



- Zurzuvae®
  - Capsules: 20mg, 25mg, 30mg

*If you or someone you know is in crisis, please call/text 988 to speak with a trained crisis counselor 24/7 and/or call 911 for emergency services. A helpline and other resources are also available through the National Alliance on Mental Illness at [nami.org](https://www.nami.org).*



## What is zuranolone and what does it treat?

Zuranolone is an antidepressant medication that works in the brain. It is approved for the treatment of postpartum depression (PPD).

Symptoms of postpartum depression include:

- Feeling sad, hopeless, empty, or overwhelmed
- Crying more often than usual or for no apparent reason
- Worrying or feeling overly anxious
- Oversleeping, or being unable to sleep even when her baby is asleep
- Having trouble concentrating, remembering details, and making decisions
- Experiencing anger or rage
- Losing interest in activities that are usually enjoyable
- Suffering from physical aches and pains, including frequent headaches, stomach problems, and muscle pain
- Eating too little or too much
- Withdrawing from or avoiding friends and family
- Having trouble bonding or forming an emotional attachment with her baby
- Persistently doubting her ability to care for her baby
- Thinking about harming herself or her baby

## What is the most important information I should know about zuranolone?

Zuranolone may cause you to feel very sleepy (excessive sedation). It is not recommended to drive a motor vehicle or engage in other potentially hazardous activities like operating machinery until at least 12 hours after the dose was taken. This applies to the full 14 day treatment course.

## Are there specific concerns about zuranolone and pregnancy?

Based on animal studies, zuranolone may cause fetal harm. Patients who may become pregnant should use effective contraception during treatment and for 1 week after the final dose of taking zuranolone. If you become pregnant during treatment with zuranolone, talk to your health care provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>.

Let your health care provider know if you are breastfeeding or plan to breastfeed. Zuranolone passes into breast milk at low levels. Talk to your health care provider about the risks and benefits of breastfeeding and about the best way to feed your baby while receiving zuranolone.

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

## What should I discuss with my health care provider before taking zuranolone?

- Symptoms of your condition that bother you the most
- If you have thoughts of suicide or harming yourself
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you experience side effects from your medications, discuss them with your provider. Some side effects may pass with time, but others may require changes in the medication.
- Any other psychiatric or medical problems you have, including kidney problems.
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies you have
- Other non-medication treatment you are receiving, such as talk therapy or substance abuse treatment. Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breastfeeding
- If you drink alcohol or use drugs

## How should I take zuranolone?

Zuranolone is usually taken once daily in the evening with fat-containing food (400 to 1,000 calories). It is typically taken for 14 days. The usual dose is 50 mg daily but may be reduced to 40 mg daily in the evening based on tolerability.

Zuranolone may be given alone or in addition to another oral antidepressant.

## What should I avoid while taking zuranolone?

Zuranolone may make you feel dizzy and sleepy. Do not drive a car or do other activities that require mental alertness for at least 12 hours after taken a dose.

Do not drink alcohol. Drinking alcohol while receiving zuranolone can increase the risk of excess sleepiness.

## What are the possible side effects of zuranolone?

Sleepiness, fatigue, dizziness, diarrhea, nasopharyngitis and urinary tract infection

### **Suicidal Thoughts or Actions in Children and Young Adults**

Postpartum depression and certain other psychiatric disorders are themselves associated with the risk of suicide. Women with postpartum depression, may experience worsening of their depression and/or emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications. This risk may persist until significant remission occurs. Zuranolone and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger. All patients being treated with antidepressants for any indication should watch for and notify their health care provider for worsening symptoms, suicidality and unusual changes in behavior, during treatment.

## Are there any risks for taking zuranolone for long periods of time?

There is a risk of physical and/or emotional dependence including addiction. Talk to your provider about the risk.

## What other medications may interact with zuranolone?

Central nervous system depressants, such as benzodiazepines, opioids, or tricyclic antidepressants, may enhance the feeling of sedation when taken with zuranolone.

Certain medications and supplements like St. John's Wort, phenobarbital, phenytoin, rifampin, carbamazepine may decrease levels of zuranolone and how effective it is.

Certain medications like clarithromycin, cobicistat, itraconazole, ketoconazole, voriconazole, ritonavir may increase levels of zuranolone and your doctor may adjust the zuranolone dose if needed.

## Summary of Black Box Warnings

In clinical studies, zuranolone caused sleepiness and confusion in a dose dependent way. This risk can be even higher if taking another central nervous system depressant (like alcohol, opioids, benzodiazepines) at the same time. Patients taking zuranolone should let their health care providers know about any other medications they may be taking at the same time.

Due to the higher risk of sleepiness and confusion, people taking zuranolone may be at higher risk of falls and dizziness. This sometimes required changing the dose for certain individuals in the clinical studies. If patients experience sleepiness, confusion, falls or dizziness while taking zuranolone, they should talk to their health care provider.

The level of sleepiness due to zuranolone also caused impaired driving ability in two driving simulation studies. Patients taking zuranolone should avoid driving, operating machinery or other potentially dangerous activities that require mental alertness for at least 12 hours after each zuranolone dose.

**Important Disclosure:** This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.