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 risk 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.

Healthcare Settings

- CERTIFY IN THE ZULRESSO REMS
- HOW TO ADMINISTER ZULRESSO

Pharmacies

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

Patients

1. Understand the risks associated with ZULRESSO
2. Learn how to enroll in the ZULRESSO REMS

Healthcare Professionals

1. Review education materials

Forms and Resources

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

ZULRESSO is indicated for the treatment of postpartum depression (PPD) in patients 16 years and older.

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 www.fda.gov/medwatch.
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, and 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 resources 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.

**STOP 4: Complete**
Complete the ZULRESSO REMS Healthcare Setting Enrollment Form.

**STOP 5: Submit**
If you haven't completed the form online, submit the completed ZULRESSO REMS Healthcare Setting Knowledge Assessment and ZULRESSO REMS Healthcare Enrollment Form.

Completed forms not submitted online can be sent to the ZULRESSO REMS via email at information@zulresso.com, via fax at 837-564-7156, or mailed to the ZULRESSO REMS at 750 Pkwy, Creek Parkway, Suite 310, Fremont, Calif. 94539.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.

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

If you have questions about the ZULRESSO REMS or need help, call 844-472-4379 Monday - Friday 8 a.m.- 6 p.m. ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 888-463-6332 or www.fda.gov/medwatch.
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.

**PATIENT INFORMATION GUIDE**

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

**PATIENT ENROLLMENT FORM**

**STEP 3: Submit**
Submit the completed ZULRESSO REMS Patient Enrollment Form.

Complained forms can be faxed to the ZULRESSO REMS at 833-946-7424, emailed to the ZULRESSO REMS at information@zulressoemc.com, or mailed to the ZULRESSO REMS at P.O. Box 2013, P.O. Box 2013, Raleigh, NC 27617.

**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 receives any part of the infusion, or if the infusion has been interrupted, 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 Excessive Sedation and Loss of Consciousness Adverse Event Form to the ZULRESSO REMS within 3 business days of the patient completing the infusion or the scheduled infusion date.

**How to Submit**
- Submit the Post Infusion Form and, if needed, the Excessive Sedation and Loss of Consciousness Adverse Event Form to the ZULRESSO REMS within 3 business days of the patient completing the infusion or the scheduled infusion date.
- You can only submit an Excessive Sedation and Loss of Consciousness Adverse Event Form via the website.
- For more information, visit www.zulressoemc.com.

**Online**
- POST INFUSION FORM
- EXCESSIVE SEDATION AND LOSS OF CONSCIOUSNESS ADVERSE EVENT FORM

By Fax/Email

To report any adverse events contact Sage Therapeutics at 844-472-4778 or FDA at 855-FDA-1088 or on FDA's MedWatch site.

**Please see Prescribing Information (Including BOXED WARNING).**

If you have questions about the ZULRESSO REMS or need help, call 844-472-4778 Monday - Friday 8am-6pm ET.

For more information, contact Sage Therapeutics, Inc. at 844-472-4778 or Zulressoemc.com.

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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 Pharmacies.

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

Completed forms not submitted online can be sent to the ZULRESSO REMS via email at information@zulressoremss.com, via fax at 800-554-7243, or mailed to the ZULRESSO REMS at 7750 Brier Creek Parkway, Suite 200, Raleigh, NC 27616.

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 a certified Healthcare Setting enrolled in the ZULRESSO REMS Program.

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

Please see Prescribing Information, including DPDx® Warning.

If you have questions about the ZULRESSO REMS or need help, call 844-472-4578 Monday – Friday 8am-5pm ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4578 or FDA at 800-FDA-1088 or www.fda.gov/medwatch.
ZULRESSO® REMS Pharmacy Enrollment Form

Complete and submit this form by clicking "Submit" below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.

1. Review REMS Program Overview
2. Review and complete this Pharmacy Enrollment Form
3. Submit the completed form by clicking "Continue" below

* Indicates Required Field

PHARMACY INFORMATION

* National Provider Identifier (NPI#)

CONTINUE

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 www.fda.gov/medwatch.
ZULRESSO® REMS Pharmacy Enrollment Form

Complete and submit this form by clicking "Submit."
ZULRESSO® REMS Pharmacy Enrollment Form

Complete and submit this form by clicking “Submit” below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.

1. Review REMS Program Overview
2. Review and complete this Pharmacy Enrollment Form
3. Submit the completed form by clicking “Continue” below

Pharmacy Information

- National Provider Identifier (NPI)
- Pharmacy Name
- Pharmacy Type
  - Specialty
  - Facility
- National Council for Prescription Drug Programs (NCPDP)
- Pharmacy DEA Number
- Address 1
  - Unit
  - Street
  - City
  - State
  - Zip
- National Provider Identifier (NPI)
- Pharmacy Location Name
- Pharmacy Type
  - Specialty
  - Facility
- National Council for Prescription Drug Programs (NCPDP)
- Pharmacy DEA Number
- Address 1
  - Unit
  - Street
  - City
  - State
  - Zip

Click below to enroll an additional Pharmacy location (optional)

- ADDITIONAL PHARMACY LOCATION

Non-Pharmacy Information will be shared with Sage Therapeutics, Inc. A health care provider and distributor of patients, to allow your Pharmacy to purchase product.

Authorized Representative Information

- First Name
- Last Name
- Title
- Credential Type
- Credential
- Representative (New Representative)
- Phone Number
- Fax Number
- Email Address
- Address 1
  - Unit
  - Street
  - City
  - State
  - Zip

Pharmacy Attestations

As the Authorized Pharmacy Representative, I hereby attest:

- I have reviewed the Program Overview.
- I have completed the Pharmacy Enrollment Form for this ZULRESSO REMS.
- I agree to complete all required staff training in dispensing ZULRESSO, must be dispatched to a designated Healthcare Setting.
- I agree to all conditions and procedures in place to ensure the proper dispensing of ZULRESSO and that the healthcare settings are informed of the patient's REMS.
- I agree not to distribute to patients using ZULRESSO.
- I understand and report all adverse events.
- I agree not to distribute ZULRESSO.
- I understand and report all adverse events.
- I agree not to distribute ZULRESSO.

Signature

Please see Prescribing Information Including BOXED WARNING.

If you have questions about the ZULRESSO REMS or need help, please call 844-472-0379 Monday – Friday 8:00 AM – 6:00 PM EST.

To report any SUSPECTED ADVERSE EVENTS, contact Sage Therapeutics, Inc. at 844-472-0379 or fax at 609-734-5850 or www.fda.gov/medwatch.
ZULRESSO® REMS Pharmacy Enrollment Form

Pharmacy Enrollment Submitted Successfully.

Thank you for submitting your information to enroll in the ZULRESSO REMS.

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 www.fda.gov/medwatch.
ZULRESSO REMS Patient Enrollment

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

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

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

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

Please see Prescribing Information, including BOXED WARNING.

If you have questions about the ZULRESSO REMS Program 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 use this directory or call the ZULRESSO REMS at 844-472-4379.

Please see Prescribing Information, including BOXED WARNING.

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This site is intended for residents of the United States only.
ZULRESSO REMS Program 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](#).

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### Materials for Pharmacies

To learn more about these documents please visit the [Pharmacies page](#).

| ZOCO 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 |

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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](http://www.fda.gov/medwatch).
Healthcare Setting Locator

Search for Healthcare Settings that are enrolled and certified in the ZULRESSO REMS and able to administer ZULRESSO.

To search for a specific location, please complete the following:

Please enter a street address, city, state, or ZIP Code you would like to search for.

Search

Healthcare settings included in the Locator tool have completed the requirements to enroll and certify in the ZULRESSO REMS; however, not all healthcare settings listed are accepting new patients. Please call to confirm.

Inclusion of a certified healthcare setting in the Locator tool does not represent an endorsement, referral or recommendation from Sage Therapeutics, Inc. (Sage) and is not intended as medical advice. Inclusion of a healthcare setting in this Locator tool is based on approval by the Authorized Representative for each healthcare setting and no fees have or will be received in exchange for participation in this Locator tool.

This Locator tool is intended to provide users with the opportunity to locate nearby ZULRESSO REMS-certified healthcare settings and is compiled for informational purposes only. In no event shall Sage or its employees or agents be liable for the actions of any of the healthcare settings listed herein or any damages resulting from or related to this Locator tool. All users agree that use of this Locator tool is at their own risk.

Sage makes no representations as to whether any of the healthcare settings included in this Locator tool are covered by healthcare plans or insurers. Insurance verification is the responsibility of the provider and patient. Users of this Locator tool are solely responsible for interactions with any of the listed healthcare settings, and any information sent is not governed by Sage’s Terms of Use and Privacy Policy.

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 www.fda.gov/medwatch.
Healthcare Setting Locations

Listing of Healthcare Settings that are enrolled and certified in the ZULRESSO REMS and able to administer ZULRESSO.

Download the list to spreadsheet format by clicking on the Excel icon just above the column headers
This list is updated in real-time and displays the current Healthcare Setting Locations. You may refresh this page at any time for an updated list.

Search/Filter the list by entering information in the text box below any column header

Sort the list by clicking on any column header

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone Number</th>
<th>Fax Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Healthcare Setting</td>
<td>546-546-4545</td>
<td>564-564-5646</td>
</tr>
</tbody>
</table>

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 www.fda.gov/medwatch.
Login

Login is available to certified Healthcare Settings in the ZULRESSO REMS.

Don't have an online account?

Register

Note: Online registration is required for Healthcare Settings only.

In order to complete the certification process online, an Authorized Representative for the Healthcare Setting must register for an account. To create your account, please enter your Healthcare Setting NPI Number and click "Continue".

Please see Prescribing Information, including BOXED WARNING.

If you have questions about the ZULRESSO REMS or need help, call 844-472-4378 Monday - Friday 8AM-8PM ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4378 or FDA at 800-FDA-1088 or www.fda.gov/medwatch.
Login

Login is available to certified Healthcare Settings in the ZULRESSO REMS.

Don't have an online account?

Register

In order to complete the certification process online, an Authorized Representative for the Healthcare Setting must register for an account. To create your account, please enter your Healthcare Setting NPI Number and click "Continue".

- NPI Number
  1234567890
- First Name
  John
- Last Name
  Smith
- Phone Number
  555-555-1234
- Email Address

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 www.fda.gov/medwatch.
ZULRESSO REMS Healthcare Setting Certification

Thank you for submitting your information to create your web account for the ZULRESSO REMS.

Create Account Submitted Successfully

A confirmation of this submission has been sent to the email address provided. You can expect to receive 2 emails, one contains your username and the second contains your temporary password. Please login with the username provided. You will then be prompted to update your password.

If you do not receive the emails within the next few hours, or would like to update your enrollment information at any time, please contact the ZULRESSO REMS at 844-472-4379.

Please see full 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 www.fda.gov/medwatch.
Login

Login is available to certified Healthcare Settings in the ZULRESSO REMS.

Don't have an online account?

Register

Note: Online registration is required for Healthcare Settings only.
In order to complete the certification process online, an Authorized Representative for the Healthcare Setting must register for an account. To create your account, please enter your Healthcare Setting NPI Number and click "Continue".

* NPI Number

Please see Prescribing Information, including BOXED WARNING.

If you have questions about the ZULRESSO REMS or need help, call 844-472-4378 Monday - Friday 8AM-8PM ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4378 or FDA at 800-FDA-1088 or www.fda.gov/medwatch.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

1. Registration
2. Review Materials
3. Knowledge Assessment
4. Online Enrolment

ZULRESSO REMS Training for Healthcare Settings
Risk Evaluation and Mitigation Strategy (REMS)

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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

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ZULESSO REMS Healthcare Setting Certification

Review the ZULESSO REMS Training.

Training for Healthcare Settings
What Is ZULRESSO® (brexanolone) injection?

- ZULRESSO is indicated for the treatment of postpartum depression (PPD) in patients 15 years and older.
- Pregnancy: Based on findings from animal studies of other drugs that enhance GABAergic inhibition, ZULRESSO may cause fetal harm.
- ZULRESSO is intended for dilution and administration as a continuous intravenous infusion.
- ZULRESSO is available only through the ZULRESSO REMS.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

ZULRESSO Has a Boxed Warning

WARNING: EXCESSIVE SEDATION AND SUDDEN LOSS OF CONSCIOUSNESS

• Patients are at risk of excessive sedation or sudden loss of consciousness during administration of ZULRESSO.

• Because of the risk of serious harm, patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring. Patients must be accompanied during interactions with their child(ren).

• ZULRESSO is available only through a restricted program called the ZULRESSO REMS.
What Was Observed in the ZULRESSO Clinical Program?

- In premarketing clinical studies, the following observations were noted:
  - ZULRESSO caused sedation and somnolence that required in some patients with PPD dose interruption or reduction during the infusion (5% of ZULRESSO-treated patients compared to 0% of placebo-treated patients).
  - Some patients with PPD were also reported to have loss of consciousness or altered state of consciousness during the ZULRESSO infusion (4% of the ZULRESSO-treated patients compared with 0% of the placebo-treated patients).
  - All patients with loss of or altered state of consciousness recovered with dose interruption; time to full recovery from loss or altered state of consciousness, after dose interruption, ranged from 15 to 60 minutes.
  - Three ZULRESSO-treated patients who had a dosage interruption because of loss of consciousness subsequently resumed and completed treatment after resolution of symptoms; two patients who had dosage interruption because of loss of consciousness did not resume the infusion.
  - There was no clear association between loss or alteration of consciousness and pattern or timing of dose. Not all patients who experienced a loss or alteration of consciousness reported sedation or somnolence before the episode.
  - A healthy 55-year-old man participating in a cardiac repolarization study experienced severe somnolence and <1 minute of apnea while receiving two times the maximum recommended dosage of ZULRESSO (180 mcg/kg/hour).
  - There is limited clinical trial experience regarding human overdosage with ZULRESSO. In premarketing clinical studies, two cases of accidental overdosage due to infusion pump malfunction resulted in transient loss of consciousness. Both patients regained consciousness approximately 15 minutes after discontinuation of the infusion without supportive measures. After full resolution of symptoms, both patients subsequently resumed and completed treatment. Overdosage may result in excessive sedation, including loss of consciousness and the potential for accompanying respiratory changes.
  - These are not all of the adverse events observed in these trials.*

*Please see Prescribing Information, including Boxed Warning and Medication Guide.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

What Is the ZULRESSO REMS?

- The ZULRESSO Risk Evaluation and Mitigation Strategy (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.
- A REMS is required by the Food and Drug Administration (FDA) to ensure the potential benefits of a treatment outweigh its risks.

ZULRESSO REMS Overview:

- Administration of ZULRESSO to patients only in a medically supervised Healthcare Setting that provides monitoring while ZULRESSO is being administered.
- Only certified Pharmacies and Healthcare Settings can dispense ZULRESSO.
- Educate patients on the risk of serious harm from excessive sedation and sudden loss of consciousness and the need for monitoring while ZULRESSO is administered.
- Enroll all patients in a registry to characterize these risks and support safe use.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

How to Become a Certified Healthcare Setting

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

- An Authorized Representative is a responsible individual assigned by the Healthcare Setting and its associated clinic(s).
- Each Healthcare Setting must designate one Authorized Representative who enrolls in the ZULRESSO REMS on behalf of the Healthcare Setting and attests to comply with the REMS requirements included in the Healthcare Setting Enrollment Form.
- A Healthcare Setting must be recertified in the ZULRESSO REMS if a new Authorized Representative is designated.
The Authorized Representative will complete the following steps:

STEP 2: Review this Training and the Prescribing Information.

STEP 3: Complete the Healthcare Setting Knowledge Assessment. All questions in the Healthcare Setting Knowledge Assessment must be answered correctly to become certified.

STEP 4: Complete the Healthcare Setting Enrollment Form.

STEP 5: Submit the completed Healthcare Setting Knowledge Assessment and the Healthcare Setting Enrollment Form.

STEP 6: Implement the necessary processes and procedures to administer the ZULRESSO REMS. The ZULRESSO REMS will notify the Authorized Representative of successful certification within 2 business days.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

Healthcare Setting Requirements

- A healthcare provider must be available continuously on-site to oversee each patient for the duration of the infusion, and trained on the requirements of the ZULRESSO REMS. As a continuous intravenous (IV) infusion, treatment lasts a total of 60 hours (2.5 days).
- The facility must have a fall precautions protocol in place and be equipped with a programmable peristaltic IV infusion pump with alarm and continuous pulse oximetry with an alarm.
- Staff at the Healthcare Setting must be trained on the processes and procedures to administer ZULRESSO.

The Healthcare Setting must comply with audits by Sage Therapeutics, Inc., the FDA, or a third party acting on behalf of Sage Therapeutics, Inc. to ensure that all training, processes, and procedures are in place and are in compliance with the ZULRESSO REMS. The Authorized Representative of the Healthcare Setting must maintain documentation that all ZULRESSO REMS-required processes and procedures are in place and are being followed.
Before Administering ZULRESSO

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

Enroll the patient in the ZULRESSO REMS by providing the Patient Enrollment Form and ask the patient or parent/guardian to complete and sign the form. The ZULRESSO REMS trained healthcare provider assisting the patient with enrollment must also sign the Patient Enrollment Form and include their name and title. Retain a copy of the completed form in the patient's record.

Submit the completed Patient Enrollment Form.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

Patient Counseling

Patients need to know that:

• They may experience excessive sedation or loss of consciousness during the ZULRESSO infusion, which could cause serious harm.
• They must alert a healthcare provider during the infusion if they have any symptoms associated with excessive sedation, such as:
  - Feeling extremely sleepy and being unable to stay awake when not planning to sleep
  - Impaired alertness and attention
  - Difficulty following simple instructions
  - Feeling lightheaded, dizzy, or like they are going to pass out
• They must enroll in the ZULRESSO REMS in order to receive ZULRESSO.
• They will be continuously monitored by pulse oximetry during the infusion.
• A healthcare provider will oversee the ZULRESSO infusion.
• They cannot be the primary caregiver for their child(ren) during the infusion. They must be accompanied during interactions with their child(ren) while receiving the infusion because of the risk of serious harm from excessive sedation and sudden loss of consciousness.
• Taking certain other medications or alcohol together with ZULRESSO can make these side effects more likely to occur.
• They should not engage in potentially hazardous activities requiring mental alertness, such as driving, after the infusion until any sedative effects of ZULRESSO have dissipated.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

During the Administration of ZULRESSO

The infusion must be administered using an intravenous programmable infusion pump with alarms to alert if the pump malfunctions and started early enough during the day in order to monitor for excessive sedation.

Patient Monitoring:

- A healthcare provider must monitor the patient every 2 hours during the ZULRESSO infusion during planned, non-sleep periods.
- Patients must be continuously monitored for hypoxia by pulse oximetry with an alarm during the infusion.
- Immediately stop the infusion if pulse oximetry indicates hypoxia. If hypoxia occurs the infusion should not be restarted.
- Immediately stop the infusion if there are signs or symptoms of excessive sedation. After symptoms resolve, the infusion may be resumed at the same or lower dose as clinically appropriate.
- Staff at the Healthcare Setting should report all adverse events by contacting Sage Therapeutics, Inc. at 844-472-4379 or FDA at www.fda.gov/medwatch or call 800-FDA-1088.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

After the Administration of ZULRESSO

After treatment discontinuation, and prior to discharge:

- Assess the patient’s level of sedation.

Submit the Post Infusion Form:

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

- Submit the Post Infusion Form to the ZULRESSO REMS within 3 business days from the date of the patient completing the infusion or the scheduled infusion completion date.

- The Post Infusion Form is available at the ZULRESSO REMS website (www.zulressorems.com).
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

How to Report an Event of Excessive Sedation or Loss of Consciousness

Reporting Procedures:

If a patient experiences an event of excessive sedation or loss of consciousness:

1) Indicate the event on the Post Infusion Form.
2) Complete the Excessive Sedation and Loss of Consciousness Adverse Event Form.
3) Submit both forms to the ZULRESSO REMS.

• The Post Infusion Form and Excessive Sedation and Loss of Consciousness Adverse Event Form are available at www.zulressorems.com.
• You may be contacted for further information on reported events by the Sage Therapeutics, Inc. Drug Safety Department.
• For the purposes of this REMS and event reporting, the events are further characterized below:
  - Excessive sedation: impaired alertness and attention or difficulty following simple instructions, which precludes the patient from completing daily tasks. Patient is frequently drowsy and may fall asleep during activities (e.g., conversation, eating).
  - Loss of consciousness: total loss of awareness of the patient’s self and surroundings manifest by lack of responsiveness to loud or noxious stimuli. Patient is not rousable to loud voice or with firm physical contact, including shaking. This is in contrast to sleep which is physiologic and intrinsically reversible with sufficient stimuli.

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.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

REMS Requirements Specific for Pharmacies within the Certified Healthcare Setting

Pharmacies within the certified Healthcare Setting must:
- Maintain records of all prepared and dispensed ZULRESSO.
- Maintain records documenting that all ZULRESSO REMS-required processes and procedures are in place and being followed, including records of staff training.
- Not distribute, transfer, loan, or sell ZULRESSO.
- Comply with audits carried out by Sage Therapeutics, Inc., or a third party acting on behalf of Sage Therapeutics, Inc. to ensure all processes and procedures are in place and being followed.

Any Pharmacy not part of the certified Healthcare Setting must be certified before they can dispense ZULRESSO. For more information, see Program Overview for Pharmacies.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

Ordering Instructions
How to Order Product

To order vials of ZULRESSO:
- Contact the ZULRESSO REMS at 844-472-4379 for a current list of enrolled distributors.

To order ZULRESSO prepared for administration:
- If product will be prepared within the certified Healthcare Setting, follow the protocol and procedures established by the Authorized Representative.
- If product will be prepared outside the Healthcare Setting, contact an enrolled Pharmacy to place an order for ZULRESSO. Contact the ZULRESSO REMS at 844-472-4379 for a current list of enrolled Pharmacies.
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

Resources

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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

ZULRESSO REMS Resources

For more information about the ZULRESSO REMS, visit www.zulressorems.com or call the ZULRESSO REMS at 844-472-4379. The resources below are available for download at www.zulressorems.com.

**Healthcare Settings**
- ZULRESSO Prescribing Information
- ZULRESSO Medication Guide
- ZULRESSO REMS Training
- ZULRESSO REMS Healthcare Setting Enrollment Form
- ZULRESSO REMS Healthcare Setting Knowledge Assessment
- ZULRESSO REMS Patient Enrollment Form
- ZULRESSO REMS Post Infusion Form
- ZULRESSO REMS Patient Information Guide
- Excessive Sedation and Loss of Consciousness Adverse Event Form

**Patients**
- ZULRESSO REMS Patient Information Guide
- ZULRESSO Medication Guide
- ZULRESSO REMS Patient Enrollment Form

**Pharmacies**
- ZULRESSO Prescribing Information
- ZULRESSO Medication Guide
- Program Overview for Pharmacies
ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.

Please see ZULRESSO Prescribing Information, including Boxed Warning and Medication Guide, for additional Important Safety Information.

See the Prescribing Information for ZULRESSO for more information on the risk of excessive sedation and sudden loss of consciousness.
ZULRESSO REMS Healthcare Setting Certification

Next Steps

- Now that you have reviewed the ZULRESSO REMS Training for Healthcare Settings, in order to become certified you must complete the Healthcare Setting Knowledge Assessment.
- The next 10 questions are about what you just reviewed. You are expected to achieve 100% on the Healthcare Setting Knowledge Assessment.
- You will have 3 tries to successfully complete the Healthcare Setting Knowledge Assessment.
- If you do not successfully complete the Healthcare Setting Knowledge Assessment, you will need to rereview the ZULRESSO REMS Training for Healthcare Settings.

CONTINUE
ZULRESSO® REMS Healthcare Setting Knowledge Assessment

You are required to answer all questions correctly in order to pass the assessment. You have 3 attempts to answer all questions correctly. If you do not answer all 10 questions correctly in 3 attempts, you will be instructed to re-review the ZULRESSO® REMS Training for Healthcare Settings. Once reviewed, you will have an opportunity to re-take the Healthcare Setting Knowledge Assessment.

Question 1:
The approved indication for ZULRESSO is for patients 15 years and older with:
- Migraine
- Liver failure
- Postpartum depression
- Relapsing multiple sclerosis
- Bipolar depression

Question 2:
A Healthcare Setting can administer ZULRESSO to a patient before certifying in the ZULRESSO REMS:
- True
- False

Question 3:
To become a certified Healthcare Setting in the ZULRESSO REMS, the Authorized Representative for the Healthcare Setting should (check all that apply):
- Develop processes and procedures to enrol patients in the ZULRESSO REMS prior to administration of ZULRESSO
- Develop processes and procedures to ensure staff are trained to administer ZULRESSO
- Ensure any new Authorized Representative is included in the ZULRESSO REMS and completes the Healthcare Setting Knowledge Assessment

Question 4:
The Healthcare Providers at the certified Healthcare Setting administering ZULRESSO should counsel patients on which of the following before administering ZULRESSO? (check all that apply):
- There is a risk for harm resulting from excessive sedation and sudden loss of consciousness
- Patients will be monitored for excessive sedation and sudden loss of consciousness for the duration of the infusion
- Patients will be monitored using continuous pulse oximetry
- Patients must be accompanied during interactions with their child/children while receiving the infusion

Question 5:
During the administration of ZULRESSO, staff at the Healthcare Setting must (check all that apply):
- Continuously monitor pulse oximetry
- Perform pulse oximetry every 24 hours
- Provide monitoring of the patient every 24 hours

Question 6:
A Healthcare Provider administering ZULRESSO should immediately stop the infusion pump for the following reasons (check all that apply):
- The patient is sleeping, in the evening/night
- Pulse oximeter indicates hypoxia
- The patient has excessive sedation
- The patient has loss of consciousness

Question 7:
If a patient loses consciousness during the administration of ZULRESSO, the Healthcare Provider must (check all that are true):
- Complete only the Excessive Sedation and Loss of Consciousness Adverse Event Form
- Complete both the Post Infusion Form and the Excessive Sedation and Loss of Consciousness Adverse Event Form

Question 8:
The ZULRESSO REMS Post Infusion Form should (check all that are true):
- Not be completed if the patient only received 8 hours of the infusion
- Be completed if the patient received any of the infusion or is not infused
- Indicate if a loss of consciousness or excessive sedation event occurred
- Capture the start and end date and time of the infusion if the infusion was administered

Question 9:
After treatment with ZULRESSO, the Post Infusion Form must be sent to the ZULRESSO REMS within how many business days?
- 3 business days
- 7 business days
- 14 business days
- Not necessary to return

Question 10:
It is optional to train all new Healthcare Providers involved in the administration of ZULRESSO on the processes and procedures of the ZULRESSO REMS.
- True
- False
You have successfully completed the ZULRESSO REMS Healthcare Setting Knowledge Assessment.

You must complete the ZULRESSO REMS Certified Healthcare Setting Enrollment Form and submit to the ZULRESSO REMS before administering ZULRESSO.

You will receive a notification from the ZULRESSO REMS confirming your certification in the ZULRESSO REMS. Upon receipt of this notification, you may administer ZULRESSO.
You did not achieve 100% on the ZULRESSO REMS Healthcare Setting Knowledge Assessment.

You have 2 attempt(s) to correctly answer all questions. You may click "Review Training Slides" to return to view the necessary resources. At the end of the review, you will be able to retake the assessment. Or, you may immediately retake the assessment by clicking "Retake Assessment".
Healthcare Setting Certification

You did not achieve 100% on the ZULRESSO REMS Healthcare Setting Knowledge Assessment within the last 3 attempts.

You must rereview the ZULRESSO REMS Training for Healthcare Settings before attempting the ZULRESSO REMS Healthcare Setting Knowledge Assessment again.
ZULRESSO® REMS Healthcare Setting Certification

ZULRESSO® REMS Certified Healthcare Setting Enrollment Form

Complete and submit this form by clicking "Continue" below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as Healthcare Setting only.

* Indicates Required Field

**HEALTHCARE SETTING INFORMATION**

<table>
<thead>
<tr>
<th>National Provider Identifier (NPI)</th>
<th>Site Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Academy</td>
<td>[ ] Animal Center</td>
</tr>
</tbody>
</table>

List all Associated National Provider Identifiers (NPIs)

- Associated National Provider Identifier (NPI #)
  
Click below to enter an associated National Provider Identifier (NPI #)

**HEALTHCARE SETTING INFORMATION**

- Healthcare Setting Name
- Healthcare Setting DEA Number
- Address 1
- City
- State
- Zip
- [ ] Yes
- [ ] No

Healthcare Setting Enrolling As Both Healthcare Setting and Pharmacy

**AUTHORIZED REPRESENTATIVE INFORMATION**

- First Name
- Last Name
- Title
- Degree
- Disability
- [ ] Physician
- [ ] Physician Assistant
- [ ] Nurse
- [ ] Pharmacist
- [ ] Other

- [ ] New Enrollment
- [ ] New Representative

**PHONER NUMBER**

- Phone Number
- Fax Number
- Email Address

**HEALTHCARE SETTING ATTESTATIONS**

As the Authorized Representative, I agree that:

- I have reviewed the Training Program for Healthcare Settings and successfully completed the Healthcare Setting Knowledge Assessment.
- I have read all material included in presenting, dispensing, and administering ZULRESSO and the ZULRESSO REMS requirements using the Training Program.
- I will follow the processes and procedures to identify new staff involved in dispensing, dispensing, and administering ZULRESSO, ensuring they are trained.
- I will follow the processes and procedures to ensure the patient in the ZULRESSO REMS by completing and submitting the Patient Information Form to the ZULRESSO REMS.
- I will follow the processes and procedures to ensure the patient and verify the patient is enrolled in the ZULRESSO REMS before administration.
- I will follow the processes and procedures to submit the Post-Medication and the Dosage Reduction Care Plan Form to the ZULRESSO REMS.

In order to complete the Healthcare Setting, we will comply with the following REMS requirements:

- Before dispensing:
  - Notify the patient and completing and submitting the Patient Information Form to the ZULRESSO REMS.
  - Before administering:
    - Dosage reduction in patient on signs and symptoms of exogenous sedation, without loss of consciousness, and the importance of immediately reporting to a healthcare professional.
    - Signs and symptoms of exogenous sedation using the Patient Information Guide.
    - Provide a copy of the medication to the patient.
    - Dosage reduction, 60 hours.
    - Every 2 hours during planned, non-void periods:
      - Monitor the patient's vital signs for signs and symptoms of exogenous sedation, and loss of consciousness.
    - Assess the patients oxygen saturation using continuous pulse oximetry.
    - After treatment discontinuation, prior to discharge:
      - Assess the patient's level of sedation.
    - After treatment discontinuation, within 3 business days of discharge:
      - Document and submit the patient's medication history to the ZULRESSO REMS using the Medication History Form.
      - Report any adverse event or loss of consciousness to the ZULRESSO REMS using the Dosage Reduction and Loss of Consciousness Event Form.
    - Not transfer patients to use ZULRESSO.
    - Maintain records documenting details of a patient's exposure to ZULRESSO.

- Maintain records that REMS processes and procedures are in place and are being followed.

- Evaluate impact of ZULRESSO on patients, nurses, staff, and/or other personnel.

- Comply with all audits carried out by ZULRESSO, Inc., and third parties acting on behalf of ZULRESSO, Inc., to ensure that all processes and procedures are in place and being followed.

As a condition of the certification, the Healthcare Setting must:

- Be able to monitor patients continuity for the duration of the infusion

- Have the following covenants continuously be observed:
  - No dispensation protocol, unnecessary dispensation of ZULRESSO, or dispensing of ZULRESSO to an infusion-based patient meeting the patient's health conditions will be necessary.
  - Ensure that the Healthcare Setting designates an authorized pharmacist. The authorized pharmacist will enrol in the ZULRESSO REMS by successfully completing the Healthcare Setting Knowledge Assessment and Healthcare Setting Enrollment Forms and submit both to ZULRESSO REMS.

**Signature:**

**CANCEl **CONTINUE **
ZULRESSO® REMS Healthcare Setting Certification

ZULRESSO® REMS Certified Healthcare Setting Enrollment Form

Complete and submit this form by clicking "Continue" below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as Healthcare Setting only.

* Indicates Required Field

HEALTHCARE SETTING INFORMATION

- National Provider Identifier (NPI)
- Site Type
  - Clinic
  - Hospital
  - Other

List All Associated National Provider Identifiers (NPIs)

Associated National Provider Identifier (NPI)

Click below to enter an additional Associated National Provider Identifier (NPI):

ADDITIONAL NPI

*Healthcare Setting Name

*Healthcare Setting DEA Number

*Address 1

*Address 2

City

State

ZIP

*Healthcare Setting Enrolling as both healthcare setting and pharmacy

Yes

No

For each additional Healthcare Setting where ZULRESSO will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, you will need to add the Healthcare Setting by clicking the button below.

ADDITIONAL HEALTHCARE SETTINGS

AUTHORIZED REPRESENTATIVE INFORMATION

- First Name

- Last Name

- Title

- Credentials
  - Physician
  - Physician Assistant
  - Nurse Practitioner
  - Nurse
  - Other

- Reason for Form
  - New Enrollee
  - New Representative

- Phone Number

- Fax Number

- Email Address

- Address 1

- Address 2

City

State

ZIP

- Healthcare Setting Enrolling as both healthcare setting and pharmacy

Yes

No

Healthcare Setting Setting DEA Number

Your Healthcare Setting Information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Healthcare Setting to purchase product. Your Healthcare Setting information (name, location, and phone number) will be listed on a location finder, as a certified Healthcare Setting, available to Healthcare Providers and patients seeking treatment with ZULRESSO. If you do not want your information listed, please call ZULRESSO REMS Help Desk at 844-423-4978.

HEALTHCARE SETTING ATTACHMENTS

As the Authorized Representative, I agree to:

- I have read the Training Program for Healthcare Settings and successfully completed the Healthcare Setting Certification Assessment.
- I agree to follow all relevant staff involved in prescribing, dispensing, and administering ZULRESSO to the ZULRESSO REMS requirements using the Training Program.
- I will establish processes and procedures to identify any staff involved in prescribing, dispensing, and administering ZULRESSO to ensure they are trained.
- I will establish processes and procedures to ensure the patient is the ZULRESSO REMS by completing and submitting the Patient Enrollment Forms to the ZULRESSO REMS.
- I will establish processes and procedures to enroll the patient and satisfy the criteria for the ZULRESSO REMS before administration.
- I will establish processes and procedures to submit the Post In-Hospital/Non-In-Hospital Focal Review Medication/Non_BLIND Visit Form to the ZULRESSO REMS.
- I do not believe the healthcare setting, as it complies with the following REMS requirements:
  - Before dispensing:
    - Counsel the patient by completing and submitting the Patient Enrollment Forms before ZULRESSO REMS.
    - Before administration:
      - Dose the patient on the signs and symptoms of excessive sedation, lack of consciousness, and the importance of immediately reporting to a healthcare professional any signs and symptoms of excessive sedation/subacute reaction to ZULRESSO. Provide a copy of the material to the patient.
      - Before treatment: 90 (90) hours:
        - Audit the patient for signs and symptoms of excessive sedation and loss of consciousness.
      - During treatment: 90 (90) hours:
        - Audit the patient for signs and symptoms of excessive sedation and loss of consciousness.
      - After treatment: 90 (90) hours:
        - Complete the Patient Enrollment Forms before ZULRESSO REMS.
      - Drugstore and submit the patient's information to the ZULRESSO REMS using the Post In-Hospital/Non-In-Hospital Focal Review Medication/Non_BLIND Visit Form.
      - Report excessive sedation or loss of consciousness to the ZULRESSO REMS using the Excessive Sedation and Loss of Consciousness Adverse Event Form.
    - Do not discontinue, discontinue, and dose ZULRESSO REMS.
    - Maintain records documenting staff completion of training.
    - Maintain records that all ZULRESSO REMS processes and procedures are in place and being followed.
    - I will maintain records of all shipments of ZULRESSO REMS received and dispensed to healthcare settings in which the patient name, dose, number, and date administered.
    - Complete audits and/or exit checks for ZULRESSO REMS, or third party audits on behalf of Sage Therapeutics, Inc. to ensure all processes and procedures are in place.

As a condition of the certification, the Healthcare Setting must:

- Be able to monitor patients continuously for the duration of the infusion.
- Have the following to ensure continuous patient safety, but monitoring is recommended, intravenous programming infusion pumps with alarms to alert when the pump malfunctions, healthcare providers to be curiously available online to monitor the patient and intervene as necessary.
- Be able to ensure that the healthcare setting designates a new Authorized Representative, who will be responsible for submitting the healthcare setting's healthcare setting knowledge assessment and Healthcare Setting Enrollment Form and submitting both to the ZULRESSO REMS.

*Signature:

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ZULRESSO® REMS Healthcare Setting Certification

ZULRESSO® REMS Certified Healthcare Setting Enrollment Form

Complete and submit by logging into "Central Desk".

If your Healthcare Setting and Pharmacy are within the same institution, enroll as Healthcare Setting only.

Instructed by: Written Form

Click here to view additional Healthcare Setting Information.

Healthcare Setting Information

First Name

Last Name

Title

Home Address Line 1

City

State

ZIP

Healthcare Setting Certification

Healthcare Setting ECA Location

Address Line 1

Address Line 2

City

State

ZIP

Healthcare Setting Certification

On-Board Healthcare Setting Certification in Pharmacy

Address Line 1

Address Line 2

City

State

ZIP

Healthcare Setting Certification

If you require additional Healthcare Setting where ZULRESSO® will be delivered, dispensed, and administered within your healthcare system for which the same certification requirements will be responsible, you need to fill in the Healthcare Setting by clicking the bottom label.

THEMATIC INFORMATION

For each additional Healthcare Setting where ZULRESSO® will be delivered, dispensed, and administered within your healthcare system for which the same certification requirements will be responsible, you need to fill in the Healthcare Setting by clicking the bottom label.

LEP RESPONSE BUREAU: INFORMATION

Your Healthcare Setting information will be shared with SAGE Therapeutics, Inc. patient support and distribution partners, to allow your Healthcare Setting to purchase product. Your Healthcare Setting information is shared with those partners to allow them to enroll in our Healthcare Setting enrollment, which will allow Healthcare Providers and patients seeking treatment with ZULRESSO®. If you do not want your information listed, please call ZULRESSO REMS at 844-472-4770

LEP SETTINGS ADDITIONS

In order to participate in the Program, a healthcare setting must have a completed ZULRESSO REMS certification. A completed ZULRESSO REMS certification must be submitted to SAGE Therapeutics for a healthcare setting to be approved for participation in the Program. ZULRESSO REMS certified healthcare settings are responsible for enrolling ZULRESSO REMS physicians and patients who seek treatment with ZULRESSO®. A healthcare setting is defined as a healthcare setting that has been certified to the Program and is responsible for enrolling ZULRESSO REMS physicians and patients who seek treatment with ZULRESSO®. ZULRESSO REMS certified healthcare settings are responsible for enrolling ZULRESSO REMS physicians and patients who seek treatment with ZULRESSO®. ZULRESSO REMS certified healthcare settings are responsible for enrolling ZULRESSO REMS physicians and patients who seek treatment with ZULRESSO®.
You have successfully completed and submitted the ZULRESSO REMS Certified Healthcare Setting Enrollment Form.

You are now certified in the ZULRESSO REMS.
## Patients

Below is a list of patients enrolled at your healthcare setting(s):

- Download the list to spreadsheet format by clicking the Excel icon just above the column headers.
- Search/Filter the list by entering information in the textbox below any column header.
- Sort the list by clicking on any column header.

### Healthcare Setting

- **Healthcare Facility 1**

### Patient Information

<table>
<thead>
<tr>
<th>REMS ID</th>
<th>First Name</th>
<th>Last Name</th>
<th>Date of Birth</th>
<th>Healthcare Setting</th>
<th>Status</th>
<th>Action</th>
<th>Patient Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>12345</td>
<td>Peggy</td>
<td>Sue</td>
<td>1/1/2000</td>
<td>Healthcare Facility 1</td>
<td>Enrolled</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[Table continues]

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Patients

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<th>Status</th>
<th>Action</th>
<th>Patient Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>98765</td>
<td>Robert</td>
<td>Peterson</td>
<td>1/1/2000</td>
<td>Healthcare Facility 2</td>
<td>Enrolled</td>
<td>SUBMIT A POST INFUSION FORM</td>
<td>GENERATE PATIENT ENROLLMENT NOTIFICATION</td>
</tr>
</tbody>
</table>

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ZULRESSO Post Infusion Form

INSTRUCTIONS

ZULRESSO is only available through the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS). A Post Infusion Form must be submitted to the ZULRESSO REMS for all patients who are enrolled in the ZULRESSO REMS. Please complete and submit this form within 3 business days of the patient completing the infusion or the scheduled infusion completion date.

Please complete and submit this Post Infusion Form to the ZULRESSO REMS by clicking "Submit" below. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

*Indicates required field

<table>
<thead>
<tr>
<th>Patient First Name: Peggy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle Initial:</td>
</tr>
<tr>
<td>Patient Last Name: Sue</td>
</tr>
<tr>
<td>Patient Date of Birth (MM/DD/YYYY): 1/1/2000</td>
</tr>
<tr>
<td>REMS ID: 123467890</td>
</tr>
</tbody>
</table>

Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered: Professional Associates
Address 1: 123 Main Street
Address 2: City: Malvern
State: PA
Phone Number: 555-123-4567
Email: abc@abc.com
ZIP: 19542

HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

*First Name

*Last Name

*Credentials
- MD/DD
- NP/PA
- Pharmacist
- Nurse
- Other

*Specialty
- Psychiatry
- OB/GYN
- Family Practice
- Other

*Did the Patient Receive ZULRESSO?
- Yes
- No

*Administering HCP Signature:

HCP Email (Optional)

*HCP Phone Number

*If you have any questions, require additional information or need additional copies of any of the ZULRESSO REMS documents, please visit the ZULRESSO REMS website at www.zulressorems.com or call 844-472-4379.

Healthcare Providers must report to the ZULRESSO REMS any event of excessive sedation or loss of consciousness using the Excessive Sedation and Loss of Consciousness Adverse Event Form.

To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
ZULRESSO Post Infusion Form

INSTRUCTIONS

ZULRESSO is only available through the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS). A Post Infusion Form must be submitted to the ZULRESSO REMS for all patients who are enrolled in the ZULRESSO REMS. Please complete and submit this form within 3 business days of the patient completing the infusion or the scheduled infusion completion date.

Please complete and submit this Post Infusion Form to the ZULRESSO REMS by clicking "Submit" below. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

*Indicates required field

PATIENT AND HEALTHCARE SETTING INFORMATION

Patient First Name: Peggy
Middle Initial: 
Patient Last Name: Sue
Patient Date of Birth (MM/DD/YYYY): 1/1/2000
REMS ID: 1234567890
Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered: Professional Associates
Address 1: 123 Main Street
City: Malvern
State: PA
Address 2: 
Phone Number: 855-555-1212
Email: abc@abc.com
ZIP: 19542

HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

* First Name

* Last Name

* Credentials
☐ MD/DO  ☐ NP/PA  ☐ Pharmacist  ☐ Nurse  ☐ Other

* Specialty
☐ Psychiatry  ☐ OB/GYN  ☐ Family Practice  ☐ Other

* Did the Patient Receive ZULRESSO?
☐ Yes  ☐ No

* Date Infusion Started (MM/DD/YYYY)  

* Date Infusion Ended (MM/DD/YYYY)  

* Did the Patient Experience Loss of Consciousness While on ZULRESSO?
☐ Yes  ☐ No

* Did the Patient Experience Excessive Sedation While on ZULRESSO?
☐ Yes  ☐ No

* Administering HCP Signature:

HCP Email (Optional)

* HCP Phone Number

*If you have any questions, require additional information or need additional copies of any of the ZULRESSO REMS documents, please visit the ZULRESSO REMS website at www.zulressorems.com or call 844-472-4379.

Healthcare Providers must report to the ZULRESSO REMS any event of excessive sedation or loss of consciousness using the Excessive Sedation and Loss of Consciousness Adverse Event Form.

To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
# ZURIXX Post Injection Form

This is a form used by medical professionals to record details of a patient's injection. It is typically used in the context of administering medication in hospitals or clinics. The form includes sections for personal details, the date of injection, the type of medication administered, and any adverse reactions that may occur. It is essential for ensuring accurate and complete record-keeping in medical practice.

### Personal Information
- **Name:** [Redacted]
- **Date of Birth:** [Redacted]
- **Medical Identification Number:** [Redacted]

### Injection Details
- **Injection Date:** March 26, 2019
- **Injection Site:** [Redacted]
- **Medication Administered:** [Redacted]
- **Dosage:** [Redacted]

### Adverse Reactions
- **None reported**

This form is part of the standard procedures in healthcare facilities to ensure patient safety and compliance with regulatory requirements.
ZULRESSO Post Infusion Form

INSTRUCTIONS
ZULRESSO is only available through the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS). A Post Infusion Form must be submitted to the ZULRESSO REMS for all patients who are enrolled in the ZULRESSO REMS. Please complete and submit this form within 3 business days of the patient completing the infusion or the scheduled infusion completion date.

Please complete and submit this Post Infusion Form to the ZULRESSO REMS by clicking “Submit” below. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

*Indicates required field

PATIENT AND HEALTHCARE SETTING INFORMATION

<table>
<thead>
<tr>
<th>Patient First Name: Peggy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle Initial:</td>
</tr>
<tr>
<td>Patient Last Name: Sue</td>
</tr>
<tr>
<td>Patient Date of Birth (MM/DD/YYYY): 1/1/2000</td>
</tr>
<tr>
<td>REMS ID: 1234567890</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered: Professional Associates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address 1: 123 Main Street</td>
</tr>
<tr>
<td>Address 2:</td>
</tr>
<tr>
<td>City: Malvern</td>
</tr>
<tr>
<td>State: PA</td>
</tr>
<tr>
<td>ZIP: 19542</td>
</tr>
<tr>
<td>Phone Number: 555 555-1212</td>
</tr>
<tr>
<td>Email: <a href="mailto:abc@abc.com">abc@abc.com</a></td>
</tr>
</tbody>
</table>

HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

* First Name

* Last Name

* Credentials
  - [ ] MD/DO
  - [ ] NP/PA
  - [ ] Pharmacist
  - [ ] Nurse
  - [ ] Other

* Specialty
  - [ ] Psychiatry
  - [ ] OB/GYN
  - [ ] Family Practice
  - [ ] Other

* Did the Patient Receive ZULRESSO?
  - [ ] Yes
  - [ ] No

* Please check all reasons that apply
  - [ ] Logistic challenges
  - [ ] Change in treatment plan
  - [ ] Other

* Administering HCP Signature: [ ]

HCP Email (Optional)

HCP Phone Number

*If you have any questions, require additional information or need additional copies of any of the ZULRESSO REMS documents, please visit the ZULRESSO REMS website at www.zulressorems.com or call 844-472-4379.

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To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
My Profile

Below is a list of your associated Healthcare Settings and associated Delegates who require access to the online ZULRESSO REMS portal.

**Healthcare Setting 1**

123 Main Street
City, State Zip
Healthcare Setting DEA Number: 11111
Site Type: Hospital
Enrolled as Both Healthcare Setting and Pharmacy: Yes

<table>
<thead>
<tr>
<th>Delegates</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loretta Maybly</td>
<td>(555)555-1212</td>
</tr>
<tr>
<td></td>
<td>(555)555-9999</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:lmabyl@hcs1.com">lmabyl@hcs1.com</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Delegates</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steve Mason</td>
<td>(555)555-3434</td>
</tr>
<tr>
<td></td>
<td>(555)555-8888</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:smason@hcs1.com">smason@hcs1.com</a></td>
</tr>
</tbody>
</table>

**Associated NPI #’s**

- 2345678901
- 4567890123

**Healthcare Setting 2**

100 Broadway
City State ZIP
Healthcare Setting DEA Number: 22222
Site Type: Hospital
Enrolled as Both Healthcare Setting and Pharmacy: No

<table>
<thead>
<tr>
<th>Delegates</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corey Pearson</td>
<td>Phone #: 555 555-1212</td>
</tr>
<tr>
<td></td>
<td>Fax #: 555 555-8888</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:spearsong@hcs1.com">spearsong@hcs1.com</a></td>
</tr>
</tbody>
</table>

**Associated NPI #’s**

There are no NPI#s associated with this Healthcare Setting
ZULRESSO Add Healthcare Setting

- **National Provider Identifier (NPI #)**
- **Site Type**
  - Hospital
  - Infusion Center
  - Other
- **Associated National Provider Identifier (NPI #)**
- **Healthcare Setting Name**
- **Healthcare Setting DEA Number**
- **Address 1**
- **Address 2**
- **City**
- **State**
- **ZIP**
- **Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy**
  - Yes
  - No

[Options: CANCEL, SUBMIT]
Below is a list of your associated Healthcare Settings and associated Delegates who require access to the online ZULRESSO REMS portal.

Healthcare Setting 1
123 Main Street
City, State Zip
Healthcare Setting DEA Number:

Site Type: Hospital

Enrolled as Both Healthcare Setting and DEA:

Please click on the Delegate's first or last name in the grid to select the delegate, then hit "Continue". If this is a new delegate, click "New Delegate".

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loretta</td>
<td>Maybly</td>
<td>555 555-3434</td>
<td><a href="mailto:lmaybly@hcs1.com">lmaybly@hcs1.com</a></td>
</tr>
<tr>
<td>Steve</td>
<td>Mason</td>
<td>555 555-3434</td>
<td><a href="mailto:smason@abc.com">smason@abc.com</a></td>
</tr>
</tbody>
</table>

NEW DELEGATE  CONTINUE
Below is a list of your associated Healthcare Settings and associated Delegates who require access to the online ZULRESSO REMS portal.

Healthcare Setting 1

123 Main Street
City, State Zip

Healthcare Setting DEA Number:

Site Type: Hospital

Enrolled as Both Healthcare Setting and Hospital

SELECT EXISTING DELEGATE OR ADD A NEW DELEGATE

Please click on the Delegate’s first or last name in the grid to select the delegate, then hit “Continue”. If this is a new delegate, click “New Delegate”.

<table>
<thead>
<tr>
<th>First Name</th>
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<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loretta</td>
<td>Maybly</td>
<td>555-555-3434</td>
<td><a href="mailto:lmaybly@host1.com">lmaybly@host1.com</a></td>
</tr>
<tr>
<td>Steve</td>
<td>Mason</td>
<td>555-555-3434</td>
<td><a href="mailto:smason@abc.com">smason@abc.com</a></td>
</tr>
</tbody>
</table>

NEW DELEGATE  CONTINUE
SELECT EXISTING DELEGATE OR ADD A NEW DELEGATE

Please click on the Delegate's first or last name in the grid to select the delegate, then hit "Continue". If this is a new delegate, click "New Delegate".

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Phone</th>
<th>Email</th>
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</thead>
<tbody>
<tr>
<td>LORETTA</td>
<td>MAYBLY</td>
<td>555 556-3434</td>
<td><a href="mailto:lmaybly@hcs1.com">lmaybly@hcs1.com</a></td>
</tr>
<tr>
<td>STEVE</td>
<td>MASON</td>
<td>555 556-3434</td>
<td><a href="mailto:smason@abc.com">smason@abc.com</a></td>
</tr>
</tbody>
</table>

Modify Delegate Information

*First Name
Loretta

*Last Name
Maybly

*Phone
555 556-3434

Fax
555 556-9999
SELECT EXISTING DELEGATE OR ADD A NEW DELEGATE

Please click on the Delegate’s first or last name in the grid to select the delegate, then hit “Continue”. If this is a new delegate, click “New Delegate”.

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<td>Maybly</td>
<td>555 556-3434</td>
<td><a href="mailto:lmaybly@hcs1.com">lmaybly@hcs1.com</a></td>
</tr>
<tr>
<td>Steve</td>
<td>Mason</td>
<td>655 556-3434</td>
<td><a href="mailto:smason@sbc.com">smason@sbc.com</a></td>
</tr>
</tbody>
</table>

Enter Delegate Information

* First Name

* Last Name

Healthcare Facility

Healthcare Facility 1

* Phone

* Fax

* Email

NEW DELEGATE  CONTINUE
Below is a list of your associated Healthcare Settings and associated Delegates who require access to the online ZULRESSU REMS portal.

Healthcare Setting 1

123 Main Street
City, State Zip

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pharmacy: Yes

Delegates

Delegate has been added successfully
Emails containing a username and temporary password will be sent shortly to the delegate.

- Loretta Maybly
  - (555) 555-1212
  - (555) 555-9089
  - lmaybly@hcs1.com

- Steve Mason
  - (555) 555-3434
  - (555) 555-8888
  - smason@hcs1.com

- Molly Malone
  - (555) 555-5858
  - (555) 555-7777
  - mmalone@hcs1.com

Associated NPI #'s

- NPI 2345678901
- NPI 3456789012
- NPI 4567890123
ZULRESSO Add National Provider Identifier (NPI #)

National Provider Identifier (NPI#)
<table>
<thead>
<tr>
<th>Healthcare Setting DEA Number: 22222</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Type: Hospital</td>
</tr>
<tr>
<td>Enrolled as Both Healthcare Setting and Pharmacy: Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Loretta Maybly</th>
</tr>
</thead>
<tbody>
<tr>
<td>(655) 556-1212</td>
</tr>
<tr>
<td>(655) 556-9999</td>
</tr>
<tr>
<td><a href="mailto:lmaybly@hcs1.com">lmaybly@hcs1.com</a></td>
</tr>
<tr>
<td>Add NPI #</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Steve Mason</th>
</tr>
</thead>
<tbody>
<tr>
<td>(655) 556-3434</td>
</tr>
<tr>
<td>(655) 556-8888</td>
</tr>
<tr>
<td><a href="mailto:smason@hcs1.com">smason@hcs1.com</a></td>
</tr>
<tr>
<td>Add NPI #</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Molly Malone</th>
</tr>
</thead>
<tbody>
<tr>
<td>(655) 556-5666</td>
</tr>
<tr>
<td>(655) 556-7777</td>
</tr>
<tr>
<td><a href="mailto:mmalone@hcs1.com">mmalone@hcs1.com</a></td>
</tr>
<tr>
<td>Add NPI #</td>
</tr>
</tbody>
</table>

Associated NPI #’s

<table>
<thead>
<tr>
<th>2345878901</th>
<th>REMOVE ASSOCIATION</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>3456789012</th>
<th>REMOVE ASSOCIATION</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>4567890123</th>
<th>REMOVE ASSOCIATION</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>5678901234</th>
<th>REMOVE ASSOCIATION</th>
</tr>
</thead>
</table>
My Profile

Below is a list of your associated Healthcare Settings and associated Delegates who require access to the online ZULRESSO REMS portal.

Healthcare Settings

**Healthcare Setting 1**
123 Main Street  
City, State Zip  
Healthcare Setting DEA Number: 11111  
Site Type: Hospital  
Enrolled as Both Healthcare Setting and Pharmacy: Yes

Delegates

- **Loretta Maybly**  
  - Phone: (555) 555-1212  
  - Fax: (555) 555-9999  
  - Email: lmaybly@hcs1.com

- **Steve Mason**  
  - Phone: (555) 555-3434  
  - Fax: (555) 555-8888  
  - Email: smason@hcs1.com

Are you sure you want to remove this Delegate from this Healthcare Setting?

- Yes
- No

**Associated NPI #’s**

- 2345678901  
  - REMOVE ASSOCIATION
- 4567890123  
  - REMOVE ASSOCIATION


**Healthcare Setting 2**
100 Broadway  
City State ZIP  
Healthcare Setting DEA Number: 22222  
Site Type: Hospital  
Enrolled as Both Healthcare Setting and Pharmacy: No

Delegates

- **Corey Pearson**  
  - Phone: (555) 555-1212  
  - Fax: (555) 555-8888  
  - Email: spearsone@hcs1.com

**Associated NPI #’s**

- There are no NPI#s associated with this Healthcare Setting