

Zulresso® (brexanolone) - Expanded indication

- On June 16, 2022, the <u>FDA approved</u> Sage Therapeutics' <u>Zulresso (brexanolone)</u>, for the treatment of postpartum depression (PPD) in patients 15 years and older.
 - Zulresso was previously approved for this indication in adults only.
 - Zulresso is a Schedule IV controlled substance.
- The approval of Zulresso for the expanded indication is supported by evidence from adequate and well-controlled studies in adults with PPD, pharmacokinetic data in adults and patients 15 to 17 years, and safety data in patients 15 to 17 years.
- Zulresso carries a boxed warning for excessive sedation and sudden loss of consciousness.
 - Because of these risks, Zulresso is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Zulresso REMS.
- Zulresso is administered for the treatment of PPD as a continuous intravenous infusion over a total of 60 hours (2.5 days). Refer to the drug label for complete dosing information.
- A healthcare provider must be available on site to continuously monitor the patient, and intervene
 as necessary, for the duration of the Zulresso infusion.



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