

**MEDICATION GUIDE**  
**ZURZUVAE™** (zur-ZOO-vay)  
(zuranolone)  
capsules, for oral use, CIV

**What is the most important information I should know about ZURZUVAE?**

**ZURZUVAE may cause serious side effects, including:**

- **Decreased ability to drive or do other dangerous activities.** ZURZUVAE may decrease your awareness and alertness, which can affect your ability to drive safely or safely do other dangerous activities.
  - **Do not** drive, operate machinery, or do other dangerous activities **until at least 12 hours after taking each dose** during your 14-day treatment course of ZURZUVAE.
  - You may not be able to tell on your own if you can drive safely or tell how much ZURZUVAE is affecting you.
- **Decreased awareness and alertness [central nervous system (CNS) depressant effects].** ZURZUVAE may cause sleepiness, drowsiness, slow thinking, dizziness, confusion, and trouble walking.
  - Because of these symptoms, you may be at a higher risk for falls during treatment with ZURZUVAE.
  - Taking alcohol, other medicines that cause CNS depressant effects, or opioids while taking ZURZUVAE can make these symptoms worse and may also cause trouble breathing.
  - Tell your healthcare provider if you develop any of these symptoms, or if they get worse during treatment with ZURZUVAE. Your healthcare provider may decrease your dose or stop ZURZUVAE treatment if you develop these symptoms.

**What is ZURZUVAE?**

ZURZUVAE is a prescription medicine used to treat adults with postpartum depression (PPD).

It is not known if ZURZUVAE is safe and effective for use in children.

ZURZUVAE is a federal controlled substance (C-IV) because it contains zuranolone that can be abused or lead to dependence. Keep ZURZUVAE in a safe place to protect it from theft. Do not sell or give away ZURZUVAE because it may harm others and is against the law.

**Before taking ZURZUVAE, tell your healthcare provider about all of your medical conditions, including if you:**

- drink alcohol
- have abused or been dependent on prescription medicines, street drugs, or alcohol
- have liver or kidney problems
- are pregnant or plan to become pregnant. ZURZUVAE may harm your unborn baby.

**Females who are able to become pregnant:**

- Tell your healthcare provider right away if you become pregnant or plan to become pregnant during treatment with ZURZUVAE.
- You should use effective birth control (contraception) during treatment with ZURZUVAE and for 1 week after the final dose.
- There is a pregnancy registry for females who are exposed to ZURZUVAE during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ZURZUVAE and their baby. If you become pregnant during treatment with ZURZUVAE, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>
- are breastfeeding or plan to breastfeed. ZURZUVAE passes into breast milk, and it is not known if it can harm your baby. Talk to your healthcare provider about the risks and benefits of breastfeeding and about the best way to feed your baby during treatment with ZURZUVAE.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ZURZUVAE and some medicines may interact with each other and cause serious side effects. ZURZUVAE may affect the way other medicines work and other medicines may affect the way ZURZUVAE works.

**Especially tell your healthcare provider if you take:**

- antidepressants
- opioids
- CNS depressants such as benzodiazepines

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider will decide if other medicines can be taken with ZURZUVAE.

**How should I take ZURZUVAE?**

- Take ZURZUVAE exactly as your healthcare provider tells you to take it.

- Take ZURZUVAE 1 time daily in the evening with fat-containing food for 14 days (a treatment course). Talk to your healthcare provider about examples of foods you should eat.
- If you forget to take ZURZUVAE, skip the missed dose and take the next dose at your regular time the next evening. **Do not** take extra capsules to make up for the missed dose. Continue taking ZURZUVAE 1 time daily until you complete the rest of your treatment course.
- Your healthcare provider may change your dose of ZURZUVAE if you have certain side effects. Do not change your dose without talking to your healthcare provider.
- If you take too much ZURZUVAE, call your healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

#### **What should I avoid while taking ZURZUVAE?**

- **Do not** drive a car, operate machinery, or do other dangerous activities until **at least 12 hours after taking each dose of ZURZUVAE** because ZURZUVAE may make you feel sleepy, confused, or dizzy.
- **Do not** drink alcohol or take other medicines that make you sleepy or dizzy while taking ZURZUVAE without talking to your healthcare provider.

See **“What is the most important information I should know about ZURZUVAE?”**

#### **What are the possible side effects of ZURZUVAE?**

**ZURZUVAE may cause serious side effects, including:**

- See **“What is the most important information I should know about ZURZUVAE?”**
- **Increased risk of suicidal thoughts or actions.** ZURZUVAE and other antidepressant medicines may increase the risk of suicidal thoughts and actions in people 24 years of age and younger. **ZURZUVAE is not for use in children.**
  - Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.

#### **How can I watch for and try to prevent suicidal thoughts and actions?**

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

**Tell your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:**

- |                                     |   |
|-------------------------------------|---|
| ▪ attempts to commit suicide        | ▪ panic attacks                                       |
| ▪ thoughts about suicide or dying   | ▪ new or worse irritability                           |
| ▪ new or worse depression           | ▪ acting aggressive, being angry, or violent          |
| ▪ feeling very agitated or restless | ▪ an extreme increase in activity and talking (mania) |
| ▪ trouble sleeping (insomnia)       | ▪ acting on dangerous impulses                        |
| ▪ new or worse anxiety              | ▪ other unusual changes in behavior or mood           |

#### **The most common side effects of ZURZUVAE include:**

- |                            |  |
|----------------------------|--|
| • sleepiness or drowsiness | • diarrhea                                 |
| • dizziness                | • feeling tired, weak, or having no energy |
| • common cold              | • urinary tract infection                  |

These are not all of the possible side effects of ZURZUVAE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store ZURZUVAE?**

- Store ZURZUVAE at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep ZURZUVAE and all medicines out of the reach of children.**

#### **General information about the safe and effective use of ZURZUVAE.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZURZUVAE for a condition for which it was not prescribed. Do not give ZURZUVAE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ZURZUVAE that is written for health professionals.

#### **What are the ingredients in ZURZUVAE?**

**Active ingredient:** zuranolone

**Inactive ingredients:** ZURZUVAE capsules contain colloidal silicon dioxide, croscarmellose sodium, mannitol, microcrystalline cellulose, and sodium stearyl fumarate. The capsule shells contain gelatin, red iron oxide, titanium dioxide, and yellow iron oxide. The imprinting ink contains ammonium hydroxide, black iron oxide, propylene glycol, and shellac glaze.

Manufactured for:

Biogen Inc., 225 Binney Street, Cambridge, MA 02142

ZURZUVAE is a trademark of Sage Therapeutics, Inc.

For more information about ZURZUVAE go to [www.ZURZUVAE.com](http://www.ZURZUVAE.com) or call 1-844-987-9882.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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