

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ZURZUVAE™**

Zuranolone Capsules

This Patient Medication Information is written for the person who will be taking **ZURZUVAE**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ZURZUVAE**, talk to a healthcare professional.

Serious warnings and precautions box

Addiction, Abuse and Misuse: Even if you take ZURZUVAE exactly as you are told, you may be at risk for abuse, misuse and addiction, physical dependence and withdrawal. Abuse and misuse can result in overdose or death, especially if you take ZURZUVAE with:

- Opioids.
- Alcohol.
- Illicit drugs.

Your healthcare professional should:

- talk to you about the risks of treatment with ZURZUVAE as well as other treatment (including nondrug) options.
- assess your risk for these behaviours before prescribing ZURZUVAE.
- monitor you while you are taking ZURZUVAE for the signs and symptoms of misuse and abuse. If you feel like you are craving ZURZUVAE, or not using it as directed, talk to your healthcare professional right away.

Store ZURZUVAE in a secure place to avoid theft or misuse.

Impaired Alertness and Coordination: ZURZUVAE may decrease your awareness and alertness, which can affect your ability to safely drive, operate machinery, or perform other activities requiring alertness or physical coordination (such as caring for a child).

- Do not drive, operate machinery, or do other dangerous activities for at least 12 hours after taking each dose during your 14-day treatment course of ZURZUVAE.
- ZURZUVAE may affect you for longer than 12 hours. You may not be able to tell on your own if you can drive safely or how much ZURZUVAE affects you.
- If you are caring for a child, consider arranging for alternative childcare until you know how ZURZUVAE affects you.
- Taking ZURZUVAE with other central nervous system depressants (such as alcohol, opioids, benzodiazepines) can make these symptoms worse.

Tell your healthcare professional if you develop any of these symptoms and if they get worse during your treatment with ZURZUVAE.

Self-Harm or Suicide:

- Antidepressants, such as ZURZUVAE, can increase the risk of suicidal thoughts and actions in some children, teenagers, or young adults at the beginning of treatment, or when the dose is changed. ZURZUVAE is not approved for use in children or teenagers.
- **If you have thoughts of harming or killing yourself at any time, tell your healthcare professional or go to a hospital right away.** You will be closely observed by your healthcare professional in this situation.

New or Worsened Emotional or Behavioural Problems:

- When you first start taking ZURZUVAE or when your dose is adjusted, you may feel worse instead of better. You may feel new or worsened feelings of agitation, hostility, anxiety, or impulsivity.
- During your treatment with ZURZUVAE, it is important that you and your healthcare professional talk regularly about how you are feeling. They will closely monitor you for signs of new or worsened emotions or behaviours while you are taking ZURZUVAE.
- You may find it helpful to tell a relative or close friend that you are depressed. Ask them to read this leaflet. You might ask them to tell you if they:
 - think your depression is getting worse, or
 - are worried about changes in your behaviour.
- If your depression worsens or you experience changes in your behaviour, tell your healthcare professional right away. Do not stop taking ZURZUVAE on your own.

What ZURZUVAE is used for:

ZURZUVAE is an antidepressant medicine used to treat moderate or severe postpartum depression (PPD) in adults, following childbirth.

How ZURZUVAE works:

ZURZUVAE increases the activity of gamma-aminobutyric acid (GABA) on receptors in the brain. GABA is involved in the regulation of mood. It is thought that by increasing the activity of GABA, ZURZUVAE may help the parts of the brain affected by depression.

The ingredients in ZURZUVAE are:

Medicinal ingredient(s): zuranolone.

Non-medicinal ingredients: colloidal silicon dioxide; croscarmellose sodium; mannitol; microcrystalline cellulose; silica, colloidal anhydrous; sodium stearyl fumarate. The capsule shell contains gelatin; red iron oxide; titanium dioxide; yellow iron oxide. The capsule print (black ink) contains ammonium hydroxide; black iron oxide; propylene glycol; shellac glaze.

ZURZUVAE comes in the following dosage form(s):

Capsules (immediate release): 20 mg, 25 mg, 30 mg.

Do not use ZURZUVAE if:

- You are allergic to zuranolone or to any of the other ingredients of this medicine.
- You are pregnant.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZURZUVAE. Talk about any health conditions or problems you may have, including if you:

- have kidney problems.
- have liver problems.
- have a history of abuse or dependence on prescription drugs, street drugs, or alcohol.
- have had depression, mood problems or suicidal thoughts or behaviour.
- think you are pregnant or are planning to become pregnant.
- are breastfeeding or plan to breastfeed.

Other warnings you should know about:

Pregnancy: If you think you are pregnant, or planning to become pregnant, talk to your healthcare professional before taking ZURZUVAE. Reliable contraception should be used during your treatment and for at least 7 days after stopping treatment. To rule out pregnancy, your healthcare professional may require you to take a pregnancy test before you start treatment with ZURZUVAE.

Breastfeeding: ZURZUVAE passes into breast milk. If you are breastfeeding, it is recommended that you stop during treatment with ZURZUVAE. However, you and your healthcare professional should discuss the risks and benefits to breastfeeding while taking ZURZUVAE. If it is decided that you should breastfeed, monitor your child for potential side effects, such as excessive sleepiness or poor feeding. If you notice any of these symptoms, tell your healthcare professional.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious drug interactions:

Serious drug interactions with ZURZUVAE include:

- other central nervous system depressants such as alcohol, benzodiazepines, opioids, hypnotics, gabapentinoids or sedatives. Taking ZURZUVAE with these may make any impairment you experience worse.

The following may interact with ZURZUVAE:

- Certain antibiotic medicines such as rifampin.
- Certain antifungal medicines such as ketoconazole, posaconazole, voriconazole, itraconazole.
- Certain HIV medicines such as ritonavir, elvitegravir, lopinavir, efavirenz.
- Certain medicines used to treat epilepsy such as carbamazepine, phenytoin, phenobarbital.
- Certain medicines used to treat cancer such as ceritinib, idelalisib, ribociclib, tucatinib.
- St. John's Wort, an herbal remedy taken for depression.
- Food or drink containing grapefruit.

How to take ZURZUVAE:

- Always take this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Swallow ZURZUVAE capsules whole without chewing, crushing, or opening it.
- **Take ZURZUVAE with a fat-containing food.** Typical fat-containing foods include nuts, peanut butter, avocado, eggs, and cheese.

Usual dose:

The recommended dose is 50 mg (two 25 mg capsules) taken once daily in the evening for 14 days, as a single course of treatment.

Your healthcare professional may reduce your dose to 40 mg (two 20 mg capsules) taken once daily in the evening if you have trouble with side effects.

Do not stop taking ZURZUVAE until you finish your 14-day treatment course, even if you feel better. If you feel you need to stop your treatment, talk to your healthcare professional first.

Overdose:

If you think you, or a person you are caring for, have taken too much ZURZUVAE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms. Do not drive yourself because you may start to feel sleepy. Always take the labelled medicine container with you to show the healthcare professional, even if there are no capsules left.

Missed dose:

If you forget to take ZURZUVAE, skip the missed dose and take the next dose at your regular time the next day. **Do not take a double dose or additional capsules to make up for forgetting to take your daily dose.** Continue taking ZURZUVAE once daily until the remainder of the 14-day treatment course is completed.

Possible side effects from using ZURZUVAE:

These are not all the possible side effects you may have when taking ZURZUVAE. If you experience any side effects not listed here, tell your healthcare professional.

- drowsiness or sleepiness
- dizziness
- diarrhea
- lack of energy
- trouble remembering information
- stomach pain
- trembling or shaking
- muscle twitching
- muscle pain

- numbness
- rash
- anxiety
- urinary tract infection

Serious side effects and what to do about them:

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Confusional state (feeling confused): not thinking clearly		✓	
Unknown			
New or worsened emotional or behavioural problems: feeling detached, restless, agitated, angry, aggressive, nervous, short tempered		✓	
Severe allergic reactions: swelling of the tongue or throat, trouble breathing, sudden wheeziness, chest pain or tightness, shortness of breath, throat closing, nausea, or vomiting. Other allergic reactions may include rashes, spots on your skin, or itchy skin			✓
Thoughts of death or suicide: thoughts of hurting yourself or other people			✓
Withdrawal: Severe symptoms may include: Convulsions (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature 15°C to 25°C.

Keep out of reach and sight of children.

Return any unused or expired medication to your pharmacy for disposal.

If you want more information about ZURZUVAE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.biogen.ca/products/ZURZUVAE_PM_EN; or by calling 1-866-477-3462.

This leaflet was prepared by Biogen Canada Inc.

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