Zuranolone (ZURZUVAE)
Criteria for Use
March 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive zuranolone.

- ☐ Patient is receiving a CYP3A4 inducer
- ☐ Active or untreated substance use disorder (SUD)

Inclusion Criteria

All of the following criteria must be met.

- ☐ Diagnosis of postpartum unipolar depression without psychosis
- ☐ Patient is 12 months or less postpartum
- ☐ Rapid response needed due to suicidality or homicidality
- ☐ The prescriber is a VA/VA Community Care Mental Health Provider
- ☐ Patient has been counseled about lack of data in human pregnancy and has made an informed decision about whether to use contraception during the 14-day treatment course and for 1 week following the completion of therapy
- ☐ Patient agrees not to drive or engage in other potentially hazardous activities until at least 12 hours after administration for the duration of the 14-day treatment course

Note: 1. Take zuranolone with fat-containing food (e.g., 400 to 1,000 calories, 25-50% fat) for optimal absorption

2. Zuranolone passes into breast milk, although with a relative infant dose (RID) lower than that of SSRIs. There are no data on effects on a breastfed infant and limited data on milk production. The patient's clinical need for zuranolone and the developmental and health benefits of breastfeeding should be balanced through a shared decision-making process that considers continuation, pumping and discarding milk through 1-week past treatment completion, and cessation.

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