What is the ZULRESSO REMS (Risk Evaluation and Mitigation Strategy)?

The ZULRESSO REMS is a safety program to manage the risk of serious harm resulting from excessive sedation and sudden loss of consciousness during the ZULRESSO infusion. The REMS is required by the U.S. Food and Drug Administration (FDA) to ensure the potential benefits of ZULRESSO outweigh its risks.

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.

ZULRESSO is indicated for the treatment of postpartum depression (PPD) in adults.

Please see Prescribing Information including BOXED WARNING.

If you have questions about the ZULRESSO REMS or need help, call 844-472-4379 Monday - Friday 8 AM - 8 PM ET.

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

1. **Pharmacies**
   - Designate an Authorized Representative
   - Review the Program Overview for Pharmacies
   - Complete the Pharmacy Enrollment Form

1. **Patients**
   - Understand the risks associated with ZULRESSO
   - Learn how to enroll in the ZULRESSO REMS

1. **Healthcare Providers**
   - Review education materials

1. **Forms and Resources**

   Downloadable forms and educational resources to learn about and enroll in the ZULRESSO REMS.

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ZULRESSO REMS Healthcare Setting Enrollment

Healthcare Settings must be certified in the ZULRESSO REMS to administer ZULRESSO.

To enroll and become certified in the program, the Healthcare Setting must complete the following steps:

**STEP 1**
**Designate and Maintain**
Identify an Authorized Representative. The Authorized Representative will carry out the certification process, oversee implementation and compliance with the ZULRESSO REMS on behalf of the Healthcare Setting.

The Authorized Representative will complete the following steps:

**STEP 2**
**Review**
The Authorized Representative should review the Training for Healthcare Settings through the module on this site as well as the Prescribing Information.

**STEP 3**
**Complete**
Complete the ZULRESSO REMS Healthcare Setting Knowledge Assessment. All questions must be answered correctly to become certified.

**STEP 4**
**Complete**
Complete the ZULRESSO REMS Healthcare Setting Enrollment Form.

**STEP 5**
**Submit**
Submit the completed ZULRESSO REMS Healthcare Setting Enrollment Form. Completed forms can be sent to the ZULRESSO REMS via email at information@zulresso.com, via fax at 850-944-7945, or mailed to the ZULRESSO REMS at 775 Silver Creek Parkway, Suite 300, Raleigh, NC 27617.

**STEP 6**
**Implement**
Implement the necessary processes and procedures to comply with the ZULRESSO REMS.

Please see Prescribing Information, including BOXED WARNING.

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ZULRESSO REMS Healthcare Setting Administration

Healthcare Settings must be certified in the ZULRESSO REMS to administer ZULRESSO.

Before Administering ZULRESSO

STEP 1
Counsel
Counsel the patient using the Patient Information Guide and provide a copy to the patient.

STEP 2
Enroll
Enroll the patient in the ZULRESSO REMS by enrolling trained staff complete the ZULRESSO REMS Patient Enrollment Form with the patient. Retain a copy of the completed form in the patient's record.

STEP 3
Submit
Submit the completed ZULRESSO REMS Patient Enrollment Form. Completed forms can be faxed to the ZULRESSO REMS at 800-44-3-730 or emailed to the ZULRESSO REMS at information@zulresso.com.

POST ADMINISTRATION REQUIREMENTS

Post Infusion Form
The Post Infusion Form must be submitted to the ZULRESSO REMS after the completion of the infusion. If the patient experiences any part of the infusion, or if the infusion has been canceled, if the infusion has been rescheduled, the form should be completed at that time.

Adverse Event Form
If a patient experiences an event of excessive sedation or loss of consciousness this should be indicated on the Post Infusion Form. Fill out an Adverse Event Form to the ZULRESSO REMS within 1 business day.

How to Submit
- Submit the Post Infusion Form and, if needed, the Adverse Event Form to the ZULRESSO REMS within 1 business day.
- You can only submit an Adverse Event Form if the patient experienced an event of excessive sedation or loss of consciousness.

The Post Infusion Form and the Adverse Event Form can be faxed to the ZULRESSO REMS at 800-44-3-730 or emailed to information@zulresso.com.

To report any other adverse events contact Sage Therapeutics at 844-472-4379 or FDA at 888-FDA-1088 or www.fda.gov/medwatch.

Contact the ZULRESSO REMS at 844-472-4379 to obtain contact information for certified Pharmacists and/or distributors who are authorized to ship to certified hospitals.

If you have questions about the ZULRESSO REMS or need help, call 844-472-4379 Monday - Friday 8am - 8pm ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 888-FDA-1088 or http://www.fda.gov/medwatch.
ZULRESSO REMS Pharmacy Enrollment

Pharmacies must be enrolled in the ZULRESSO REMS to be able to prepare and ship ZULRESSO.

Pharmacies outside the Healthcare Setting that are preparing ZULRESSO for administration must enroll in the program and complete the following steps:

STEP 1
Designate
Designate an Authorized Representative to carry out the enrollment process and oversee implementation and compliance with the ZULRESSO REMS on behalf of the Pharmacy.

The Authorized Representative will complete the following steps:

STEP 2
Review
The Pharmacy should review the ZULRESSO REMS Program Overview for Pharmacists.

STEP 3
Enroll
Enroll in the ZULRESSO REMS by completing and submitting the Pharmacy Enrollment Form.

- Forms can be sent to the ZULRESSO REMS via email at information@zulresso.com, via fax at 831-962-7035, or mailed to the ZULRESSO REMS at TRI Birk Chen Parkway, Suite 200, Raleigh, NC 27607.
- If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.

STEP 4
Establish
Establish processes and procedures to ensure ZULRESSO is dispensed only to patients who are enrolled in the ZULRESSO REMS at a certified Healthcare Setting.

STEP 5
Train
Train all relevant staff involved in dispensing ZULRESSO on the relevant processes and procedures.

Completed forms can be sent to the ZULRESSO REMS via email at information@zulresso.com, via fax at 831-962-7035, or mailed to the ZULRESSO REMS at TRI Birk Chen Parkway, Suite 200, Raleigh, NC 27607.

If you have questions about the ZULRESSO REMS or need help, call 844-472-4379 Monday - Friday 8am-8pm ET.

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ZULESSO REMS Patient Enrollment

Work with your certified Healthcare Setting to enroll in the ZULESSO REMS so you can start treatment.

STEP 1
Discuss
Discuss risks of treatment with ZULESSO with your Healthcare Provider, including that ZULESSO can cause excessive sedation (extreme sleepiness) and sudden loss of consciousness (passing out).

STEP 2
Receive and review
Receive and review the ZULESSO Patient Information Guide with your Healthcare Provider.

STEP 3
Complete
Complete the ZULESSO REMS Patient Enrollment Form at your certified Healthcare Setting.

Please see Prescribing Information, including BOXED WARNING.

If you have questions about the ZULESSO REMS or need help, call 844-472-4379 Monday – Friday 8AM-8PM ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.
ZULRESSO REMS Information for Healthcare Providers

Patients can only be treated with ZULRESSO at a REMS certified Healthcare Setting.

Please review the materials below

Healthcare Providers must be affiliated with a REMS certified Healthcare Setting in order to prescribe ZULRESSO. Please review the materials below.

If you are affiliated with a REMS certified Healthcare Setting, follow your institution’s REMS procedures for ZULRESSO. Otherwise, to locate a REMS certified Healthcare Setting call the ZULRESSO REMS at 844-472-4379.

Please see Prescribing Information, including BOXED WARNING.

If you have questions about the ZULRESSO REMS or need help, call 844-472-4379 Monday – Friday 8AM-8PM ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.
ZULRESSO REMS Forms and Resources

Below are downloadable resources to support the ZULRESSO REMS.

Materials for Healthcare Settings
To learn more about these documents please visit the healthcare settings page.

- Certification Materials
  - TRAINING FOR HEALTHCARE SETTINGS
  - HEALTHCARE SETTING KNOWLEDGE ASSESSMENT
  - HEALTHCARE SETTING ENROLLMENT FORM
  - PRESCRIBING INFORMATION

- Administration Materials
  - PATIENT INFORMATION GUIDE
  - PATIENT ENROLLMENT FORM
  - PEST INFOSHEET FORM
  - ADVERSE EVENT FORM

Materials for Pharmacies
To learn more about these documents please visit the Pharmacy page.

- PROGRAM OVERVIEW FOR PHARMACIES
- PHARMACY ENROLLMENT FORM

Materials for Patients
To learn more about these documents please visit the Patients page.

- PATIENT INFORMATION GUIDE

Materials for Healthcare Providers
To learn more about these documents please visit the Healthcare Providers page.

- LETTER FOR HEALTHCARE PROVIDERS
- PRESCRIBING INFORMATION
- PATIENT INFORMATION GUIDE

Please see Prescribing Information, including BOXED WARNING.

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