

# ZELDOX®

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## Consumer Medicine Information (CMI) summary

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

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### 1. Why am I taking ZELDOX?

ZELDOX contains the active ingredient ziprasidone hydrochloride monohydrate. ZELDOX is used to treat schizophrenia and bipolar disorder. For more information, see Section [1. Why am I taking ZELDOX?](#) in the full CMI.

### 2. What should I know before I take ZELDOX?

Do not take if you have ever had an allergic reaction to ZELDOX 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 take ZELDOX?](#) in the full CMI.

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### 3. What if I am taking other medicines?

Some medicines may interfere with ZELDOX 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 do I take ZELDOX?

- The usual starting dose is one 40 mg capsule taken twice daily with food.
- Take your capsule(s) with food, i.e. in the morning with breakfast and in the evening with your evening meal.

More instructions can be found in Section [4. How do I take ZELDOX?](#) in the full CMI.

### 5. What should I know while taking ZELDOX?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking ZELDOX.
- Talk to your doctor or mental health professional if you have thoughts or talk about death, suicide or self-harm.
- Check with your doctor if you are pregnant

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|----------------------------------|--|
|                                  | <p>or intend to become pregnant.</p> <ul style="list-style-type: none"> <li>• Talk to your doctor if you are breastfeeding or intend to breastfeed.</li> </ul>   |
| <b>Things you should not do</b>  | <ul style="list-style-type: none"> <li>• Do not stop taking ZELDOX or change the dosage, even if you feel better, without checking with your doctor.</li> </ul>  |
| <b>Driving or using machines</b> | <ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how ZELDOX affects you.</li> <li>• ZELDOX may cause drowsiness and sleepiness in some people.</li> </ul>  |
| <b>Drinking alcohol</b>          | <ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol.</li> <li>• 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.</li> </ul> |

### Looking after your medicine

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

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

## 6. Are there any side effects?

**Speak to your doctor if you have any of the following:** headache; nausea; vomiting; sleepiness; dry mouth; indigestion; constipation; diarrhoea; muscle stiffness; anxiety; blackouts or feeling faint; restlessness or difficulty sitting still. **Tell your doctor immediately if you notice any of the following:** 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. **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of the following:** 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.

**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®

**Active ingredient(s):** *ziprasidone hydrochloride monohydrate*

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I taking ZELDOX?

**ZELDOX contains the active ingredient ziprasidone hydrochloride monohydrate.** It belongs to a group of medicines called atypical antipsychotics/neuroleptics.

**ZELDOX is used to treat schizophrenia and bipolar disorder.**

## **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**

### **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.

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.

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.

## **2. What should I know before I take ZELDOX?**

### **Warnings**

#### **Do not take ZELDOX if:**

- you are allergic to any medicine containing ziprasidone, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can take this medicine.

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.
- 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.

### **Check with your doctor if you:**

- have any allergies to:
  - any other medicines
  - any other substances such as foods, preservatives or dyes.
- have or have had any other 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.
- 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.
- take any medicines for any other condition.

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

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**

**Check with your doctor 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.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

ZELDOX is not recommended while you are breastfeeding. It is thought that low levels of ZELDOX passes into breast milk.

### **3. What if I am taking other medicines?**

**Some medicines may interfere with ZELDOX 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.

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.

**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.**

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

## **4. How do I 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 long to take ZELDOX

**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.

## When to take ZELDOX

- 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 to take ZELDOX

- Swallow the capsules whole with a full glass of water.

## If you forget to take ZELDOX

ZELDOX should be taken regularly at the same time each day.

**If you miss your dose at the usual time and 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 take a double dose to make up for the dose you 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 ZELDOX**

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.

If you think that you or anyone else may have taken too much ZELDOX, urgent medical attention may be needed.

### **You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

## **5. What should I know while taking ZELDOX?**

### **Things you should do**

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

- Remind any doctor, dentist or pharmacist you visit 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.

### **Call your doctor straight away if you:**

- become pregnant while taking ZELDOX.

### **Things you should not do**

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

### **Driving or using machines**

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

ZELDOX may cause drowsiness and sleepiness in some people.

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.

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

## **Drinking alcohol**

### **Tell your doctor if you drink alcohol.**

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.

## **Looking after your medicine**

- 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.

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.**

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

### **Getting rid of any unwanted medicine**

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

Do not take this medicine after the expiry date.

## **6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

| Less serious side effects   | What to do  |
|---|---|
| <p><b>Physical problems:</b></p> <ul style="list-style-type: none"><li>● headache</li><li>● feeling sick (nausea)</li><li>● vomiting</li><li>● sleepiness</li><li>● difficulty sleeping</li><li>● dizziness on standing up, especially when getting up from a sitting or lying position</li><li>● dry mouth</li><li>● too much saliva</li><li>● indigestion</li><li>● constipation</li><li>● diarrhoea</li><li>● restlessness</li><li>● muscle stiffness</li><li>● blurred vision</li><li>● palpitations</li><li>● weakness or loss of strength</li><li>● male sexual dysfunction</li><li>● In schizophrenia studies of 4-6 weeks duration,</li></ul> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p>These are common side effects of ZELDOX.</p> |

| <b>Less serious side effects</b>   | <b>What to do</b> |
|--|-------------------|
| <p>the incidence of weight gain in people taking ZELDOX was low and comparable to those who took a placebo or inactive medicine.</p> <p><b>Mental or emotional problems:</b></p> <ul style="list-style-type: none"> <li>● drowsiness or sleepiness</li> <li>● trouble sleeping</li> <li>● restlessness or difficulty sitting still</li> <li>● dizziness, blackouts or feeling faint</li> <li>● anxiety or agitation</li> <li>● loss of control of your bladder</li> <li>● unusual secretion of breast milk.</li> </ul> |                   |

**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"><li>● any worm-like movements of the tongue</li><li>● any other uncontrolled movements of the tongue, mouth, cheeks or jaw</li><li>● any uncontrolled movements spreading to the arms and legs</li><li>● sleepwalking</li><li>● eating during sleepwalking</li><li>● breathing stops and starts while sleeping. Symptoms can be loud or frequent snoring, silent pauses in breathing, choking or gasping sounds.</li></ul> <p>These are symptoms of a condition called Tardive Dyskinesia. Tardive Dyskinesia is more likely in people who have been taking ZELDOX or other</p> | <p><b>Tell your doctor immediately if you notice any of these serious side effects.</b></p> <p>Medical attention may be required.</p> |

| <b>Serious side effects</b>   | <b>What to do</b> |
|---|-------------------|
| 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. |                   |

## Very serious side effects

| <b>Very serious side effects</b>  | <b>What to do</b>   |
|---|---|
| <ul style="list-style-type: none"> <li>● convulsions, fit or seizures</li> <li>● trembling and shaking of the hands and fingers</li> <li>● shuffling walk and stiffness of the arms and legs</li> <li>● sudden uncontrollable muscle spasms in the eyes, head, neck and body</li> <li>● sudden signs of allergy - including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing (symptoms</li> </ul> | <p><b>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.</b></p> <p>These symptoms can also sometimes happen after you stop taking Zeldox. You may need urgent medical attention or hospitalisation.</p> |



| <b>Very serious side effects</b>   | <b>What to do</b> |
|--|-------------------|
| <p>resembling a condition called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))</p> <ul style="list-style-type: none"> <li>● pain and swelling in the large veins of your legs or hip</li> <li>● sharp chest pain, shortness of breath or and coughing up blood</li> </ul> |                   |

**Stop taking Zeldox and contact your doctor immediately or go straight to the Emergency Department at your nearest hospital 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).

**Tell your doctor or pharmacist 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](http://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 pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What ZELDOX contains

|   |   |
|---|---|
| <b>Active ingredient<br/>(main ingredient)</b>      | Ziprasidone 20 mg, 40 mg, 60 mg or 80 mg per capsule  |
| <b>Other ingredients<br/>(inactive ingredients)</b> | <ul style="list-style-type: none"><li>• Lactose monohydrate</li><li>• Pregelatinised maize starch</li><li>• Magnesium stearate</li><li>• Gelatin</li><li>• Titanium dioxide</li></ul> |

|                            |  |
|----------------------------|--|
|                            | <ul style="list-style-type: none"> <li>• TekPrint SW-9008 Black Ink (ARTG PI No. 2328)</li> <li>• Indigo carmine CI73015 (20 mg, 40 mg and 80 mg capsules only)</li> </ul> |
| <b>Potential allergens</b> | Lactose monohydrate  |

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

## **What ZELDOX looks like**

ZELDOX 20 mg capsule: No.4 blue cap/white body capsule marked "ZDX 20" and "Pfizer". (AUST R 65526)

ZELDOX 40 mg capsule: No.4 blue cap/blue body capsule marked "ZDX 40" and "Pfizer". (AUST R 65527)

ZELDOX 60 mg capsule: No.3 white cap/white body capsule marked "ZDX 60" and "Pfizer". (AUST R 65528)

ZELDOX 80 mg capsule: No.2 blue cap/white body capsule marked "ZDX 80" and "Pfizer". (AUST R 65529)

Available in blister packs of 60 capsules.

## **Who distributes ZELDOX**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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