Generic Name:
Brexanolone
Trade Name:
Zulresso
Company:
Sage Therapeutics
Notes:

FDA approved brexanolone injection for I.V. use for treatment of postpartum depression (PPD) in adult women. This is the first drug approved by FDA specifically for PPD.

Brexanolone will be available only through a restricted REMS Program that requires the drug to be administered by a health care provider in a certified health care facility. The REMS requires that patients be enrolled in the program prior to administration of the drug.

Brexanolone is administered as a continuous I.V. infusion over 60 hours (2.5 d). Because of the risk of serious harm from sudden loss of consciousness, patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring. While receiving the infusion, patients must be accompanied during interactions with their child(ren). The need for these steps is addressed in a boxed warning in the drug?s prescribing information.

Patients will be counseled on the risks of brexanolone treatment and instructed that they must be monitored for these effects at a health care facility for the entire 60 hours of infusion. Patients should not drive, operate machinery, or do other dangerous activities until feelings of sleepiness from the treatment have completely gone away.

Brexanolone's effectiveness was shown in two clinical studies in participants who received a 60-hour continuous I.V. infusion of brexanolone or placebo and were then followed for 4 weeks. One study included patients with severe PPD, and the other included patients with moderate PPD. The primary measure in the study was the mean change from baseline in depressive symptoms as measured by a depression rating scale.

In both placebo-controlled studies, brexanolone demonstrated superiority to placebo in improvement of depressive symptoms at the end of the first infusion. The improvement in depression was also observed at the end of the 30-day follow-up period.

The most common adverse reactions reported by patients included sleepiness, dry mouth, loss of consciousness, and flushing. Health care providers should consider changing the therapeutic regimen, including discontinuing brexanolone in patients whose PPD becomes worse or who experience emergent suicidal thoughts and behaviors.

Medication Monitor Categories:
New Drug Approvals