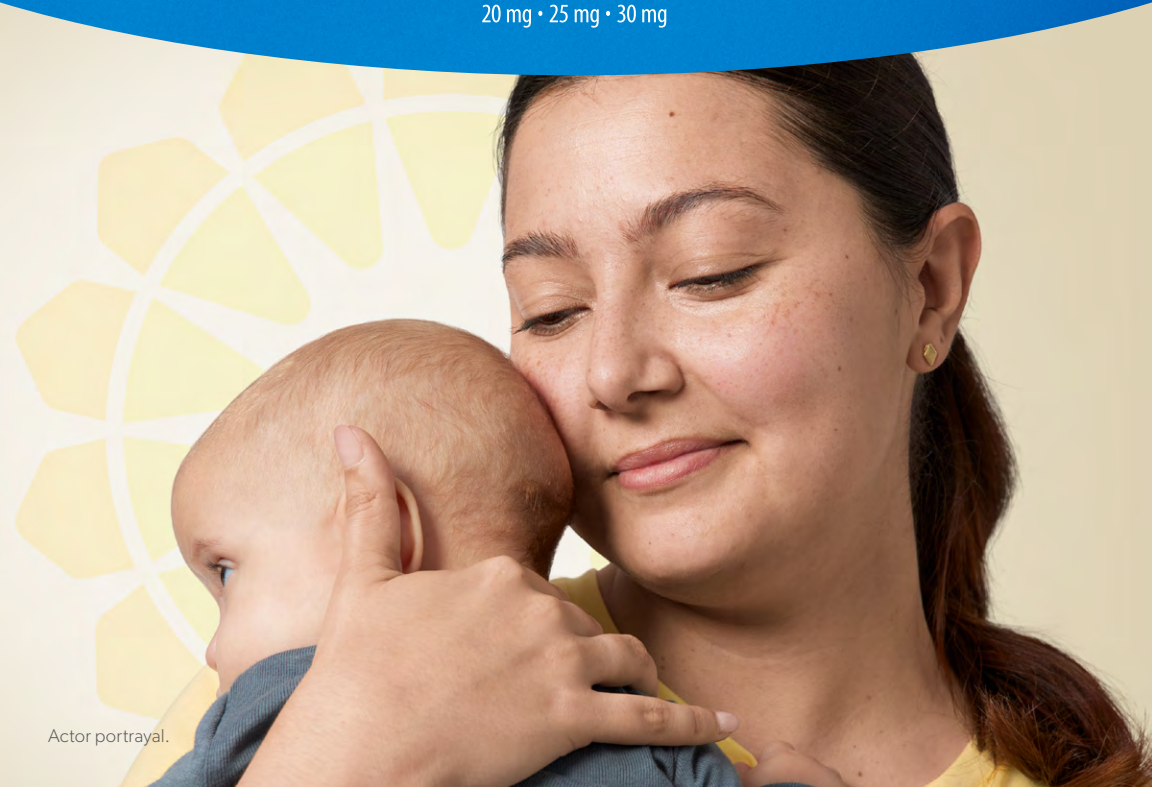
For adults with postpartum depression (PPD)

A quick-reference guide on how to

Get your patients started

ZURZUVAE™
(zuranolone) capsules CIV
20 mg • 25 mg • 30 mg



Actor portrayal.

INDICATION

ZURZUVAE is indicated for the treatment of postpartum depression (PPD) in adults.

IMPORTANT SAFETY INFORMATION

WARNING: IMPAIRED ABILITY TO DRIVE OR ENGAGE IN OTHER POTENTIALLY HAZARDOUS ACTIVITIES

ZURZUVAE causes driving impairment due to central nervous system (CNS) depressant effects.

Advise patients not to drive or engage in other potentially hazardous activities until at least 12 hours after ZURZUVAE administration for the duration of the 14-day treatment course. Inform patients that they may not be able to assess their own driving competence, or the degree of driving impairment caused by ZURZUVAE.

Please see additional Important Safety Information on pages 2 and 6, and full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Impaired Ability to Drive or Engage in Other Potentially Hazardous Activities

- ZURZUVAE causes driving impairment due to central nervous system (CNS) depressant effects
- Advise patients not to drive a motor vehicle or engage in other potentially hazardous activities requiring complete mental alertness, such as operating machinery, until at least 12 hours after ZURZUVAE administration for the duration of the 14-day treatment course. Inform patients that they may not be able to assess their own driving competence or the degree of driving impairment caused by ZURZUVAE

Central Nervous System Depressant Effects

- ZURZUVAE can cause CNS depressant effects such as somnolence and confusion
- Somnolence developed in 36% of patients who received ZURZUVAE (50 mg) and in 6% of patients who received placebo daily. Some ZURZUVAE-treated patients developed confusional state. One of these cases was severe, and was also associated with somnolence, dizziness, and gait disturbance
- A higher percentage of ZURZUVAE-treated patients, compared to placebo-treated patients, experienced somnolence, dizziness, or confusion that required dosage reduction, interruption, or discontinuation
- Because ZURZUVAE can cause CNS depressant effects, patients may be at higher risk of falls
- Other CNS depressants such as alcohol, benzodiazepines, opioids, tricyclic antidepressants, or drugs that increase zuranolone concentration, may increase impairment of psychomotor performance or CNS depressant effects such as somnolence, cognitive impairment, and the risk of respiratory depression in ZURZUVAE-treated patients
- To reduce the risk of CNS depressant effects and/or mitigate CNS depressant effects that occurs with ZURZUVAE treatment:
  - If patients develop CNS depressant effects, consider dosage reduction or discontinuation of ZURZUVAE
  - If use with another CNS depressant is unavoidable, consider dosage reduction
  - Reduce the ZURZUVAE dosage in patients taking strong CYP3A4 inhibitors

Suicidal Thoughts and Behavior

- In pooled analyses of placebo-controlled trials of chronically administered antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and 4,500 pediatric patients, the incidence of suicidal thoughts and behaviors in antidepressant-treated patients age 24 years and younger was greater than in placebo-treated patients. There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risk of suicidal thoughts and behaviors across the different indications, with the highest incidence in patients with major depressive disorder (MDD)
- ZURZUVAE does not directly affect monoaminergic systems. Consider changing the therapeutic regimen, including discontinuing ZURZUVAE, in patients whose depression becomes worse or who experience emergent suicidal thoughts and behaviors

Embryo-fetal Toxicity

- Based on findings from animal studies, ZURZUVAE may cause fetal harm when administered to a pregnant woman
- Advise a pregnant woman of the potential risk to an infant exposed to ZURZUVAE in utero. Advise females of reproductive potential to use effective contraception during treatment with ZURZUVAE and for one week after the final dose

Please see additional Important Safety Information on pages 1 and 6, and full Prescribing Information, including **Boxed Warning**.

ZURZUVAE™
(zuranolone) capsules ℞
20 mg • 25 mg • 30 mg

ZURZUVAE is taken as a 14-day treatment course[1]

ZURZUVAE is available as 20 mg, 25 mg, and 30 mg capsules. For illustration purposes only.

Recommended dosage

50 mg orally once daily

Two 25 mg capsules

In the evening

With fat-containing food

400–1,000 calories, 25%–50% fat

For 14 days

If patients experience central nervous system (CNS) depressant effects within the 14-day period, consider reducing the dosage to 40 mg once daily in the evening within the 14-day period.

ZURZUVAE can be used **alone or as an adjunct** to oral antidepressant therapy.

The safety and effectiveness of ZURZUVAE use beyond 14 days in a single treatment course have not been established.

If a ZURZUVAE evening dose is missed, patients should be advised:

- Take the next dose at the regular time the following evening
- Do not take extra capsules on the same day to make up for the missed dose
- Continue taking ZURZUVAE once daily until the remainder of the 14-day treatment course is completed

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ZURZUVAE™
(zuranolone) capsules IV
20 mg • 25 mg • 30 mg

Actor portrayal.

Dose adjustment recommendations

CYP3A4 inhibitors and inducers

- For patients taking **strong CYP3A4 inhibitors**, reduce the ZURZUVAE dosage to **30 mg** orally once daily in the evening for 14 days
  - No dosage modification is recommended when ZURZUVAE is concomitantly used with a moderate CYP3A4 inhibitor
- For patients taking **CYP3A4 inducers, avoid** concomitant use

Hepatic impairment

- For patients with **severe hepatic impairment** (Child-Pugh C), the recommended dosage is **30 mg** orally once daily in the evening for 14 days
  - The recommended dosage in patients with mild or moderate hepatic impairment (Child-Pugh A or Child-Pugh B, respectively) is the same as those in patients with normal hepatic function

Renal impairment

- For patients with **moderate or severe renal impairment** (eGFR <60 mL/min/1.73 m^2), the recommended dosage is **30 mg** orally once daily in the evening for 14 days
  - The recommended dosage in patients with mild renal impairment (eGFR 60 to 89 mL/min/1.73 m^2) is the same as those in patients with normal renal function

If use with another CNS depressant is unavoidable, consider dosage reduction. Caution should be used when ZURZUVAE is administered in combination with other CNS drugs or alcohol.

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Just 3 steps to get your patients with PPD started on ZURZUVAE

Sage Therapeutics and Biogen offer support services delivered through participating specialty pharmacies to help streamline patient access

STEP 1

Send your patient's ZURZUVAE prescription to a specialty pharmacy within our network*

Pharmacies will initiate the approval process and contact your office if any steps are needed to complete a prior authorization or appeal request.

STEP 2

Alert your patient that the pharmacy will call them to confirm insurance and contact information

Patient financial assistance programs, if appropriate, will be applied directly by the pharmacy when the prescription is filled.

Eligible patients who opt in to one of our affordability programs **may pay as little as $0** for their medication.†

STEP 3

The pharmacy will ship ZURZUVAE to your patient's preferred address after insurance approvals are complete

ZURZUVAE can be ordered from Accredo®, Alto Pharmacy®, CVS Specialty™, Special Care Pharmacy Services‡, or Walmart Specialty Pharmacy

Please contact your ZURZUVAE representative or call 1-844-987-9882 if you have questions about obtaining ZURZUVAE.§

In addition to the above network, ZURZUVAE will be made available at the Veterans Health Administration (VA) and may be made available at select IDN, Health System, Hospital, and other pharmacies.

*In accordance with your practice and state laws for a Schedule IV product.
†Additional terms and conditions apply.
‡Special Care Pharmacy Services is for Puerto Rico residents only.
§Specialty pharmacy network as of January 2024.

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IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

- The most common adverse reactions (≥5% and greater than placebo) in ZURZUVAE-treated patients (50 mg) were somnolence, dizziness, diarrhea, fatigue, and urinary tract infection

DRUG INTERACTIONS

CNS Depressant Drugs and Alcohol

- Caution should be used when ZURZUVAE is administered in combination with other CNS drugs or alcohol. If use with another CNS depressant is unavoidable, consider dosage reduction

Strong CYP3A4 Inhibitors

- Reduce the ZURZUVAE dosage when used with a strong CYP3A4 inhibitor

CYP3A4 Inducers

- Avoid concomitant use of ZURZUVAE with CYP3A4 inducers

USE IN SPECIFIC POPULATIONS

Pregnancy

- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including ZURZUVAE, during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visiting online at https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/
- Based on findings from animal studies, ZURZUVAE may cause fetal harm. Advise pregnant women of the potential risk to a fetus. Available data on ZURZUVAE use in pregnant women from the clinical development program are insufficient to evaluate for a drug- associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes

Lactation

- Available data from a clinical lactation study in 14 women indicate that zuranolone is present in low levels in human milk. There are no data on the effects of zuranolone on a breastfed infant and limited data on the effects on milk production
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZURZUVAE and any potential adverse effects on the breastfed child from ZURZUVAE or from the underlying maternal condition

Hepatic Impairment

- The recommended ZURZUVAE dosage in patients with severe hepatic impairment (Child-Pugh C) is lower than patients with normal hepatic function

Renal Impairment

- The recommended ZURZUVAE dosage in patients with moderate and severe renal impairment is lower than those with normal renal function

DRUG ABUSE AND DEPENDENCE

- ZURZUVAE contains zuranolone, a Schedule IV controlled substance under the Controlled Substances Act
- Zuranolone has abuse potential with associated risks of misuse, abuse, and substance use disorder including addiction
- ZURZUVAE may produce physical dependence

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ZURZUVAE™
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20 mg • 25 mg • 30 mg

Have questions or need assistance getting your patients started?

Contact your ZURZUVAE representative for any questions or call 1-844-987-9882 for more information on patient support services

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Reference: ZURZUVAE Prescribing Information. Cambridge, MA: Biogen and Sage Therapeutics, Inc; 11/2023.

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