Drug of the Month
ZURZUVUE™
For Postpartum Depression

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ZURZUVAE safely and effectively. See full prescribing information for ZURZUVAE.

ZURZUVAETM (zuranolone) capsules, for oral use, CIV
Initial U.S. Approval: 2023

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

See full prescribing information for complete boxed warning.
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 administration. Patients may not be able to assess their own driving competence or the degree of impairment caused by ZURZUVAE (5.1, 5.2).

_____ INDICATIONS AND USAGE_____

ZURZUVAE is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults. (1)

_____ DOSAGE AND ADMINISTRATION_____

- Administer with fat-containing food. (2.1)
- Recommended dosage is 50 mg orally once daily in the evening for 14 days. (2.1)
- Dosage may be reduced to 40 mg once daily if CNS depressant effects occur. (2.1)
- ZURZUVAE can be used alone or as an adjunct to oral antidepressant

therapy. (2.1)
• Severe Hepatic Impairment: Recommended dosage is 30 mg orally once daily in the evening for 14 days. (2.3, 8.6)
• Moderate or Severe Renal Impairment: Recommended dosage is 30 mg orally once daily in the evening for 14 days. (2.4, 8.7)

_____ DOSAGE FORMS AND STRENGTHS _____

Capsules: 20 mg, 25 mg, and 30 mg. (3)

_____ CONTRAINDICATIONS _____

None. (4)

_____WARNINGS AND PRECAUTIONS _____

• CNS Depressant Effects: ZURZUVAE can cause CNS depressant effects such as somnolence and confusion. If patients develop CNS depression, consider dosage reduction or discontinuation of ZURZUVAE. (5.2)
• Suicidal Thoughts and Behavior: Consider changing the therapeutic regimen, including discontinuing ZURZUVAE, in patients whose PPD worsens, or who experience emergent suicidal thoughts and behaviors. (5.3)
• Embryo-fetal Toxicity: May cause fetal harm. Advise a pregnant woman of the potential risk to an infant exposed to ZURZUVAE in utero. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during ZURZUVAE treatment and for one week after the final dose. (5.4, 8.1, 8.2, 8.3)

_____ ADVERSE REACTIONS _____

Most common adverse reactions (incidence ≥5% and greater than placebo) were somnolence, dizziness, diarrhea, fatigue, nasopharyngitis, and urinary tract infection. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Biogen at 1-844-987-9882 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

_____ DRUG INTERACTIONS _____

• CNS Depressants: Concomitant use may increase impairment of psychomotor performance or CNS depressant effects. If use with another CNS depressant is unavoidable, consider dosage reduction. (7)
• Strong CYP3A4 Inhibitors: Concomitant use may increase the risk of ZURZUVAE-associated adverse reactions. Reduce the ZURZUVAE dosage to 30 mg orally once daily in the evening for 14 days when used concomitantly with a strong CYP3A4 inhibitor. (2.2, 7)
• CYP3A4 Inducers: Concomitant use may decrease the efficacy of ZURZUVAE. Avoid concomitant use. (2.2, 7)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.
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