

ZULRESSO™ Risk Evaluation and Mitigation Strategy (REMS)

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ZULRESSO™ (brexanolone) injection for intravenous use

FDA-REQUIRED REMS SAFETY INFORMATION

Subject:

- **Risk of serious harm associated with excessive sedation and sudden loss of consciousness**
- **Restricted administration of ZULRESSO in certified Healthcare Settings**

Dear Healthcare Provider:

The purpose of this letter is to inform you about the serious risks of ZULRESSO and the requirements of the ZULRESSO REMS. The U.S. Food and Drug Administration (FDA) has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of ZULRESSO outweigh its risks.

ZULRESSO is indicated for the treatment of postpartum depression (PPD) in adults. Because of the **risk of serious harm, patients must be monitored for excessive sedation and sudden loss of consciousness.**

Counsel Your Patient:

Counsel your patient on the following risks and requirements of the ZULRESSO REMS. Provide your patients with the **ZULRESSO REMS Patient Information Guide** (available at www.zulressorems.com):

- **Patients treated with ZULRESSO are at risk of serious harm from excessive sedation or sudden loss of consciousness during administration of ZULRESSO.**
- Patients must be monitored by a Healthcare Provider for these risks and have continuous pulse oximetry monitoring while receiving ZULRESSO in a certified Healthcare Setting.
- ZULRESSO is an infusion given over a period of 60 hours. Patients must not be the primary caregiver for dependents and must be accompanied during interactions with their child(ren) while receiving their infusion.

A list of REMS certified Healthcare Settings is available by calling 844-472-4379 or online at www.zulressorems.com. Contact a certified Healthcare Setting to initiate the patient admittance process.

Complete details about the ZULRESSO REMS can be found at www.zulressorems.com. Complete safety information can be found in the Prescribing Information (including the Boxed Warning).

Adverse Event Reporting:

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 800-FDA-1088 or www.fda.gov/medwatch.

Sincerely,
Sage Therapeutics, Inc.



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ZULRESSO REMS Changes



The ZULRESSO REMS was updated recently to reflect the following:

- Healthcare Setting and Pharmacy Authorized Representatives may complete the certification/enrollment process online
- Healthcare Setting Authorized Representatives and trained staff may login to the REMS website to complete the Post Infusion Form and if necessary, the Excessive Sedation and Loss of Consciousness Adverse Event Form for enrolled patients. Additionally, patient enrollment notifications are available via login to confirm patient enrollment prior to ZULRESSO administration.
- A Healthcare Setting Locator page was added to support healthcare providers or patients in locating a REMS certified Healthcare Setting

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ZULRESSO REMS Overview

- Only administer ZULRESSO to patients in a medically supervised setting that provides monitoring during administration.
- Only certified Pharmacies and Healthcare Settings can dispense ZULRESSO.
- Educate patients on the risks of serious harm from excessive sedation and loss of consciousness and the need for monitoring while ZULRESSO is administered.
- Enroll all patients in a registry.