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

Getting Your Patients Started

Through the ZURZUVAE Specialty Pharmacy Network

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.

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

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

3 Steps to Get Your Adult Patients With PPD Started on ZURZUVAE® (zuranolone)

STEP 1 Send Rx and Submit Completed PA

Send the Rx, the patient's medical and pharmacy insurance information, and the patient's demographics to a specialty pharmacy within the ZURZUVAE network

Be sure to obtain the appropriate pharmacy insurance information from your patient, such as the **Rx BIN and PCN**, and submit this with the Rx to the specialty pharmacy

Create PA in CoverMyMeds® or using the health plan's specific PA form, complete, and submit PA and any supporting documentation to the health plan

If applicable, send the 6-digit **CoverMyMeds** PA key code with the Rx to the specialty pharmacy via fax or in the notes field of the eRx

Please note: *The Rx may be sent to the specialty pharmacy to run the benefits investigation (BI) and initiate the PA. However, this may delay patient access as your office will still need to complete and submit the PA to the health plan.*

Send the Prescription to the Appropriate Specialty Pharmacy in the ZURZUVAE Network

- ZURZUVAE is available through a specialty pharmacy network; it is not available through retail pharmacies (see page 5 for list of network specialty pharmacies)
- Verify specialty pharmacy options or requirements with your patient's insurance to prevent potential delays in the process

Ensure the PA Is Complete and Accurate Prior to Submitting to the Health Plan, With the Following Information Included:

- ☐ **ICD-10 code**
  The correct ICD-10 code for patients with PPD[1]: F53.0. Not using the correct code may result in delays.*
- ☐ All patient, provider, and visit information

If required by health plan, also include:

- ☐ Previous treatments and length of trial
- ☐ Relevant chart notes/documentation that support the treatment decision for ZURZUVAE

*This code is presented for informational purposes only. It is not a statement, promise, or guarantee concerning coverage and/or levels of reimbursement, payment, or charge and is not intended as a recommendation to increase or maximize reimbursement by any payer. It is the responsibility of the healthcare provider to determine the appropriate code(s) for diagnosis or service provided to their patient.

CoverMyMeds® is a registered trademark of CoverMyMeds, LLC.
BIN=bank identification number; eRx=electronic prescription; ICD-10=International Classification of Diseases, Tenth Revision; PCN=primary care network.

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3 Steps to Get Your Adult Patients With PPD Started on ZURZUVAE® (zuranolone) (cont'd)

STEP 2

Alert Patient to Expect and Answer All Calls From Specialty Pharmacy

Alert your patient that they will receive 2 calls from the specialty pharmacy to confirm their insurance, contact, and shipping information

It Is Important Your Patient Answers All Calls* From the Specialty Pharmacy

- Please note that the specialty pharmacy will contact the patient twice; once to confirm their insurance and contact information and a second time after insurance approval to coordinate shipment (see Step 3)
- The specialty pharmacy cannot dispense ZURZUVAE prescriptions until they have verified the delivery address for shipment and reviewed appropriate financial assistance options with the patient
- Consider suggesting that your patient add the specialty pharmacy phone number as a contact in their phone to avoid the calls going to spam

***Note: If a patient has previously opted in, the specialty pharmacy may text the patient instead of calling, if the specialty pharmacy has the ability to do so.**

Eligible Patients May Pay as Little as $0 for Their Prescription With the ZURZUVAE Savings Card Program

Financial assistance for eligible commercially insured adult patients with PPD under the ZURZUVAE Savings Card Program will be applied directly by the specialty pharmacy filling the prescription. Restrictions apply. For full terms and conditions, visit **ZurzuvaeForYouTermsAndConditions.com**.

3 Steps to Get Your Adult Patients With PPD Started on ZURZUVAE® (zuranolone) (cont'd)

STEP 3

ZURZUVAE Is Shipped to Patient Upon Approval

APPROVED
Health plan approves ZURZUVAE for patient

To help speed up the process, you can notify the specialty pharmacy that the PA has been approved

Specialty pharmacy will contact your patient to coordinate shipping and delivery

Remind your patient that they must answer the second call from the specialty pharmacy to receive the medication after approval

Specialty pharmacy ships ZURZUVAE to patient's preferred address

ZURZUVAE PA Denials May Be Successfully Appealed

- If an appeal is required, visit the **"Resources"** page of **www.zurzuvaehcp.com** to see the *Sample Letters of Medical Necessity and Appeal Guide* for more information
- If your patient is denied a second time additional steps may be required to obtain coverage. Contact your ZURZUVAE representative to discuss potential options for your patient

For Questions or More Information on Patient Support Services, Contact Your ZURZUVAE Representative or Call 1-844-987-9882

3 Steps to Get Your Adult Patients With PPD Started on ZURZUVAE® (zuranolone)

STEP 1

Send Rx, complete insurance information, and patient demographics to the correct specialty pharmacy and submit completed PA

STEP 2

Alert patient that they will receive 2 calls from the specialty pharmacy to confirm insurance and contact information and then coordinate shipping

STEP 3

ZURZUVAE is shipped and delivered to patient upon insurance approval

ZURZUVAE Is Available Through a Participating Specialty Pharmacy Network

Specialty pharmacy contact details as of March 2024 are shown below. Individual patient insurance coverage is not guaranteed. Your patient's insurance may require the use of a specific specialty pharmacy.

Specialty Pharmacy	NPI/ID Number for EHR Lookup	Address	Contact Information	Notes
Accredo	Select any Accredo location in drop down	Choose any Accredo location and prescription will be routed appropriately (do not select Accredo Health Group)	Phone: 800-272-3858 Fax: 888-302-1028 7 AM–7 PM CT	Select option 5 if calling (for dedicated ZURZUVAE team)
Alto Pharmacy®	0552403	Choose any Alto location and prescription will be routed appropriately	Phone: 800-874-5881 Fax: 415-484-7058 10 AM–8:30 PM ET	CA, NY, TX, WA, NV, CO only
CVS Specialty®	1466033	CVS Specialty #02921 105 Mall Boulevard Monroeville, PA 15146 OR CVS Specialty #48031 800 Biermann Ct, Ste B Mount Prospect, IL 60056	Phone: 866-993-4779 Fax: 844-850-7915 7 AM–7 PM CT	Select CVS Specialty location
Special Care Pharmacy Services	205819729	1109 Calle Brumbaugh San Juan, PR 00925	Phone: 888-727-1727 Fax: 787-783-2951 8 AM–5 PM AT	For Puerto Rico residents only
Walmart Specialty Pharmacy	1013934413	Walmart #10-5315 2354 Commerce Park Drive Ste 100 Orlando, FL 32837	Phone: 877-453-4566 Fax: 866-537-0877 7 AM–8:30 PM ET	Select option 3 for provider. Then ask for the "high touch team"

For other helpful ZURZUVAE access resources, visit the "Resources" page on www.zurzuvaehcp.com.

EHR=electronic health record; ID=identification; NPI=National Provider Identifier; PA=prior authorization; Rx=prescription.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

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

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

Reference: 1. ICD-10-CM Tabular List of Diseases and Injuries. Centers for Medicare & Medicaid Services. Updated February 1, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm. Accessed July 26, 2024.