 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.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Your doctor and nurse need to know if you are pregnant or intend to become pregnant.

Your doctor and nurse need to know if you are breastfeeding or intend to breastfeed.

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

Babies exposed to antipsychotic drugs (including ZELDOX IM) 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with ZELDOX IM and affect how 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZELDOX IM.

4. 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 ZELDOX IM

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, you should immediately:

- tell your doctor or nurse, or
- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while I am given ZELDOX IM?

Remind any doctor, nurse, dentist or pharmacist you visit that you are using ZELDOX IM.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZELDOX IM affects you.

ZELDOX IM may cause drowsiness in some people. If affected, do not drive a vehicle or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid alcohol.

Looking after your medicine

- ZELDOX IM is stored by your doctor or nurse.
- Store below 30 °C. Protect from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about 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 IM may also cause falls resulting in fractures or other injuries in some people.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Physical side effects:• weakness or loss of strength	Speak to your doctor or nurse if you notice any of these less serious

Less serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	<p data-bbox="807 250 1382 353">side effects and they worry you.</p> <p data-bbox="807 389 1382 721">The 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.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Mental or emotional side effects: ● 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.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● any worm-like movements of the tongue ● any other uncontrolled movements of the 	<p>Call your doctor or nurse straight away if you notice any of these serious side effects. The list includes serious side</p>

Serious side effects	What to do
<p>tongue, mouth, cheeks or jaw</p> <ul style="list-style-type: none"> ● 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. ● <p>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.</p>	<p>effects which may require medical attention.</p>

Very serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none">● 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	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>These symptoms can also sometimes happen after you stop ZELDOX IM treatment. You may need urgent medical attention or hospitalisation.</p>

Very Serious side effects	What to do
<ul style="list-style-type: none"> ● sharp chest pain, shortness of breath or/ and coughing up blood ● symptoms of a condition called Neuroleptic Malignant Syndrome (NMS) which include: <ul style="list-style-type: none"> ○ 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.

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or nurse before you decide to stop taking any of your medicines.

7. Product details

This medicine is available only in a hospital with a doctor's prescription.

What ZELDOX IM contains

Active ingredient (main ingredient)	Ziprasidone mesilate
Other ingredients (inactive ingredients)	Sulfobutyl betadex sodium

Do not take this medicine if you are allergic to any of these ingredients.

What ZELDOX IM looks like

ZELDOX IM is white to off-white lyophile powder in a single dose vial (AUST R 408532).

ZELDOX IM is supplied to the hospital as a sterile powder for injection. The hospital will mix the ZELDOX IM and water for injections to produce a solution containing ziprasidone 20 mg/mL.

Who distributes ZELDOX IM

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

This leaflet was prepared in August 2023.

ZELDOX IM® is a Viatrix company trade mark

ZELDOX IM_cmi\Aug23/00