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Immediate Release:
New Drug for Postpartum Depression

In March 2019, the U.S. Food and Drug Administration (FDA) approved Zulresso® (brexanolone), the first treatment available for postpartum depression in adults. It is supplied as a 100 mg/20 mL single-dose vial to be diluted and administered as a continuous intravenous (IV) infusion over 60 hours (2.5 days).

Postpartum depression is the most common medical complication of childbirth. It is an episode of major depression that can occur during pregnancy or after delivery. Postpartum depression can affect the mother's relationship with a partner, the partner's mental health, and/or the infant's physical, mental and emotional development.

Zulresso carries a black box warning for excessive sedation and sudden loss of consciousness. Due to these risks, it is only available through a restricted distribution program called the Zulresso Risk Evaluation and Mitigation Strategy (REMS). Patients must be enrolled in the program prior to receiving treatment.

The Zulresso REMS program requires the medication to be administered by a healthcare provider at a certified healthcare facility. Patients must be monitored throughout treatment and assessed every two hours for signs and symptoms of excessive sedation and loss of consciousness.

Zulresso is the first drug approved for managing postpartum depression in adults and received Priority Review and Breakthrough Therapy Designation from the FDA. For additional information on this new therapy, view the FDA's press release.

References

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2. FDA approves first treatment for post-partum depression. FDA News Release. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm633919.htm. Updated March 20, 2019. Accessed April 17, 2019.
3. Sage Therapeutics Announces FDA Approval of ZULRESSO™ (brexanolone) Injection, the First and Only Treatment Specifically Indicated for Postpartum Depression. Sage Therapeutics News. https://investor.sagerx.com/news-releases/news-release-details/sage-therapeutics-announces-fda-approval-zulressotm-brexanolone. Updated March 19, 2019. Accessed April 17, 2019.
4. Postpartum Depression: The most common medical complication of pregnancy/childbirth. Sage Therapeutics. https://mms.businesswire.com/media/20190319005938/en/711507/1/FINAL_PPD_Fact_Sheet_Updated_031819.pdf?download=1. Updated March 2019. Accessed April 17, 2019.
5. Risk Evaluation and Mitigation Strategy (REMS) Document ZULRESSO (Brexanolone) REMS Program. Sage Therapeutics, Inc.; 2019. https://www.accessdata.fda.gov/drugsatfda_docs/rems/Zulresso_2019_03_19_REMS_Document.pdf. Updated April 18, 2019. Accessed April 18, 2019.