

ZURZUVAE is the first and only FDA-approved oral treatment for postpartum depression that may offer rapid relief starting in 3 days.

ZURZUVAE 50 mg was studied in women whose PPD symptoms started in the third trimester or within 4 weeks of delivery in a 6-week trial. During the trial, patients took either ZURZUVAE or placebo for 14 days, and were followed up for another 4 weeks. Significantly greater PPD symptom improvement was demonstrated at **Day 3**, **Day 15** (the primary endpoint), and **Day 45** compared to placebo, using a standard depression rating scale.

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 in children

IMPORTANT SAFETY INFORMATION

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

Please see Important Safety Information throughout and full <u>Prescribing Information</u>, including **Boxed Warning** and <u>Medication Guide</u>.



Postpartum depression is more common than you may think

It's common to go through hormonal, physical, and emotional changes during and after pregnancy. Symptoms of postpartum depression can start while you're pregnant, or after you've given birth.



About **1 in 8 women** report experiencing symptoms of PPD.



PPD is underdiagnosed and undertreated even though it is one of the most common medical conditions associated with pregnancy.



PPD can affect any adult woman regardless of age,
ethnicity, marital status,
or income.

There are risk factors associated with PPD, which may include increased stress, family or personal history of depression, and hormonal changes due to pregnancy.



What are some of the signs and symptoms of postpartum depression?

Postpartum depression can cause a number of symptoms. Although you may experience different symptoms, some of the more common symptoms include:

- Persistent sad, anxious, or "empty" mood
- Irritability
- Feelings of guilt, worthlessness, hopelessness, or helplessness
- Loss of interest or pleasure in hobbies and activities
- Trouble bonding or forming an emotional attachment with the new baby
- Fatigue or abnormal decrease in energy
- Persistent doubts about the ability to care for the new baby

- Feeling restless or having trouble sitting still
- Difficulty concentrating, remembering, or making decisions
- Difficulty sleeping (even when the baby is sleeping), awakening early in the morning, or oversleeping
- Abnormal appetite, weight changes, or both
- Aches or pains, headaches, cramps, or digestive problems that do not have a clear physical cause or do not ease even with treatment
- Thoughts about death, suicide, or harming oneself or the baby



If you're thinking about suicide, call the confidential National Suicide Prevention Lifeline 24/7 at **988**. If you're having a medical emergency, call **911**. If you fear for your safety or the safety of your child, get help immediately. If you are experiencing any of these or other symptoms, talk to your healthcare provider right away.

Rapid relief may start in 3 days

In a clinical study, ZURZUVAE provided a fast way to feel symptom relief



Rapid relief

Women experienced PPD symptom improvement at **day 15** and as early as **day 3**.



Results that lasted

Women continued to feel relief for about 4 weeks after they finished taking ZURZUVAE.

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What is the most important information I should know about ZURZUVAE? (continued)

- 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



treatment. It is taken once daily in the evening with fat-containing food.

What is the most important information I should know about ZURZUVAE? (continued)

- Decreased awareness and alertness [central nervous system (CNS) depressant effects]. (continued)
- 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

Please see Important Safety Information throughout and full <u>Prescribing Information</u>, including **Boxed Warning** and Medication Guide.



14 days of dosing and done with ZURZUVAE



Take once daily with food

Take ZURZUVAE 1 time daily with fat-containing foods. Looking for food ideas? Talk to your healthcare provider for guidance, and tell them about any food allergies you may have.



Take in the evening

Talk to your healthcare provider about the best time to take ZURZUVAE, because it may make you feel drowsy. Take ZURZUVAE exactly as your healthcare provider tells you to take it.



better sooner, you should finish all the medicine you were prescribed unless your healthcare provider tells you differently.



Take all 14 days of treatment

Even if you start feeling



at least 12 hours after taking each dose of ZURZUVAE.

What is the most important information I should know about ZURZUVAE? (continued)

ZURZUVAE is a federally controlled substance (C-IV) because it contains zuranolone, which 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.

You should not drive a car or do any dangerous activities for

Some things to keep in mind when starting ZURZUVAE



Take exactly as your healthcare provider tells you to take it

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.



Missed a dose?

If you miss a dose, skip the missed dose and take your next dose at the regular time. DO NOT take extra capsules to make up for the missed dose. Continue taking ZURZUVAE 1 time each day until you finish the rest of your 14-day treatment.

What is the most important information I should know about ZURZUVAE? (continued)

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
- 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



3 steps to getting your ZURZUVAE prescription

If you and your healthcare provider decide ZURZUVAE is right for you, here's how you'll get your medication.



Step 1: Your prescription is sent to the specialty pharmacy

Your healthcare provider will send your prescription to a specialty pharmacy. Once your insurance approves the prescription, the specialty pharmacy will ship ZURZUVAE directly to you. Ask your healthcare provider's office for the name and phone number of your specialty pharmacy, so you recognize the number when they call.



Step 2: The specialty pharmacy will contact you

The specialty pharmacy will contact you to confirm your prescription. When the specialty pharmacy calls you, it may show up as an unknown number. It's important to answer the phone when the specialty pharmacy contacts you or there may be delays in receiving your medication. If you miss the call, it's good to respond as soon as possible to avoid delays.



Step 3: Receive your prescription

Your prescription will be shipped directly to you. A signature by someone age 18 or older may be required, as well as proof of identity.



ZURZUVAE is only available from a specialty pharmacy and will be shipped to you directly because it is not stocked at your local retail pharmacy. The specialty pharmacy will work with you and your healthcare provider to make sure you receive your treatment.

Please see Important Safety Information throughout and full <u>Prescribing Information</u>, including **Boxed Warning** and Medication Guide.





ZURZUVAE Financial Assistance Programs

If you have been prescribed ZURZUVAE for the treatment of your postpartum depression (PPD), financial assistance programs such as the ZURZUVAE Savings Card Program* may be available to help you access your prescribed medication.

Please remember your healthcare provider is your best source of information for any medical questions or healthcare needs.





If you have questions about postpartum depression, ZURZUVAE, or services and resources available to support you, you can call the ZURZUVAE For You support line at **1-844-987-9882**.



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^{*}Financial assistance for eligible patients with commercial insurance under the ZURZUVAE Savings Card Program will be applied directly by the specialty pharmacy filling the prescription. Restrictions apply. For full terms and conditions, please see ZurzuvaeForYouTermsAndConditions.com.



What is the most important information I should know about ZURZUVAE? (continued)

Females who are able to become pregnant:

- Tell your healthcare provider right away if you 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/research/

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, or CNS depressants such as benzodiazepines.

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?"

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

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

The most common side effects of ZURZUVAE include:

 Sleepiness or drowsiness, dizziness, common cold, diarrhea, feeling tired, weak, or having no energy, and 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 or www.fda.gov/medwatch.

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Warning and Medication Guide.





ZURZUVAE is the first and only FDA-approved oral treatment for adults with postpartum depression (PPD) taken for 14 days once daily in the evening with fat-containing food

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Talk to your healthcare provider about ZURZUVAE

For more information about treatment with ZURZUVAE, visit ZURZUVAE.com.

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