

FDA News Release

FDA approves first treatment for postpartum depression

**For Immediate
Release**

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Release

[Español \(/NewsEvents/Newsroom/ComunicadosdePrensa/ucm634025.htm\)](#)

The U.S. Food and Drug Administration today approved Zulresso (brexanolone) injection for intravenous (IV) use for the treatment of postpartum depression (PPD) in adult women. This is the first drug approved by the FDA specifically for PPD.

"Postpartum depression is a serious condition that, when severe, can be life-threatening. Women may experience thoughts about harming themselves or harming their child. Postpartum depression can also interfere with the maternal-infant bond. This approval marks the first time a drug has been specifically approved to treat postpartum depression, providing an important new treatment option," said Tiffany Farchione, M.D., acting director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research. "Because of concerns about serious risks, including excessive sedation or sudden loss of consciousness during administration, Zulresso has been approved with a Risk Evaluation and Mitigation Strategy (REMS) and is only available to patients through a restricted distribution program at certified health care facilities where the health care provider can carefully monitor the patient."

PPD is a major depressive episode that occurs following childbirth, although symptoms can start during pregnancy. As with other forms of depression, it is characterized by sadness and/or loss of interest in activities that one used to enjoy and a decreased ability to feel pleasure (anhedonia) and may present with symptoms such as cognitive impairment, feelings of worthlessness or guilt, or suicidal ideation.

Zulresso will be available only through a restricted program called the Zulresso REMS Program that requires the drug 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. Zulresso is administered as a continuous IV infusion over a total of 60 hours (2.5 days). Because of the risk of serious harm due to the sudden

loss of consciousness, patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring (monitors oxygen levels in the blood). 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 Zulresso 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.

The efficacy of Zulresso was shown in two clinical studies in participants who received a 60-hour continuous intravenous infusion of Zulresso or placebo and were then followed for four 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, Zulresso 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 treated with Zulresso in clinical trials include sleepiness, dry mouth, loss of consciousness and flushing. Health care providers should consider changing the therapeutic regimen, including discontinuing Zulresso in patients whose PPD becomes worse or who experience emergent suicidal thoughts and behaviors.

The FDA granted this application [Priority Review \(/ForPatients/Approvals/Fast/ucm405405.htm\)](#) and [Breakthrough Therapy \(/ForPatients/Approvals/Fast/ucm405397.htm\)](#) designation.

Approval of Zulresso was granted to Sage Therapeutics, Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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