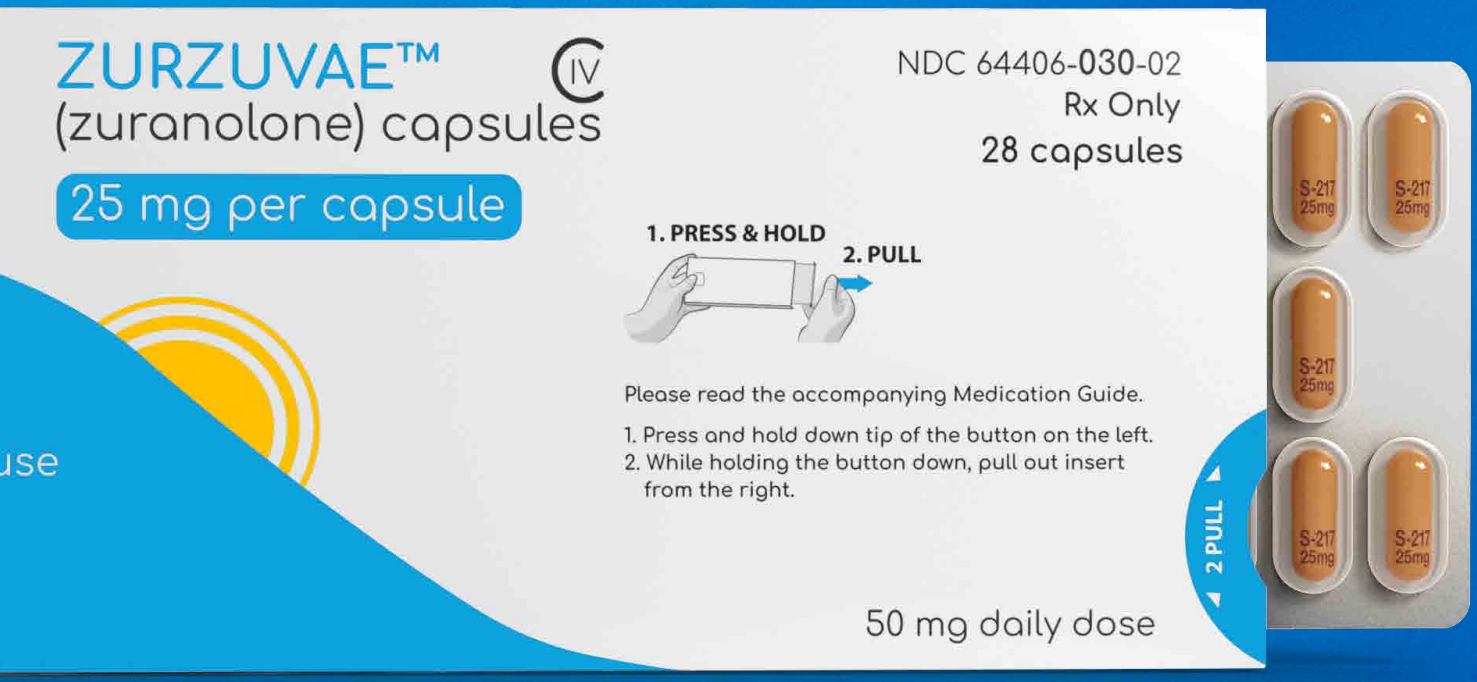
ZURZUVAE®
(zuranolone) capsules C IV
20 mg • 25 mg • 30 mg

Your guide to prescribing ZURZUVAE



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INDICATION

ZURZUVAE® (zuranolone) 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 throughout and full Prescribing Information, including **Boxed Warning**.

Prescribing the recommended dosage of ZURZUVAE (zuranolone)[1]

ZURZUVAE 25 mg
National Drug Code (NDC):
64406-030-02

Form field	Entry
Product	ZURZUVAE 25 MG PO CAPS — ZURZUVAE 50 mg (2 x 25 mg capsules daily) comes as a blister pack
Dose	25 mg — Specify the dose
Route	Oral
Frequency	Once daily
Duration	14 days
Dispense quantity	28 capsules — Indicate the number of capsules
Patient sig	Take 2 capsules orally, once a day in the evening, with fat-containing food, for 14 days — Add directions for how and when to take the medication
Notes	Diagnosis: Postpartum depression (F53.0)[2] — Including your patient's ICD-10 diagnosis code with their prescription may help expedite the insurance approval process

ZURZUVAE is available through a select specialty pharmacy network

Call 1-844-987-9882 if you have questions about obtaining ZURZUVAE. Individual patient insurance coverage is not guaranteed. A patient's insurance coverage may require the use of a specific specialty pharmacy. ZURZUVAE is not available at retail pharmacies.

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

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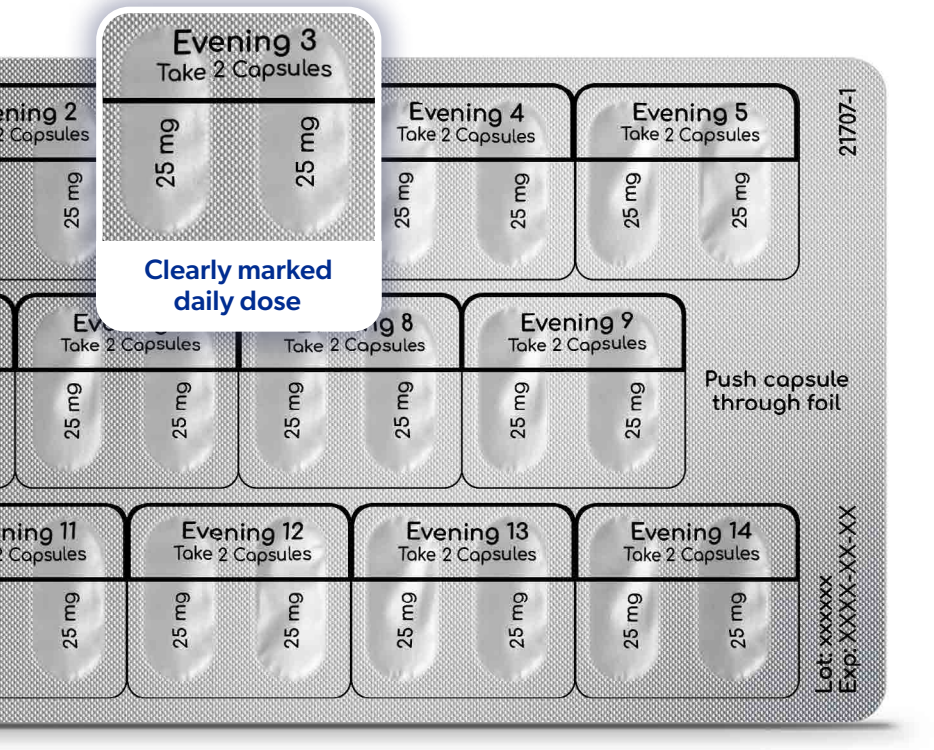
Only 14 days of dosing and done with ZURZUVAE (zuranolone)[1]



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Recommended dosage[1]

- ***50 mg orally once daily***
  2 x 25 mg capsules
- ***In the evening***
- ***With fat-containing food***
  400–1,000 calories, 25%–50% fat
- ***For 14 days***

ZURZUVAE can be used **alone or as an adjunct** to oral antidepressant therapy.[1]

The safety and effectiveness of ZURZUVAE use beyond 14 days in a single treatment course have not been established.[1]

If a ZURZUVAE dose is missed, patients should be advised[1]:

- Take the next dose at the regular time the following evening
- Do not take extra capsules on the same day
- Continue taking ZURZUVAE until the 14-day treatment course is completed

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Central Nervous System Depressant Effects (continued)

- 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

ADVERSE REACTIONS

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

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*ZURZUVAE (zuranolone) dosage adjustments for specific populations[1]**

Patients who experience CNS depressant effects within the 14-day period	 Consider dose reduction to **40 mg (2 x 20 mg capsules)** for the duration of the treatment course or discontinue therapy NDC: 64406-029-01
Taking strong CYP3A4 inhibitors	 **30 mg (1 x 30 mg capsule)** NDC: 64406-031-01
Taking CYP3A4 inducers	 **Avoid concomitant use**
With severe hepatic impairment (Child-Pugh C) Mild or moderate hepatic impairment (Child-Pugh A or B): no recommended dosage adjustment	 **30 mg (1 x 30 mg capsule)** NDC: 64406-031-01
With moderate or severe renal impairment (eGFR <60 mL/min/1.73 m^2) Mild renal impairment (eGFR 60 to 89 mL/min/1.73 m^2): no recommended dosage adjustment	 **30 mg (1 x 30 mg capsule)** NDC: 64406-031-01

*ZURZUVAE is recommended to be taken orally once daily in the evening with fat-containing food for 14 days.[1]

IMPORTANT SAFETY INFORMATION (continued)

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
- 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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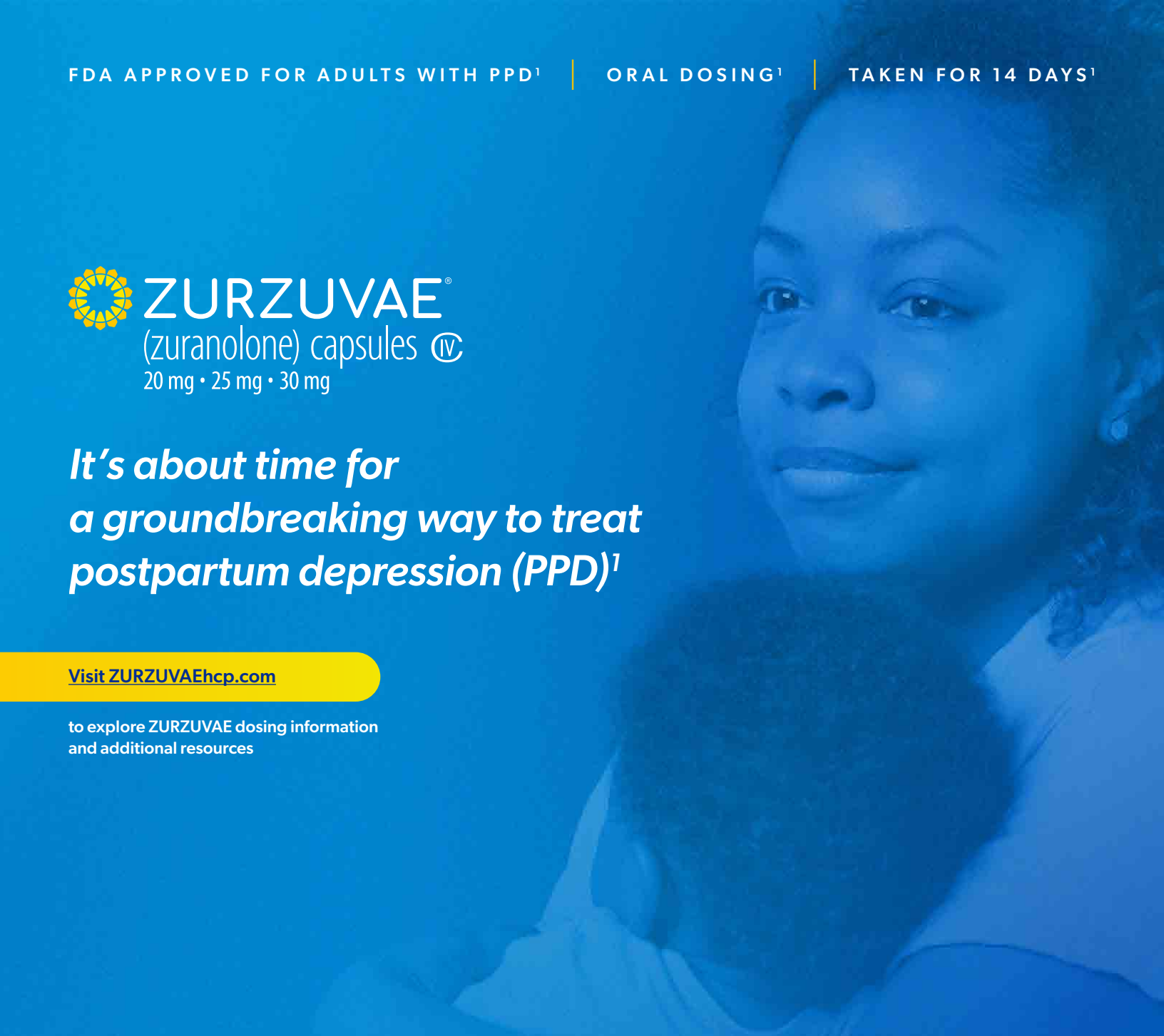
FDA APPROVED FOR ADULTS WITH PPD[1] | ORAL DOSING[1] | TAKEN FOR 14 DAYS[1]



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It's about time for a groundbreaking way to treat postpartum depression (PPD)[1]

Visit ZURZUVAEhcp.com

to explore ZURZUVAE dosing information and additional resources

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References: 1. ZURZUVAE Prescribing Information. Cambridge, MA: Biogen and Sage Therapeutics, Inc. **2.** ICD-10-CM Tabular List of Diseases and Injuries. Centers for Medicare & Medicaid Services. Last updated April 1, 2023. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2023-icd-10-cm. Accessed April 16, 2024.

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