

Risk Evaluation and Mitigation Strategy (REMS) Document

ZULRESSO (brexanolone) REMS Program

I. Administrative Information

Application Number: NDA 211371
Application Holder: Sage Therapeutics, Inc.
Initial REMS Approval: 03/2019
Most Recent REMS Update: 10/2020

II. REMS Goal

The goal of the ZULRESSO REMS Program is to mitigate the risk of serious harm resulting from excessive sedation and sudden loss of consciousness during the ZULRESSO infusion by:

- i. Ensuring that ZULRESSO is administered only to patients in a medically supervised setting that provides monitoring while ZULRESSO is administered.
- ii. Ensuring pharmacies and healthcare settings that dispense ZULRESSO are certified.
- iii. Ensuring that each patient is informed of the adverse events of excessive sedation and loss of consciousness and the need for monitoring while ZULRESSO is administered.
- iv. Enrollment of all patients in a registry to characterize the risks and support safe use.

III. REMS Requirements

Sage Therapeutics, Inc. must ensure that healthcare settings, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare settings that dispense ZULRESSO must:

- | | |
|---------------------------------|--|
| To become certified to dispense | <ol style="list-style-type: none">1. Be able to monitor patients continuously for the duration of the infusion.2. Have the following onsite: continuous pulse oximetry, fall precaution protocol, intravenous programmable infusion pumps with alarms to alert when the pump malfunctions, healthcare providers to continuously monitor patients and intervene as necessary.3. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting.4. Have the Authorized Representative review the Training for Healthcare Settings. |
|---------------------------------|--|
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5. Have the Authorized Representative successfully complete the [Healthcare Setting Knowledge Assessment](#) and submit it to the REMS Program.
 6. Have the Authorized Representative enroll in the REMS Program by completing the [Healthcare Setting Enrollment Form](#) and submitting it to the REMS Program.
 7. Train all relevant staff involved in prescribing, dispensing, and administering ZULRESSO on the REMS Program requirements using the [Training for Healthcare Settings](#).
 8. Establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering ZULRESSO and ensure they are trained.
 9. Establish processes and procedures to enroll the patient in the REMS program.
 10. Establish processes and procedures to counsel the patient and verify the patient is enrolled in the REMS Program before administration.
 11. Establish processes and procedures to submit the [Post Infusion Form](#) and [Excessive Sedation and Loss of Consciousness Adverse Event Form](#) to the REMS Program.
-

Before dispensing

12. Enroll the patient by completing and submitting the [Patient Enrollment Form](#) to the REMS Program.
-

Before administering

13. Verify the patient is enrolled through the processes and procedures established as a requirement of the REMS Program.
 14. Counsel the patient on signs and symptoms of excessive sedation, loss of consciousness, and the importance of immediately reporting to a healthcare provider any signs and symptoms of excessive sedation using the [Patient Information Guide](#). Provide a copy of the material to the patient.
-

During treatment, every 2 hours

15. Assess the patient's health status for signs and symptoms of excessive sedation and loss of consciousness.
-

During treatment

16. Assess the patient's oxygen saturation using continuous pulse oximetry.
-

After treatment discontinuation, prior to discharge

17. Assess the patient's level of sedation.
-

After treatment discontinuation, within 3 business days of completion date	<p>18. Document and submit to the REMS Program using the Post Infusion Form.</p> <p>19. Report excessive sedation or loss of consciousness to the REMS Program using the Excessive Sedation and Loss of Consciousness Adverse Event Form.</p>
To maintain certification to dispense	20. Have any new Authorized Representative enroll in the REMS Program by successfully completing the Healthcare Setting Knowledge Assessment and the Healthcare Setting Enrollment Form and submitting both to the REMS Program.
At all times	<p>21. Not distribute, transfer, loan, or sell ZULRESSO.</p> <p>22. Maintain records documenting staff's completion of training.</p> <p>23. Maintain records that all REMS processes and procedures are in place and are being followed.</p> <p>24. Maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, number of vials, and date administered for all patients.</p> <p>25. Comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics, Inc. to ensure that all processes and procedures are in place and are being followed.</p>

2. Patients who are prescribed ZULRESSO:

Before treatment initiation	<p>1. Review the Patient Information Guide with a healthcare provider.</p> <p>2. Enroll in the REMS Program by completing the Patient Enrollment Form with a healthcare provider. Enrollment information will be provided to the REMS Program.</p> <p>3. Receive counseling from a healthcare provider on the adverse events of loss of consciousness and signs and symptoms of excessive sedation.</p>
During treatment	<p>4. Be monitored for excessive sedation and loss of consciousness.</p> <p>5. Report any symptoms of excessive sedation to a healthcare provider.</p>

3. Pharmacies that dispense ZULRESSO must:

To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.
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2. Have the authorized representative review the Program Overview.
 3. Have the authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.
 4. Train all relevant staff involved in dispensing that ZULRESSO must only be dispensed to a certified healthcare setting.
 5. Establish processes and procedures to verify the healthcare setting is certified in the REMS Program.

Before dispensing

6. Verify that the healthcare setting is certified through the processes and procedures established as a requirement of the REMS Program.

At all times

7. Not distribute, transfer, loan or sell ZULRESSO.
8. Maintain records documenting staff's completion of training.
9. Maintain records that all REMS processes and procedures are in place and are being followed.
10. Maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, and number of vials.
11. Comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics to ensure that all processes and procedures are in place and are being followed.

4. Wholesalers-distributors that distribute ZULRESSO must:

To be able to distribute

1. Establish processes and procedures to distribute only to certified healthcare settings and pharmacies.
2. Train all relevant staff involved in distributing on the REMS Program requirements.

At all times

3. Distribute only to certified healthcare settings and pharmacies.
4. Maintain records of drug distribution.
5. Maintain records that all processes and procedures are in place and are being followed.
6. 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.

Sage Therapeutics, Inc. must provide training to healthcare settings that dispense ZULRESSO.

The training includes the following educational materials: [Training for Healthcare Settings](#) and [Healthcare Setting Knowledge Assessment](#). The training must be available online and in hard copy format.

Sage Therapeutics, Inc. must provide training to pharmacies that dispense ZULRESSO.

The training includes the following educational material: [Program Overview](#). The training must be available online and in hard copy format.

To inform healthcare providers about the REMS Program and the risks and safe use of ZULRESSO, Sage Therapeutics, Inc must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plan
Healthcare providers likely to prescribe ZULRESSO	REMS Letter: Letter for Healthcare Providers with attachment: Patient Information Guide <ol style="list-style-type: none">1. Email within 60 calendar days of the date ZULRESSO is first commercially distributed and again 12 months later.<ol style="list-style-type: none">a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider’s email address is not available or the email is undeliverable.b. Send a second email within 30 calendar days of the date of the first email sent if the first email is marked unopen.2. Disseminate through field-based sales and medical representatives.

To support REMS Program operations, Sage Therapeutics, Inc. must:

1. Establish and maintain a REMS Program Website, www.zulressorems.com. The REMS Program Website must include the option to print the prescribing information and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program Website must not link back to the promotional product website(s).
2. Make the REMS Program Website fully operational and all REMS materials available through the website and call center by the date ZULRESSO is first commercially distributed.
3. Establish and maintain a REMS Program coordinating center for REMS participants at 844-472-4379 and information@zulressorems.com.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the REMS Program.
5. Ensure healthcare settings and pharmacies are able to enroll online, by email, and fax.
6. Ensure healthcare providers are able to enroll patients by email and fax.
7. Ensure wholesalers-distributors and pharmacies are able to verify enrollment/certification status by phone.
8. Ensure healthcare settings are able to verify enrollment/certification status by phone and online.

9. Ensure healthcare providers are able to submit the [Post Infusion Form](#) and [Excessive Sedation and Loss of Consciousness Adverse Event Form](#) by email, fax, and online.
10. Provide the [Training for Healthcare Settings](#), [Healthcare Setting Knowledge Assessment](#), [Healthcare Setting Enrollment Form](#), [Post Infusion Form](#), [Excessive Sedation and Loss of Consciousness Adverse Event Form](#), [Program Overview](#), [Pharmacy Enrollment Form](#), [Patient Information Guide](#), [Patient Enrollment Form](#), and the Prescribing Information to REMS participants who (1) attempt to dispense or administer ZULRESSO and are not yet certified or (2) inquire about how to become certified.
11. Notify healthcare settings and pharmacies within 2 business days after they become certified in the REMS Program.
12. Provide public access to a database of certified healthcare settings and pharmacies.
13. Provide certified pharmacies access to the database of certified healthcare settings and authorized wholesalers-distributors.
14. Provide certified healthcare settings access to the database of certified pharmacies, enrolled patients, and authorized wholesalers-distributors.
15. Provide authorized wholesalers-distributors access to the database of certified pharmacies and healthcare settings.
16. Establish and maintain a registry which includes a reporting and collection system for all patients to provide information on the incidence of excessive sedation and loss of consciousness.
17. Ensure that once a report suggestive of excessive sedation and loss of consciousness is received, Sage Therapeutics, Inc. follows up with the healthcare provider to obtain all required data for the registry.

To ensure REMS participants' compliance with the REMS Program, Sage Therapeutics, Inc. must:

18. Verify annually that the designated authorized representative for the healthcare setting or pharmacy is the same. If different, the healthcare setting or pharmacy must re-certify with a new authorized representative.
19. Notify healthcare settings if a completed Post Infusion Form has not been received by the REMS Program within 3 business days from the date of the patient completing the infusion or the scheduled infusion completion date. If the [Post Infusion Form](#) is not received within 15 business days, Sage will contact the authorized representative. If the form is not received within 30 business days, Sage will investigate on site.
20. Notify healthcare settings if a completed [Excessive Sedation and Loss of Consciousness Adverse Event Form](#) is required and not received within 15 business days from receipt of the [Post Infusion Form](#). If the form is not received within 30 business days, Sage will investigate.
21. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: drug distribution and dispensing; certification of healthcare settings and pharmacies; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.
22. Establish a plan for addressing noncompliance with REMS Program requirements.
23. Monitor pharmacies and healthcare settings on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

24. Audit 10% but no less than 50 certified healthcare settings and certified pharmacies no later than 90 calendar days after they have placed the first order for ZULRESSO and annually thereafter of healthcare settings and pharmacies that have ordered ZULRESSO, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
25. Audit all wholesalers-distributors no later than 90 calendar days after they become authorized to distribute the drug and annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
26. Take reasonable steps to improve implementation of and compliance with the requirements in the ZULRESSO REMS Program based on monitoring and evaluation of the ZULRESSO REMS Program.

IV. REMS Assessment Timetable

Sage Therapeutics, Inc. must submit REMS assessments at 6 months, 12 months and annually thereafter from the date of the initial approval of the REMS (03/19/2019). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Sage Therapeutics, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the ZULRESSO REMS:

Enrollment Forms

Healthcare Setting:

1. [Healthcare Setting Enrollment Form](#)

Patient:

2. [Patient Enrollment Form](#)

Pharmacy:

3. [Pharmacy Enrollment Form](#)

Training and Educational Materials

Healthcare Setting:

4. [Training for Healthcare Settings](#)
5. [Healthcare Setting Knowledge Assessment](#)

Patient:

6. [Patient Information Guide](#)

Pharmacy:

7. [Program Overview](#)

Patient Care Form

8. [Post Infusion Form](#)
9. [Excessive Sedation and Loss of Consciousness Adverse Event Form](#)

Communication Materials

10. [Letter for Healthcare Providers](#)

Other Materials

11. [REMS Program Website](#)

ZULRESSO™ REMS Certified Healthcare Setting Enrollment Form

INSTRUCTIONS

Complete and submit this form online to the ZULRESSO REMS through the REMS Website at www.zulressorems.com, by fax to 833-564-7243, or by email to information@zulressorems.com. You can also mail this form to 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27617.

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

HEALTHCARE SETTING INFORMATION

Healthcare Setting Name		
Site Type: <input type="checkbox"/> Hospital <input type="checkbox"/> Infusion Center <input type="checkbox"/> Other		
List All Associated National Provider Identifiers (NPI #s)	Healthcare Setting DEA Number	
Address 1	Address 2	
City	State	ZIP
Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy: <input type="checkbox"/> Yes <input type="checkbox"/> 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 complete page 3.

AUTHORIZED REPRESENTATIVE INFORMATION

Name		Title	
Credentials <input type="checkbox"/> Physician <input type="checkbox"/> Physician Assistant <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other		Reason for Form: <input type="checkbox"/> New Enrollment <input type="checkbox"/> New Representative	
Phone Number	Fax Number	Email Address	
Address 1	Address 2		
City	State	ZIP	

Review the attestations and sign on page 2.

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 at 844-472-4379

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 agree to train all relevant staff involved in prescribing, dispensing, and administering ZULRESSO on the ZULRESSO REMS requirements using the *Training Program*.
- I will establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering ZULRESSO to ensure they are trained.
- I will establish processes and procedures to enroll the patient in the ZULRESSO REMS by completing and submitting the *Patient Enrollment Form* to the ZULRESSO REMS.
- I will establish processes and procedures to counsel the patient and verify the patient is enrolled in the ZULRESSO REMS before administration.
- I will establish processes and procedures to submit the *Post Infusion Form* and if needed the *Excessive Sedation and Loss of Consciousness Adverse Event Form* to the ZULRESSO REMS.
- On behalf of the Healthcare Setting, we will comply with the following REMS requirements:
 - Before dispensing:
 - Enroll the patient by completing and submitting the *Patient Enrollment Form* to the ZULRESSO REMS.
 - Before administering:
 - Counsel the patient on the signs and symptoms of excessive sedation, loss of consciousness, and the importance of immediately reporting to a Healthcare Provider any symptoms of excessive sedation using the *Patient Information Guide*. Provide a copy of the material to the patient.
 - During treatment, (60 hours):
 - Every 2 hours during planned, non-sleep periods:
 - Assess the patient’s health status for signs and symptoms of excessive sedation and loss of consciousness.

- Assess the patient’s oxygen saturation using continuous pulse oximetry.
- After treatment discontinuation, and prior to discharge:
 - Assess the patient’s level of sedation.
- After treatment discontinuation, within 3 business days of scheduled completion date:
 - Document and submit the patient’s infusion outcome to the ZULRESSO REMS using the *Post Infusion Form*.
 - Report excessive sedation or loss of consciousness to the ZULRESSO REMS using the *Excessive Sedation and Loss of Consciousness Adverse Event Form*.
- Not distribute, transfer, loan or sell ZULRESSO
- Maintain records documenting staff’s completion of training.
- Maintain records that all ZULRESSO REMS processes and procedures are in place and are being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, number of vials, and date administered.
- Comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics, 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 continuously for the duration of the infusion
- Have the following onsite: continuous pulse oximetry, fall precaution protocol, intravenous programmable infusion pumps with alarms to alert when the pump malfunctions, Healthcare Providers to be continuously available on site to monitor the patient and intervene as necessary
- Ensure that if the Healthcare Setting designates a new Authorized Representative, the new Authorized Representative will enroll in the ZULRESSO REMS by successfully completing the *Healthcare Setting Knowledge Assessment* and *Healthcare Setting Enrollment Form* and submitting both to the ZULRESSO REMS

SIGN
HERE

DATE
HERE

Date (MM/DD/YYYY)

Please visit www.zulressoems.com or call 844-472-4379 for more information about the ZULRESSO REMS.

ZULRESSO™ REMS Certified Healthcare Setting Enrollment Form

Use this page to add each additional Healthcare Setting location for which the same Authorized Representative will be responsible.

ADDITIONAL HEALTHCARE SETTING INFORMATION

Healthcare Setting Name		
Site Type: <input type="checkbox"/> Hospital <input type="checkbox"/> Infusion Center <input type="checkbox"/> Other		
List All Associated National Provider Identifiers (NPI #s)	Healthcare Setting DEA Number	
Address 1	Address 2	
City	State	ZIP
Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy: <input type="checkbox"/> Yes <input type="checkbox"/> No		

Healthcare Setting Name		
Site Type: <input type="checkbox"/> Hospital <input type="checkbox"/> Infusion Center <input type="checkbox"/> Other		
List All Associated National Provider Identifiers (NPI #s)	Healthcare Setting DEA Number	
Address 1	Address 2	
City	State	ZIP
Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy: <input type="checkbox"/> Yes <input type="checkbox"/> No		

Healthcare Setting Name		
Site Type: <input type="checkbox"/> Hospital <input type="checkbox"/> Infusion Center <input type="checkbox"/> Other		
List All Associated National Provider Identifiers (NPI #s)	Healthcare Setting DEA Number	
Address 1	Address 2	
City	State	ZIP
Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy: <input type="checkbox"/> Yes <input type="checkbox"/> No		

Healthcare Setting Name		
Site Type: <input type="checkbox"/> Hospital <input type="checkbox"/> Infusion Center <input type="checkbox"/> Other		
List All Associated National Provider Identifiers (NPI #s)	Healthcare Setting DEA Number	
Address 1	Address 2	
City	State	ZIP
Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy: <input type="checkbox"/> Yes <input type="checkbox"/> No		



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ZULRESSO™ REMS Patient Enrollment Form

INSTRUCTIONS

Complete and fax this form to the ZULRESSO REMS at 833-564-7243 or email this form to information@zulressorems.com.

PATIENT INFORMATION

First Name	Middle Initial	Last Name	Date of Birth (MM/DD/YYYY)
Address 1		Address 2	
City	State	ZIP	
Email Address	Phone Number		

By signing this form, you agree to the following:

- I have received, read, and understand the *Patient Information Guide* that my Healthcare Provider has given me.
- My Healthcare Provider has counseled me on:**
- The side effects of excessive sleepiness (excessive sedation) and passing out (loss of consciousness)
 - The signs and symptoms of excessive sleepiness (excessive sedation) and passing out (loss of consciousness)
 - The need to be monitored for these effects at a Healthcare Setting for the entire 60 hours of infusion
 - I will tell my Healthcare Provider if I am having any of these signs of extreme sleepiness:
 - Feeling overly tired
 - Feeling like I cannot stay awake during normal activities
 - Feeling like I will pass out

I understand:

- I will be monitored for extreme sleepiness, passing out, and low oxygen levels in my body.
- This risk means that I must be accompanied during all interactions with my child(ren) for the entire time of the infusion.
- My personal information will be shared to enroll me in the ZULRESSO REMS.
- Sage Therapeutics, Inc. and its agents, may contact me by phone, mail, or email to manage the ZULRESSO REMS.
- Sage Therapeutics, Inc. and its agents, may use and share my personal health information to manage the ZULRESSO REMS, including enrolling me into and managing the ZULRESSO REMS, coordinating the dispensing of ZULRESSO, and releasing and sharing my personal health information to the U.S. Food and Drug Administration (FDA), as necessary.

SIGN
HERE

DATE
HERE

Date (MM/DD/YYYY)

PRESCRIBER INFORMATION

First Name	Last Name
Prescriber National Provider Identifier (NPI#)	Prescriber Credentials <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other
DEA Number	Prescriber Specialty <input type="checkbox"/> Psychiatry <input type="checkbox"/> OB/GYN <input type="checkbox"/> Family Practice <input type="checkbox"/> Other
	Phone Number

ADMINISTERING HEALTHCARE SETTING INFORMATION (Healthcare Provider is the person who is assisting the patient with completing this form.)

Healthcare Setting Name		Specific Department/Location
Healthcare Provider First Name	Healthcare Provider Last Name	Title
Address 1		Address 2
City	State	ZIP
Phone Number	Fax Number	
A Pharmacy Outside My Institution Will Be Utilized to Prepare ZULRESSO for This Patient <input type="checkbox"/>		
Scheduled Infusion Start Date, If Known (MM/DD/YYYY)		

SIGN
HERE

DATE
HERE

Date (MM/DD/YYYY)

Please visit www.zulressorems.com or call 844-472-4379 for more information about the ZULRESSO REMS.



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ZULRESSO™ REMS Pharmacy Enrollment Form

INSTRUCTIONS

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 completed form online to the ZULRESSO REMS through the REMS Website at www.zulressorems.com, by fax to 833-564-7243, or by email to information@zulressorems.com. You can also mail this form to 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27617.

PHARMACY INFORMATION

Pharmacy Name		Pharmacy Type: <input type="checkbox"/> Specialty <input type="checkbox"/> Specialty Infusion <input type="checkbox"/> Compounding <input type="checkbox"/> Other	
National Council for Prescription Drug Program ID (NCPDP)	Pharmacy DEA Number	National Provider Identifier (NPI #)	
Address			
City	State	ZIP	

Your Pharmacy information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Pharmacy to purchase product.

AUTHORIZED REPRESENTATIVE INFORMATION

Name		Title	
Credentials		Reason for Form: <input type="checkbox"/> New Enrollment <input type="checkbox"/> New Representative	
Phone Number	Fax Number	Email Address	
Address			
City	State	ZIP	

PHARMACY ATTESTATIONS

As the Authorized Pharmacy Representative, I attest that:

- I have reviewed the *Program Overview*.
- I must complete the *Pharmacy Enrollment Form* and submit it to the ZULRESSO REMS.
- I agree to train all relevant staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting.
- I agree to put processes and procedures in place to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS.
- I agree not to distribute, transfer, loan, or sell ZULRESSO.
- I will maintain records documenting staff's completion of training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, and number of vials.
- I will comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics to ensure that all processes and procedures are in place and are being followed.

SIGN
HERE

DATE
HERE

Date (MM/DD/YYYY)

ZULRESSO™ REMS Pharmacy Enrollment Form

ADDITIONAL PHARMACY LOCATIONS TO BE ENROLLED (OPTIONAL)

Pharmacy Location Name		Pharmacy Type: <input type="checkbox"/> Specialty <input type="checkbox"/> Specialty Infusion <input type="checkbox"/> Compounding <input type="checkbox"/> Other	
National Council for Prescription Drug Program ID (NCPDP)	Pharmacy DEA Number	National Provider Identifier (NPI #)	
Address			
City	State	ZIP	

Pharmacy Location Name		Pharmacy Type: <input type="checkbox"/> Specialty <input type="checkbox"/> Specialty Infusion <input type="checkbox"/> Compounding <input type="checkbox"/> Other	
National Council for Prescription Drug Program ID (NCPDP)	Pharmacy DEA Number	National Provider Identifier (NPI #)	
Address			
City	State	ZIP	

Pharmacy Location Name		Pharmacy Type: <input type="checkbox"/> Specialty <input type="checkbox"/> Specialty Infusion <input type="checkbox"/> Compounding <input type="checkbox"/> Other	
National Council for Prescription Drug Program ID (NCPDP)	Pharmacy DEA Number	National Provider Identifier (NPI #)	
Address			
City	State	ZIP	

Please visit www.zulressoems.com or call 844-472-4379 for more information about the ZULRESSO REMS.



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Training for Healthcare Settings

What Is ZULRESSO™ (brexanolone) injection?

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

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.

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.

How to Become a Certified Healthcare Setting (continued)

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.

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 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.

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.

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.

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).

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.

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.

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.

Resources

ZULRESSO REMS Resources

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

INSTRUCTIONS

1. Review the ZULRESSO REMS Training.
2. Complete this Knowledge Assessment and ZULRESSO REMS Healthcare Setting Enrollment Form.
3. Submit both pages of the Knowledge Assessment questions and the Healthcare Setting Enrollment Form online to the ZULRESSO REMS through the REMS Website at www.zulressorems.com, by fax to 833-564-7243 or by email to information@zulressorems.com. You can also mail this form to 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27617.

You will be notified via email about the status of your certification within 2 business days of submission.

When contacted, you will receive either:

- Confirmation of your certification in the ZULRESSO REMS

OR

- Instructions on how to retake the Healthcare Setting Knowledge Assessment

If you do not answer all 10 questions correctly in 3 attempts, you will be instructed to rereview the ZULRESSO REMS Training. Once reviewed, you will have an opportunity to retake the Healthcare Setting Knowledge Assessment.

HEALTHCARE SETTING INFORMATION

Healthcare Setting Name		Department	
Site Type: <input type="checkbox"/> Hospital <input type="checkbox"/> Infusion Center <input type="checkbox"/> Other			
National Provider Identifier (NPI) #		Phone Number (Area Code/Telephone Number)	
Address			
City	State	ZIP	

AUTHORIZED REPRESENTATIVE INFORMATION

First Name		Last Name	
National Provider Identifier (NPI) #			
Phone Number (Area Code/Telephone Number)		Fax Number (Area Code/Fax Number)	
Email			

Please visit www.zulressorems.com or call 844-472-4379 for more information about the ZULRESSO REMS.

QUESTIONS 1-10

1. The approved indication for ZULRESSO is for adults with:
 - a. Migraine
 - b. Liver failure
 - c. Postpartum depression
 - d. Relapsing multiple sclerosis
 - e. Bipolar depression
2. A Healthcare Setting can administer ZULRESSO to a patient before certifying in the ZULRESSO REMS.
 - a. True
 - b. False
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 enroll 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 enrolled in the ZULRESSO REMS and completes the Healthcare Setting Knowledge Assessment
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(ren) while receiving the infusion
5. During the administration of ZULRESSO, staff at the Healthcare Setting must (check all that apply):
 - Continuously monitor pulse oximetry
 - Perform urinalysis every 24 hours
 - Provide monitoring of the patient every 2 hours
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 (planned)
 - Pulse oximeter indicates hypoxia
 - The patient has excessive sedation
 - The patient has loss of consciousness
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 only the Post Infusion Form
 - Complete both the Post Infusion Form and the Excessive Sedation and Loss of Consciousness Adverse Event Form
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 receives 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
9. After treatment with ZULRESSO, the Post Infusion Form must be sent to the ZULRESSO REMS within how many business days?
 - a. 3 business days
 - b. 7 business days
 - c. 15 business days
 - d. Not necessary to return
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.
 - a. True
 - b. False



What You Need to Know About ZULRESSO™ Patient Information Guide



Patients:

Your Healthcare Provider will go over this ZULRESSO REMS Patient Information Guide with you. It is important to ask any questions you may have. Keep this Guide for important information about ZULRESSO.



Healthcare Providers:

Counsel your patient with this Guide and give her a copy.

You and your Healthcare Provider have chosen ZULRESSO for your treatment. You can only get ZULRESSO at a ZULRESSO REMS certified Healthcare Setting, like a hospital or infusion center. Your Healthcare Provider has a list of sites where you can get ZULRESSO. Together, you can pick the one that works best for you.

What is ZULRESSO?

ZULRESSO is a medicine used to treat postpartum depression (PPD) in adults. Symptoms of PPD can start during or after pregnancy. Before receiving ZULRESSO, tell your Healthcare Provider if you are pregnant or think you may be pregnant. It is not known if ZULRESSO will harm your unborn baby.



How is ZULRESSO given?

ZULRESSO is given directly into your vein as an intravenous (IV) solution. This can also be called an infusion. The infusion lasts 60 hours without stopping. That's 2.5 days.

A trained Healthcare Provider will give you ZULRESSO at a ZULRESSO REMS certified Healthcare Setting. They will be able to help you with any side effects that might happen.



What are the serious risks of ZULRESSO?

- Risk of serious harm from extreme sleepiness (excessive sedation) or passing out (loss of consciousness) during the infusion

During the infusion, patients treated with ZULRESSO may get extremely sleepy. Sometimes they may not be easily awakened. This is different from normal sleep where you drift into sleep naturally and can wake up easily. Sudden loss of consciousness (passing out) can occur in some patients.

Because this could cause serious harm, you will be monitored during your treatment. Your Healthcare Provider will check you for symptoms of excessive sleepiness every 2 hours. Also, someone will need to care for your child(ren) and be in the room with you if you are with your child(ren) during the infusion.



What are the symptoms that I should be aware of?

It is important to tell your Healthcare Provider if you have any of the following symptoms while getting ZULRESSO:

- Feeling more sleepy than usual (you cannot stay awake when you are trying to stay awake)
- Having a hard time paying attention
- Having trouble following simple instructions
- Feeling lightheaded or dizzy or like you are going to pass out

These are not all the possible side effects of ZULRESSO. See the ZULRESSO Medication Guide for more information or talk to your Healthcare Provider further.



What should I do if I start to feel the symptoms listed above?

- If you're holding your baby, put your baby down.
- Sit or lie down.
- Tell your Healthcare Provider right away.

Your Healthcare Provider may stop your infusion with ZULRESSO. During clinical trials, once ZULRESSO was stopped, patients who passed out woke up after a short time. You and your Healthcare Provider will decide whether to continue ZULRESSO.



How should I prepare for my infusion?

- Work with your Healthcare Provider to choose a certified Healthcare Setting that works best for you.
- Find childcare for the 2.5 days of your treatment.
- Tell your Healthcare Provider about all the medicines you take.
- Especially tell your Healthcare Provider if you take:
 - Other antidepressants
 - Opioids
 - Other medicines that make you sleepy, such as benzodiazepines



What is a Risk Evaluation and Mitigation Strategy (REMS)?

REMS is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and prescribers must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of a REMS.



Why does ZULRESSO have a REMS?

ZULRESSO has a REMS because of the serious harm that could happen from extreme sleepiness or passing out during the infusion. You must be enrolled in the ZULRESSO REMS to get ZULRESSO.



What do I need to do to enroll in the ZULRESSO REMS?

- Complete the ZULRESSO REMS Patient Enrollment Form. Someone at the REMS certified Healthcare Setting will help you.
- Please look over and sign the Patient Enrollment Form.
- The information you provide will be stored in a database. The database is secure and private. The database is called the REMS Patient Registry. Information about all patients who get ZULRESSO in the United States will be stored in this database. Your personal information will only be used for the ZULRESSO REMS.

Additional questions

Talk with your Healthcare Provider if you would like more information.



If you have questions about the ZULRESSO REMS, visit www.zulressorems.com or call **844-472-4379**.

To report side effects, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 800-FDA-1088 or www.fda.gov/medwatch.

Zulresso[™]
(brexanolone) injection ^{IV}
for intravenous use



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ZULRESSO™ REMS Program Overview for Pharmacies

This Program Overview specifically applies to Pharmacies that dispense ZULRESSO that are not within the same institution as the certified Healthcare Setting.

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

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. ZULRESSO is available only through a restricted distribution program called the ZULRESSO REMS because of the **risk of serious harm resulting from excessive sedation and sudden loss of consciousness during the ZULRESSO infusion.**

ZULRESSO is intended for infusion only in a certified Healthcare Setting.

What are the ZULRESSO REMS requirements?

- 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 sudden loss of consciousness and the need for monitoring while ZULRESSO is administered.
- Enroll all patients in a registry.

How can a Pharmacy become enrolled in the ZULRESSO REMS?

In order to become enrolled, the Pharmacy must:

1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the ZULRESSO REMS on behalf of the Pharmacy, including:
 - Training all staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting
 - Establishing processes and procedures to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS
2. Have the Authorized Representative review this **Program Overview**.
3. Complete the **Pharmacy Enrollment Form** and submit it to the ZULRESSO REMS.
4. Verify, **prior to dispensing ZULRESSO**, that the Healthcare Setting is certified in the ZULRESSO REMS by calling the ZULRESSO REMS Coordinating Center at 844-472-4379.

Visit www.zulressorems.com to begin enrollment and for additional information.

You may also contact the ZULRESSO REMS at 844-472-4379.



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ZULRESSO™ REMS 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.

You can submit this form online to the ZULRESSO REMS through the REMS Website at www.zulressorems.com, by fax to 833-564-7243, or by email to information@zulressorems.com. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

PATIENT AND HEALTHCARE SETTING INFORMATION

All fields are required unless otherwise indicated.

Patient First Name	Middle Initial	Patient Last Name	
Patient Date of Birth (MM/DD/YYYY)		REMS ID	
Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to Be Administered (Include Address Below)			
Address		City	State ZIP
Phone Number		Email (Optional)	

HEALTHCARE PROVIDER (HCP) INFORMATION

All fields are required unless otherwise indicated.
The HCP identified below may be contacted for further information.

First Name	Last Name
Credentials: <input type="checkbox"/> MD/DO <input type="checkbox"/> NP/PA <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other	Specialty: <input type="checkbox"/> Psychiatry <input type="checkbox"/> OB/GYN <input type="checkbox"/> Family Practice <input type="checkbox"/> Other
Did the Patient Receive ZULRESSO? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, Please check all reasons that apply: <input type="checkbox"/> Logistical challenges <input type="checkbox"/> Change in treatment plan <input type="checkbox"/> Other If Yes, Please Complete Below	
Date Infusion Started (MM/DD/YYYY)	Time Infusion Started (24-Hour Clock HH:MM) :
Date Infusion Ended (MM/DD/YYYY)	Time Infusion Ended (24-Hour Clock HH:MM) :
Did the Patient Experience Loss of Consciousness While on ZULRESSO? <input type="checkbox"/> Yes <input type="checkbox"/> No	Did the Patient Experience Excessive Sedation While on ZULRESSO? <input type="checkbox"/> Yes <input type="checkbox"/> No
If You Answer Yes to Either of the Above Questions, Complete the Excessive Sedation and Loss of Consciousness Adverse Event Form*	
Administering HCP Signature	Date (MM/DD/YYYY)
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 any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc.
at 844-472-4379 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**



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ZULRESSO™ REMS Excessive Sedation and Loss of Consciousness Adverse Event Form

INSTRUCTIONS

ZULRESSO is only available through the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS). If a patient experienced an event of excessive sedation or loss of consciousness please complete and submit this form along with the Post Infusion Form within 3 business days of the patient completing the infusion.

You can submit this form online to the ZULRESSO REMS through the REMS Website at www.zulressoems.com, by fax to 833-564-7243, or by email to information@zulressoems.com. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

PATIENT INFORMATION

Patient First Name		Middle Initial	Patient Last Name
Patient Date of Birth (MM/DD/YYYY)			REMS ID
Healthcare Setting Where Zulresso Was Administered (Include Address Below)			
Address			
City		State	ZIP
Phone Number		Email (Optional)	

Height	ft	in	Weight	lb	Date of Delivery (MM/DD/YYYY)
Race (Mark One or More):					
<input type="checkbox"/> American Indian or Alaska Native		<input type="checkbox"/> Black or African American		<input type="checkbox"/> Asian	
<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		<input type="checkbox"/> White			
Delivery Information:			Live Birth:		
<input type="checkbox"/> Vaginal <input type="checkbox"/> Caesarean			<input type="checkbox"/> Yes <input type="checkbox"/> No		
History of:					
Postpartum Depression (With Prior Pregnancy):			Major Depressive Disorder:		
<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
Hypertension:		Hypotension/Fainting:		Substance/Alcohol Abuse:	
<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Is There Any Other Relevant Medical History? <input type="checkbox"/> Yes <input type="checkbox"/> No					
If Yes, Sage Therapeutics, Inc. Drug Safety Department will contact the site to collect additional medical history.					
Onset of Current Episode PPD Symptoms:					
<input type="checkbox"/> During Pregnancy			<input type="checkbox"/> After Delivery		
Concomitant Medications Currently Being Taken:					
<input type="checkbox"/> Oral Antidepressants <input type="checkbox"/> Benzodiazepines <input type="checkbox"/> Opioids <input type="checkbox"/> Hormonal Birth Control <input type="checkbox"/> Other: _____					
Were Clinical Labs Performed? <input type="checkbox"/> Yes <input type="checkbox"/> No					
If Yes, Sage Therapeutics, Inc. Drug Safety Department will contact the site to obtain the relevant lab information.					

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION

Event Type: <input type="checkbox"/> Excessive Sedation <input type="checkbox"/> Loss of Consciousness (LOC)	
Event Onset Date (MM/DD/YYYY)	Event Onset Time (24-Hour Clock HH:MM) :
Did the Event Resolve? <input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, Event Resolution Date (MM/DD/YYYY)
Event Resolution Time (24-Hour Clock HH:MM) :	
If Excessive Sedation or Loss of Consciousness Occurred What Was the Duration of the Event? <input type="checkbox"/> Less Than 5 Min <input type="checkbox"/> 5-15 Min <input type="checkbox"/> 15-30 Min <input type="checkbox"/> 30 Min-1 Hour <input type="checkbox"/> >1 Hour	
Dose of ZULRESSO at Time of Event (mcg/kg/h)	Was the Event Witnessed? <input type="checkbox"/> Yes <input type="checkbox"/> No
Was Infusion Stopped Due to Event? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If Yes, When: Infusion Stop Date (MM/DD/YYYY)	Infusion Stop Time (24-Hour Clock HH:MM) :
Was Infusion Restarted After the Event Resolved? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If Yes, When: Infusion Restart Date (MM/DD/YYYY)	Infusion Restart Time (24-Hour Clock HH:MM) :

ZULRESSO™ REMS Excessive Sedation and Loss of Consciousness Adverse Event Form

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION (CONT'D)

Dose of ZULRESSO Restarted (mcg/kg/h)		Did the Patient Complete the Infusion? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Was There a Desaturation Event Noted on Pulse Oximetry? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Vital Signs Prior to Infusion (if Available)			
Date (MM/DD/YYYY)		Time (24-Hour Clock HH:MM) :	
Heart Rate (BPM)	BP (mmHg) /	Respiratory Rate (Breaths/Minute)	O ₂ Saturation (%)
Vital Signs at Time (or Closest to Time) of the Event			
Date (MM/DD/YYYY)		Time (24-Hour Clock HH:MM) :	
Heart Rate (BPM)	BP (mmHg) /	Respiratory Rate (Breaths/Minute)	O ₂ Saturation (%)
Did the Event Result in a Fall? <input type="checkbox"/> Yes <input type="checkbox"/> No		Did the Event Result in an Injury? <input type="checkbox"/> Yes <input type="checkbox"/> No	
What Was the Patient's Position at the Time of the Event? <input type="checkbox"/> Supine <input type="checkbox"/> Sitting <input type="checkbox"/> Standing			
What Was the Patient's Activity at the Time of the Event? <input type="checkbox"/> Eating/Drinking <input type="checkbox"/> Awake <input type="checkbox"/> Resting <input type="checkbox"/> Sleeping <input type="checkbox"/> Other: _____			
During the Event Indicate the Minimum Stimulus to Elicit a Response From the Patient: <input type="checkbox"/> Voice <input type="checkbox"/> Light Touch <input type="checkbox"/> Deep Touch <input type="checkbox"/> Pain <input type="checkbox"/> Did Not Respond			
Within 2 Hours Prior to the Event Did the Patient Report Symptoms of: <input type="checkbox"/> Somnolence <input type="checkbox"/> Sedation <input type="checkbox"/> Dizziness <input type="checkbox"/> Vertigo <input type="checkbox"/> Other: _____			
Did the Event Need Treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, Please Provide Treatment Information in the Section Below.			
Please Include Additional Information Regarding the Event That Is Not Captured Above (Including Other Symptoms Preceding the Event, Location/Activities During the Onset of Event, Treatment for the Event [If Applicable], and Any Other Details Thought to Be Relevant or Resulting From the Event [eg, Falls, Injury]). If More Space Is Needed, Please Attach Additional Sheets.			
Did the Patient Have More Than One Event of Excessive Sedation or LOC Event During the Infusion? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, Please Include Additional Copies of This Form for Each Event.			

HEALTHCARE PROVIDER (HCP) INFORMATION

All fields are required unless otherwise indicated.
The HCP identified below may be contacted for further information.

First Name	Last Name
Administering HCP Signature	Date (MM/DD/YYYY)
HCP Email (Optional)	HCP Phone Number

The Sage Therapeutics, Inc. Drug Safety Department may follow up to obtain more information about these events.

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.

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.



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ZULRESSO™ Risk Evaluation and Mitigation Strategy (REMS)

Sage Therapeutics / 215 First Street / Cambridge, MA 02142 / P: 1-844-472-4379 / F: 1-833-564-7243 / E: information@zulressorems.com / M-F, 8AM-8PM ET

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.



ZULRESSO, the ZULRESSO logo, SAGE THERAPEUTICS, and the SAGE THERAPEUTICS logo are trademarks of Sage Therapeutics, Inc. All other trademarks referenced herein are the properties of their respective owners.
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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.



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

[ENROLL IN THE ZULRESSO REMS >](#)



Patients

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

[HOW TO RECEIVE ZULRESSO >](#)



Healthcare Professionals

1. Review education materials

[LEARN ABOUT ZULRESSO >](#)



Forms and Resources

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

[VIEW RESOURCES >](#)

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 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 module on this site as well as the Prescribing Information.

Download



TRAINING FOR HEALTHCARE SETTINGS



PRESCRIBING INFORMATION

Online



LOGIN/REGISTER



STEP 3

Complete

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

Email/Fax/Mail



HEALTHCARE SETTING KNOWLEDGE ASSESSMENT

Online



LOGIN/REGISTER



STEP 4

Complete

Complete the ZULRESSO REMS Healthcare Setting Enrollment Form.

Email/Fax/Mail



HEALTHCARE SETTING ENROLLMENT FORM

Online



LOGIN/REGISTER



STEP 5

Submit

If you haven't completed the forms 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@zulressorems.com, via fax at 833-564-7243, or mailed to the ZULRESSO REMS at 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27617.

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.

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 Administration

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

Before Administering ZULRESSO



STEP 1 Counsel

Counsel the patients 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](#).

Completed forms can be faxed to the ZULRESSO REMS at 833-564-7243, emailed to the ZULRESSO REMS at information@zulessorems.com, or mailed to the ZULRESSO REMS at 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27817.



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 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 Excessive Sedation and Loss of Consciousness Adverse Event Form. You will be contacted for further information on reported events by the ZULRESSO REMS.

How to Submit

- Submit the Post Infusion Form and, if need be, 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 start date
- You can only submit an Excessive Sedation and Loss of Consciousness Adverse Event Form with a completed Post Infusion Form

The Post Infusion Form and the Excessive Sedation and Loss of Consciousness Adverse Event Form can be completed via securely logging into this website, faxed to the ZULRESSO REMS at 833-564-7243 or emailed to information@zulessorems.com.

By Fax/Email



POST INFUSION FORM



EXCESSIVE SEDATION AND LOSS OF CONSCIOUSNESS ADVERSE EVENT FORM

Online



LOGIN/REGISTER

To report any other adverse events contact Sage Therapeutics at 844-472-4379 or FDA at 800-FDA-1088 or www.fda.gov/medwatch.

Contact the ZULRESSO REMS at 844-472-4379 to obtain contact information for certified Pharmacies and for distributors who are authorized to ship to certified inpatient Pharmacies.

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 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](#).



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@zulressorems.com, via fax at 833-564-7243, or mailed to the ZULRESSO REMS at 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27617.

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

<p>Email/Fax/Mail</p>  <p>PHARMACY ENROLLMENT FORM</p>	<p>Online</p>  <p>PHARMACY ENROLLMENT FORM</p>
---	--



STEP 4
Establish

Establish processes and procedures to ensure ZULRESSO is dispensed only to a certified Healthcare Setting enrolled in the ZULRESSO REMS Program.

[HEALTHCARE SETTINGS LIST](#) >



STEP 5
Train

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

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" 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" 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#)

1234567890

* Pharmacy Name

* Pharmacy Type

- Specialty
 Specialty Infusion
 Compounding
 Other

* National Council for Prescription Drug Program ID (NCPDP)

* Pharmacy DEA Number

* Address 1

Address 2

* City

* State

– Please Select –

* ZIP

Click below to enroll an additional Pharmacy location (optional)

[+ ADDITIONAL PHARMACY LOCATION](#)

Your Pharmacy information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Pharmacy to purchase product.

AUTHORIZED REPRESENTATIVE INFORMATION

* First Name

MI

* Last Name

* Title

* Credentials

* Reason for Form

- New Enrollment
 New Representative

* Phone Number

* Fax Number

* Email Address

* Address 1

Address 2

* City

* State

– Please Select –

* ZIP

PHARMACY ATTESTATIONS

As the Authorized Pharmacy Representative, I attest that:

- I have reviewed the *Program Overview*.
- I must complete the *Pharmacy Enrollment Form* and submit it to the ZULRESSO REMS
- I agree to train all relevant staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting.
- I agree to put processes and procedures in place to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS.
- I agree not to distribute, transfer, loan or sell ZULRESSO.
- I will maintain records documenting staff's completion of training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, and number of vials.
- I will comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics to ensure that all processes and procedures are in place and are being followed.

* Signature:

CANCEL

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" 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#)

1234567890

* Pharmacy Name

* Pharmacy Type

Specialty Specialty Infusion Compounding Other

* National Council for Prescription Drug Program ID (NCPDP)

* Pharmacy DEA Number

* Address 1

Address 2

* City

* State

— Please Select —

* ZIP

* National Provider Identifier (NPI#)

CONTINUE

Click below to enroll an additional Pharmacy location (optional)

+ ADDITIONAL PHARMACY LOCATION

Your Pharmacy information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Pharmacy to purchase product.

AUTHORIZED REPRESENTATIVE INFORMATION

* First Name

MI

* Last Name

* Title

* Credentials

* Reason for Form

New Enrollment New Representative

* Phone Number

* Fax Number

* Email Address

* Address 1

Address 2

* City

* State

— Please Select —

* ZIP

PHARMACY ATTESTATIONS

As the Authorized Pharmacy Representative, I attest that:

- I have reviewed the *Program Overview*.
- I must complete the *Pharmacy Enrollment Form* and submit it to the ZULRESSO REMS
- I agree to train all relevant staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting.
- I agree to put processes and procedures in place to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS.
- I agree not to distribute, transfer, loan or sell ZULRESSO.
- I will maintain records documenting staff's completion of training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, and number of vials.
- I will comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics to ensure that all processes and procedures are in place and are being followed.

* Signature:

CANCEL

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" 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#)

1234567890

* Pharmacy Name

* Pharmacy Type

Specialty Specialty Infusion Compounding Other

* National Council for Prescription Drug Program ID (NCPDP)

* Pharmacy DEA Number

* Address 1

Address 2

* City

* State

* ZIP

* National Provider Identifier (NPI#)

9999999999

CONTINUE

Pharmacy Location Name

* Pharmacy Type

Specialty Specialty Infusion Compounding Other

* National Council for Prescription Drug Program ID (NCPDP)

* Pharmacy DEA Number

* Address 1

Address 2

* City

* State

* ZIP

X REMOVE PHARMACY

Click below to enroll an additional Pharmacy location (optional)

+ ADDITIONAL PHARMACY LOCATION

Your Pharmacy information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Pharmacy to purchase product.

AUTHORIZED REPRESENTATIVE INFORMATION

* First Name

MI

* Last Name

* Title

* Credentials

* Reason for Form

New Enrollment New Representative

* Phone Number

* Fax Number

* Email Address

* Address 1

Address 2

* City

* State

* ZIP

PHARMACY ATTESTATIONS

As the Authorized Pharmacy Representative, I attest that:

- I have reviewed the *Program Overview*.
- I must complete the *Pharmacy Enrollment Form* and submit it to the ZULRESSO REMS
- I agree to train all relevant staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting.
- I agree to put processes and procedures in place to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS.
- I agree not to distribute, transfer, loan or sell ZULRESSO.
- I will maintain records documenting staff's completion of training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, and number of vials.
- I will comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics to ensure that all processes and procedures are in place and are being followed.

* Signature:

CANCEL

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.



Healthcare Settings

Pharmacies

Patients

Healthcare Professionals

Forms and Resources

Healthcare Setting Locator

LOG IN

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.



PATIENT INFORMATION GUIDE



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>.


[Healthcare Settings](#)
[Pharmacies](#)
[Patients](#)
[Healthcare Providers](#)
[Forms and Resources](#)
[Healthcare Setting Locator](#)
[LOG IN](#)

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.



LETTER FOR
HEALTHCARE
PROVIDERS



PRESCRIBING
INFORMATION



PATIENT
INFORMATION
GUIDE

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.



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 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](#)

Certification Materials

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

Administration Materials

- ↓ PATIENT INFORMATION GUIDE
- ↓ PATIENT ENROLLMENT FORM
- ↓ POST INFUSION FORM
- ↓ EXCESSIVE SEDATION AND LOSS OF CONSCIOUSNESS ADVERSE EVENT FORM



Materials for Pharmacies

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

- ↓ REMS 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.



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>.



Healthcare Setting Locator

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

FULL HEALTHCARE SETTING LISTING
View, filter and download all locations

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.

Find a Healthcare Setting near Within 25 miles SEARCH

HEALTHCARE SETTING NAME 3.2 miles Directions

100 Main St
Blue Bell, PA 19042
555 555-1212

HEALTHCARE SETTING NAME 3.2 miles Directions

100 Main St
Blue Bell, PA 19042
555 555-1212

HEALTHCARE SETTING NAME 3.2 miles Directions

100 Main St
Blue Bell, PA 19042
555 555-1212

HEALTHCARE SETTING NAME 3.2 miles Directions

100 Main St

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. Users are responsible for compliance with all state and federal laws and regulations.

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

Name	Phone Number	Fax Number
Test Healthcare Setting	546-546-4545	564-564-5646

Please see [Prescribing Information](#), including **BOXED WARNING**.



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[Healthcare Settings](#)
[Pharmacies](#)
[Patients](#)
[Healthcare Providers](#)
[Forms and Resources](#)
[Healthcare Setting Locator](#)
[LOG IN](#)

Login

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

Login

Please enter your User Name.

Your user name was provided to you following enrollment and/or certification in the ZULRESSO REMS.

[LOG IN](#)
[Forgot Username](#)

OR

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

[CONTINUE](#)

Please see [Prescribing Information](#), including BOXED WARNING.



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* NPI Number

* First Name

* Last Name

* Phone Number

* Email Address

CONTINUE

Please see [Prescribing Information](#), including BOXED WARNING.



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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.

[LOGIN](#)

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.

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[Patients](#)
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Login is available to certified Healthcare Settings in the ZULRESSO REMS.

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[LOG IN](#)
[Forgot Username](#)

OR

Don't have an online account?

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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

[CONTINUE](#)

Please see [Prescribing Information](#), including BOXED WARNING.



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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



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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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



Training for Healthcare Settings

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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



What Is ZULRESSOTM (brexanolone) injection?

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

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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.**

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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



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 overdose with ZULRESSO. In premarketing clinical studies, two cases of accidental overdose 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.**

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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.

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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.

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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



How to Become a Certified Healthcare Setting (continued)

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.

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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.

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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



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 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.

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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.

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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.

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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.

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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.

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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



Ordering Instructions

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ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



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.

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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.zulressoems.com or call the ZULRESSO REMS at 844-472-4379. The resources below are available for download at www.zulressoems.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.



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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 Certification

Please complete the following Healthcare Setting Knowledge Assessment and click "Submit".



ZULRESSO[™] REMS Healthcare Setting Knowledge Assessment

You are required to answer all questions correctly in order to pass the assessment.

You have **3** attempt(s) to answer all questions correctly.

If you do not answer all 10 questions correctly in 3 attempts, you will be instructed to rereview the ZULRESSO REMS Training for Healthcare Settings. Once reviewed, you will have an opportunity to retake the Healthcare Setting Knowledge Assessment.

Question 1:

The approved indication for ZULRESSO is for adults 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 enroll 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 enrolled 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(ren) 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 urinalysis every 24 hours
- Provide monitoring of the patient every 2 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 (planned)
- 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 only the Post Infusion 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 receives 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
- 15 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

ZULRESSO REMS Healthcare Setting Certification



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.

[COMPLETE ONLINE ENROLLMENT](#)

ZULRESSO REMS Healthcare Setting Certification



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".

[REVIEW TRAINING SLIDES](#)

[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.

[REVIEW TRAINING SLIDES](#)

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

Hospital Infusion Center Other

List All Associated National Provider Identifiers (NPI #s)

Associated National Provider Identifier (NPI #)

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

[+ ADD ASSOCIATED NPI #](#)

* Healthcare Setting Name

* Healthcare Setting DEA Number

* Address 1

Address 2

* City

* State

-- Please Select --

* 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.

[+ ADD HEALTHCARE SETTING](#)

AUTHORIZED REPRESENTATIVE INFORMATION

* First Name

MI

* Last Name

* Title

* Credentials

Physician Physician Assistant
 Nurse Practitioner Nurse Pharmacist
 Other

* Reason for Form

New Enrollment New Representative

* Phone Number

* Fax Number

* Email Address

* Address 1

Address 2

* City

* State

-- Please Select --

* ZIP

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 at 844-472-4379

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 agree to train all relevant staff involved in prescribing, dispensing, and administering ZULRESSO on the ZULRESSO REMS requirements using the *Training Program*.
- I will establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering ZULRESSO to ensure they are trained.
- I will establish processes and procedures to enroll the patient in the ZULRESSO REMS by completing and submitting the *Patient Enrollment Form* to the ZULRESSO REMS.
- I will establish processes and procedures to counsel the patient and verify the patient is enrolled in the ZULRESSO REMS before administration.
- I will establish processes and procedures to submit the *Post Infusion Form* and if needed the *Excessive Sedation and Loss of Consciousness Adverse Event Form* to the ZULRESSO REMS.
- On behalf of the Healthcare Setting, we will comply with the following REMS requirements:
 - Before dispensing:
 - Enroll the patient by completing and submitting the *Patient Enrollment Form* to the ZULRESSO REMS.
 - Before administering:
 - Counsel the patient on the signs and symptoms of excessive sedation, loss of consciousness, and the importance of immediately reporting to a healthcare professional any signs and symptoms of excessive sedation using the *Patient Information Guide*. Provide a copy of the material to the patient.
 - During treatment, (60 hours):
 - Every 2 hours during planned, non-sleep periods:
 - Assess the patient's health status for signs and symptoms of excessive sedation and loss of consciousness.
 - Assess the patient's oxygen saturation using continuous pulse oximetry.
 - After treatment discontinuation, and prior to discharge:
 - Assess the patient's level of sedation.
 - After treatment discontinuation, within 3 business days of scheduled completion date:
 - Document and submit the patient's infusion outcome to the ZULRESSO REMS using the *Post Infusion Form*.
 - Report excessive sedation or loss of consciousness to the ZULRESSO REMS using the *Excessive Sedation and Loss of Consciousness Adverse Event Form*.
- Not distribute, transfer, loan or sell ZULRESSO
- Maintain records documenting staff's completion of training.
- Maintain records that all REMS processes and procedures are in place and are being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, number of vials, and date administered.
- Comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics, 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 continuously for the duration of the infusion
- Have the following onsite: continuous pulse oximetry, fall precaution protocol, intravenous programmable infusion pumps with alarms to alert when the pump malfunctions. Healthcare Providers to be continuously available on site to monitor the patient and intervene as necessary
- Ensure that if the Healthcare Setting designates a new Authorized Representative, the new Authorized Representative will enroll in the ZULRESSO REMS by successfully completing the *Healthcare Setting Knowledge Assessment* and *Healthcare Setting Enrollment Form* and submitting both to the 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
 Hospital Infusion Center Other

List All Associated National Provider Identifiers (NPI #s)

Associated National Provider Identifier (NPI #)

Associated National Provider Identifier (NPI #)
 X REMOVE

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

+ ADD ASSOCIATED 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.

+ ADD HEALTHCARE SETTING

AUTHORIZED REPRESENTATIVE INFORMATION

*First Name

MI

*Last Name

*Title

*Credentials
 Physician Physician Assistant
 Nurse Practitioner Nurse Pharmacist
 Other

*Reason for Form
 New Enrollment New Representative

*Phone Number

*Fax Number

*Email Address

*Address 1

Address 2

*City

*State

*ZIP

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 at 844-472-4379

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 agree to train all relevant staff involved in prescribing, dispensing, and administering ZULRESSO on the ZULRESSO REMS requirements using the *Training Program*.
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*Signature:

CANCEL CONTINUE

ZULRESSO REMS Healthcare Setting Certification



ZULRESSO™ REMS Certified Healthcare Setting Enrollment Form

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* Indicates Required Field

HEALTHCARE SETTING INFORMATION

* National Provider Identifier (NPI#)

* Site Type
 Hospital Infusion Center Other

List All Associated National Provider Identifiers (NPI #s)

Associated National Provider Identifier (NPI #)

Associated National Provider Identifier (NPI #)
 X REMOVE

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

+ ADD ASSOCIATED 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

* National Provider Identifier (NPI#)

CONTINUE

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.

+ ADD HEALTHCARE SETTING

AUTHORIZED REPRESENTATIVE INFORMATION

* First Name

MI

* Last Name

* Title

* Credentials
 Physician Physician Assistant
 Nurse Practitioner Nurse Pharmacist
 Other

* Reason for Form
 New Enrollment New Representative

* Phone Number

* Fax Number

* Email Address

* Address 1

Address 2

* City

* State

* ZIP

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* Signature:

CANCEL
CONTINUE

ZULRESSO REMS Healthcare Setting Certification



ZULRESSO™ REMS Certified Healthcare Setting Enrollment Form

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

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* Indicates Required Field

HEALTHCARE SETTING INFORMATION

*National Provider Identifier (NPI#) *Site Type
 Hospital Infusion Center Other

List All Associated National Provider Identifiers (NPI #s)

Associated National Provider Identifier (NPI #)

 Associated National Provider Identifier (NPI #)
 REMOVE

Click below to enter an additional Associated National Provider Identifier (NPI #)
+ ADD ASSOCIATED 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

*National Provider Identifier (NPI#)

 *Site Type
 Hospital Infusion Center Other

List All Associated National Provider Identifiers (NPI #s)
 Associated National Provider Identifier (NPI #)

 Click below to enter an additional Associated National Provider Identifier (NPI #)
+ ADD ASSOCIATED NPI #

*Healthcare Setting Name *Healthcare Setting DEA Number
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 *Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy
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REMOVE HEALTHCARE SETTING

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.

+ ADD HEALTHCARE SETTING

AUTHORIZED REPRESENTATIVE INFORMATION

*First Name MI *Last Name *Title
 *Credentials
 Physician Physician Assistant
 Nurse Practitioner Nurse Pharmacist
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 *Reason for Form
 New Enrollment New Representative
 *Phone Number *Fax Number *Email Address
 *Address 1 Address 2
 *City *State *ZIP

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*Signature:

CANCEL **CONTINUE**

ZULRESSO REMS Healthcare Setting Certification



You have successfully completed and submitted the ZULRESSO REMS Certified Healthcare Setting Enrollment Form.

You are now certified in the ZULRESSO REMS.

CONTINUE

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

*Heathcare Setting

Healthcare Facility 1 ▾



REMS ID	First Name	Last Name	Date of Birth	Healthcare Setting	Status	Action	Patient Authorization
12345	Peggy	Sue	1/1/2000	Healthcare Facility 1	Enrolled	SUBMIT A POST INFUSION FORM	GENERATE PATIENT ENROLLMENT NOTIFICATION



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

*Heathcare Setting

Healthcare Facility 2 ▾



REMS ID	First Name	Last Name	Date of Birth	Healthcare Setting	Status	Action	Patient Authorization
98765	Robert	Peterson	1/1/2000	Healthcare Facility 2	Enrolled	SUBMIT A POST INFUSION FORM	GENERATE PATIENT ENROLLMENT NOTIFICATION



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

HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

*First Name <input type="text"/>	*Last Name <input type="text"/>
-------------------------------------	------------------------------------

*Credentials <input type="checkbox"/> MD/DO <input type="checkbox"/> NP/PA <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other	*Specialty <input type="checkbox"/> Psychiatry <input type="checkbox"/> OB/GYN <input type="checkbox"/> Family Practice <input type="checkbox"/> Other
---	---

*Did the Patient Receive ZULRESSO?
 Yes No

*Administering HCP Signature:

HCP Email (Optional) <input type="text"/>	*HCP Phone Number <input type="text"/>
--	---

*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

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Patient Date of Birth (MM/DD/YYYY): 1/1/2000	City: Malvern	State: PA	ZIP: 19542
REMS ID: 1234567890	Phone Number: 555 555-1212		
	Email: abc@abc.com		

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) *Time Infusion Started (24-Hour Clock HH:MM)

*Date Infusion Ended (MM/DD/YYYY) *Time Infusion Ended (24-Hour Clock HH:MM)

*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.zulressoems.com or call 844-472-4379.

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*First Name	<input type="text"/>	*Last Name	<input type="text"/>
*Credentials	<input type="checkbox"/> MD/DO <input type="checkbox"/> NP/PA <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other	*Specialty	<input type="checkbox"/> Psychiatry <input type="checkbox"/> OB/GYN <input type="checkbox"/> Family Practice <input type="checkbox"/> Other
*Did the Patient Receive ZULRESSO?			
<input checked="" type="radio"/> Yes <input type="radio"/> No			
*Date Infusion Started (MM/DD/YYYY)	<input type="text"/>	*Time Infusion Started (24-Hour Clock HH:MM)	<input type="text"/>
*Date Infusion Ended (MM/DD/YYYY)	<input type="text"/>	*Time Infusion Ended (24-Hour Clock HH:MM)	<input type="text"/>
*Did the Patient Experience Loss of Consciousness While on ZULRESSO?			
<input checked="" type="radio"/> Yes <input type="radio"/> No			
*Did the Patient Experience Excessive Sedation While on ZULRESSO?			
<input checked="" type="radio"/> Yes <input type="radio"/> No			

If You Answer Yes to Either of the Above Questions, Complete the Excessive Sedation and Loss of Consciousness Adverse Event Form*

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS ADVERSE EVENT SECTION

Please complete the following

ADDITIONAL PATIENT INFORMATION

*Height (feet/inches)	<input type="text"/>	*Weight (lbs)	<input type="text"/>	*Date of Delivery (MM/DD/YYYY)	<input type="text"/>
*Race (Mark One or More)					
<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White					
*Delivery Information			*Live Birth		
<input type="radio"/> Vaginal <input type="radio"/> Caesarean			<input type="radio"/> Yes <input type="radio"/> No		
History of:					
*Postpartum Depression (with Prior Pregnancy)			*Major Depressive Disorder		
<input type="radio"/> Yes <input type="radio"/> No			<input type="radio"/> Yes <input type="radio"/> No		
*Hypertension			*Hypotension/Fainting		
<input type="radio"/> Yes <input type="radio"/> No			<input type="radio"/> Yes <input type="radio"/> No		
*Substance/Alcohol Abuse			<input type="radio"/> Yes <input type="radio"/> No		
*Is There Any Other Relevant Medical History?					
<input type="radio"/> Yes <input type="radio"/> No					
*Onset of Current Episode PPD Symptoms			*Concomitant Medications Currently Being Taken		
<input type="radio"/> During Pregnancy <input type="radio"/> After Delivery			<input type="checkbox"/> Oral Antidepressants <input type="checkbox"/> Benzodiazepines <input type="checkbox"/> Opioids		
			<input type="checkbox"/> Hormonal Birth Control <input type="checkbox"/> Other		
*Were Clinical Labs Performed?					
<input type="radio"/> Yes <input type="radio"/> No					

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION

*Event Type	
<input type="radio"/> Excessive Sedation <input type="radio"/> Loss of Consciousness (LOC)	
*Event Onset Date (MM/DD/YYYY)	*Event Onset Time (24-Hour Clock HH:MM)
<input type="text"/>	<input type="text"/>
*Did the Event Resolve?	
<input type="radio"/> Yes <input type="radio"/> No	
*If Excessive Sedation or Loss of Consciousness Occurred What Was the Duration of the Event?	
<input type="radio"/> Less than 5 Min <input type="radio"/> 5-15 Min <input type="radio"/> 15-30 Min <input type="radio"/> 30 Min - 1 Hour <input type="radio"/> >1 Hour	
*Dose of ZULRESSO at Time of Event (mcg/kh/h)	*Was the Event Witnessed?
<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
*Was Infusion Stopped Due to Event?	
<input type="radio"/> Yes <input type="radio"/> No	
*Was Infusion Restarted After the Event Resolved?	
<input type="radio"/> Yes <input type="radio"/> No	
*Was There a Desaturation Event Noted on Pulse Oximetry?	
<input type="radio"/> Yes <input type="radio"/> No	

Vital Signs Prior to Infusion (if Available)

Date (MM/DD/YYYY)	<input type="text"/>	Time (24-Hour Clock HH:MM)	<input type="text"/>
Heart Rate (BPM)	<input type="text"/>	BP (mmHg)	<input type="text"/>
Respiratory Rate (Breaths/Minute)	<input type="text"/>	O₂ Saturation (%)	<input type="text"/>

Vital Signs at Time (or Closest to Time) of the Event

*Date (MM/DD/YYYY)	<input type="text"/>	*Time (24-Hour Clock HH:MM)	<input type="text"/>
*Heart Rate (BPM)	<input type="text"/>	*BP (mmHg)	<input type="text"/>
*Respiratory Rate (Breaths/Minute)	<input type="text"/>	*O₂ Saturation (%)	<input type="text"/>

*Did the Event Result in a Fall?	<input type="radio"/> Yes <input type="radio"/> No	*Did the Event Result in an Injury?	<input type="radio"/> Yes <input type="radio"/> No
*What Was the Patient's Position at the Time of the Event?			
<input type="radio"/> Supine <input type="radio"/> Sitting <input type="radio"/> Standing			
*What was the Patient's Activity at the Time of the Event?			
<input type="checkbox"/> Eating/Drinking <input type="checkbox"/> Awake <input type="checkbox"/> Resting <input type="checkbox"/> Sleeping <input type="checkbox"/> Other			
*During the Event Indicate the Minimum Stimulus to Elicit a Response From the Patient			
<input type="radio"/> Voice <input type="radio"/> Light Touch <input type="radio"/> Deep Touch <input type="radio"/> Pain <input type="radio"/> Did Not Respond			
*Within 2 Hours Prior to the Event Did the Patient Report Symptoms of			
<input type="checkbox"/> Somnolence <input type="checkbox"/> Sedation <input type="checkbox"/> Dizziness <input type="checkbox"/> Vertigo <input type="checkbox"/> Other			
*Did the Event Need Treatment?			
<input type="radio"/> Yes <input type="radio"/> No			
*Did the Patient Have More Than One Event of Excessive Sedation or LOC Event During the Infusion?			
<input type="radio"/> Yes <input type="radio"/> No			

***Administering HCP Signature:**

HCP Email (Optional)	<input type="text"/>	*HCP Phone Number	<input type="text"/>
-----------------------------	----------------------	--------------------------	----------------------

*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, Address 2: , City: Malvern, State: PA, ZIP: 19542, Phone Number: 555 555-1212, Email: abc@abc.com

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?, *Date Infusion Started (MM/DD/YYYY), *Time Infusion Started (24-Hour Clock HH:MM), *Date Infusion Ended (MM/DD/YYYY), *Time Infusion Ended (24-Hour Clock HH:MM), *Did the Patient Experience Loss of Consciousness While on ZULRESSO?, *Did the Patient Experience Excessive Sedation While on ZULRESSO?, If You Answer Yes to Either of the Above Questions, Complete the Excessive Sedation and Loss of Consciousness Adverse Event Form*

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS ADVERSE EVENT SECTION

Please complete the following

ADDITIONAL PATIENT INFORMATION

*Height (feet/inches), *Weight (lbs), *Date of Delivery (MM/DD/YYYY), *Race (Mark One or More), *Delivery Information, *Live Birth, *History of: *Postpartum Depression (with Prior Pregnancy), *Major Depressive Disorder, *Hypertension, *Hypotension/Fainting, *Substance/Alcohol Abuse, *Is There Any Other Relevant Medical History?, *Onset of Current Episode PPD Symptoms, *Concomitant Medications Currently Being Taken, *Other Concomitant Medication, *Were Clinical Labs Performed?

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION

*Event Type, *Event Onset Date (MM/DD/YYYY), *Event Onset Time (24-Hour Clock HH:MM), *Did the Event Resolve?, *Event Resolution Date (MM/DD/YYYY), *Event Resolution Time (24-Hour Clock HH:MM), *If Excessive Sedation or Loss of Consciousness Occurred What Was the Duration of the Event?, *Dose of ZULRESSO at Time of Event (mcg/kh/h), *Was the Event Witnessed?, *Was Infusion Stopped Due to Event?, *Infusion Stop Date (MM/DD/YYYY), *Infusion Stop Time (24-Hour Clock HH:MM), *Was Infusion Restarted After the Event Resolved?, *Infusion Restart Date (MM/DD/YYYY), *Infusion Restart Time (24-Hour Clock HH:MM), *Dose of Zulresso Restarted (mcg/kg/h), *Did the Patient Complete the Infusion?, *Was There a Desaturation Event Noted on Pulse Oximetry?

Vital Signs Prior to Infusion (if Available) Date (MM/DD/YYYY), Time (24-Hour Clock HH:MM), Heart Rate (BPM), BP (mmHg), Respiratory Rate (Breaths/Minute), O2 Saturation (%)

Vital Signs at Time (or Closest to Time) of the Event *Date (MM/DD/YYYY), *Time (24-Hour Clock HH:MM), *Heart Rate (BPM), *BP (mmHg), *Respiratory Rate (Breaths/Minute), *O2 Saturation (%)

*Did the Event Result in a Fall?, *Did the Event Result in an Injury?, *What Was the Patient's Position at the Time of the Event?, *What was the Patient's Activity at the Time of the Event?, *Patient Activity Other, *During the Event Indicate the Minimum Stimulus to Elicit a Response From the Patient, *Within 2 Hours Prior to the Event Did the Patient Report Symptoms of, *Symptoms Other, *Did the Event Need Treatment?, If Yes, Please Provide Treatment Information in the Section Below.

Please Include Additional Information Regarding the Event That Is Not Captured Above (Including Other Symptoms Preceding the Event, Location/Activities During the Onset of Event, Treatment for the Event [If Applicable], and Any Other Details Thought to Be Relevant or Resulting From the Event [eg, Falls, Injury]).

*Did the Patient Have More Than One Event of Excessive Sedation or LOC Event During the Infusion?

Please Click "Additional Adverse Event" to Report Each Additional Event. + ADDITIONAL ADVERSE EVENT

The Sage Therapeutics, Inc. Drug Safety Department may follow-up to obtain more information about these events.

*Administering HCP Signature: , HCP Email (Optional), *HCP Phone Number, CANCEL, SUBMIT

*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

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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

Form fields for Patient Name (Peggy Sue), Middle Initial, Patient Last Name, Patient Date of Birth (1/1/2000), REMS ID (1234567890), Healthcare Setting, Address 1 (123 Main Street), Address 2, City (Malvern), State (PA), ZIP (19542), Phone Number (555 555-1212), and Email (abc@abc.com).

HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

Form fields for HCP information including First Name, Last Name, Credentials (MD/DO, NP/PA, Pharmacist, Nurse, Other), Specialty (Psychiatry, OB/GYN, Family Practice, Other), Did the Patient Receive ZULRESSO?, Date and Time of Infusion Started/Ended, Did the Patient Experience Loss of Consciousness or Excessive Sedation?, and a link to the Adverse Event Form.

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS ADVERSE EVENT SECTION

Please complete the following

ADDITIONAL PATIENT INFORMATION

Form fields for additional patient information including Height, Weight, Date of Delivery, Race, Live Birth, History of Postpartum Depression, Hypertension, Substance/Alcohol Abuse, Major Depressive Disorder, Hypotension/Fainting, Onset of Current Episode PPD Symptoms, Concomitant Medications, and Were Clinical Labs Performed.

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION

Form fields for event information including Event Type, Onset Date/Time, Resolution Date/Time, Duration, Dose at Time of Event, Was the Event Witnessed, Infusion Stop/Restart details, Desaturation Event, Vital Signs Prior to and at Time of Event, Patient Position/Activity, and Did the Event Result in a Fall or Injury.

Please Include Additional Information Regarding the Event That Is Not Captured Above (Including Other Symptoms Preceding the Event, Location/Activities During the Onset of Event, Treatment for the Event [If Applicable], and Any Other Details Thought to Be Relevant or Resulting From the Event [eg, Falls, Injury]).

Form field for Did the Patient Have More Than One Event of Excessive Sedation or LOC Event During the Infusion?

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION

Form fields for event information (repeated), including Event Type, Onset Date/Time, Resolution Date/Time, Duration, Dose at Time of Event, Was the Event Witnessed, Infusion Stop/Restart details, Desaturation Event, Vital Signs Prior to and at Time of Event, Patient Position/Activity, and Did the Event Result in a Fall or Injury.

REMOVE ADVERSE EVENT

Please Click "Additional Adverse Event" to Report Each Additional Event.

+ ADDITIONAL ADVERSE EVENT

The Sage Therapeutics, Inc. Drug Safety Department may follow-up to obtain more information about these events.

Form fields for HCP signature, HCP Email (Optional), and HCP Phone Number.

CANCEL SUBMIT

*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.zulressoems.com or call 844-472-4379.

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

HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

*First Name	*Last Name
<input type="text"/>	<input type="text"/>
*Credentials	*Specialty
<input type="checkbox"/> MD/DO <input type="checkbox"/> NP/PA <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other	<input type="checkbox"/> Psychiatry <input type="checkbox"/> OB/GYN <input type="checkbox"/> Family Practice <input type="checkbox"/> Other

*Did the Patient Receive ZULRESSO?

Yes No

*Please check all reasons that apply

Logistical challenges Change in treatment plan Other

*Administering HCP Signature:

HCP Email (Optional)

*HCP Phone Number

CANCEL

SUBMIT

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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 ADD HEALTHCARE SETTING

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 ADD/MODIFY DELEGATE

Loretta Maybly

(555) 555-1212

(555) 555-9999

lmably@hcs1.com

REMOVE ASSOCIATION

Steve Mason

(555) 555-3434

(555) 555-8888

smason@hcs1.com

REMOVE ASSOCIATION

Associated NPI #'S ADD NPI

2345678901

REMOVE ASSOCIATION

3456789012

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 ADD/MODIFY DELEGATE

Corey Pearson

Phone #: 555 555-1212

Fax #: 555 555-8888

Email: spearson@hcs1.com

REMOVE ASSOCIATION

Associated NPI #'S ADD NPI

There are no NPI#s associated with this Healthcare Setting

My Profile

Below is a list of your associated

REMS portal.

Healthcare Settings

Healthcare Setting 1

123 Main Street
City, State Zip

Healthcare Setting DEA Number:

Site Type: Hospital

Enrolled as Both 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

CANCEL **SUBMIT**

 2345678901

 REMOVE ASSOCIATION

 3456789012

 REMOVE ASSOCIATION

 4567890123

 REMOVE ASSOCIATION

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:

Site Type: Hospital

Enrolled as Both Healthcare Setti

ZULRESSO Add/Modify Delegate

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".

First Name	Last Name	Phone	Email
LORETTA	MAYBLY	555 555-3434	lmaybly@hcs1.com
STEVE	MASON	555 555-3434	smason@abc.com



Page 1 of 11 | Total Records: 55

NEW DELEGATE

CONTINUE

 4567890123

 REMOVE ASSOCIATION

ATION

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:

Site Type: Hospital

Enrolled as Both Healthcare Setti

ZULRESSO Add/Modify Delegate

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".

First Name	Last Name	Phone	Email
LORETTA	MAYBLY	555 555-3434	lmaybly@hcs1.com
STEVE	MASON	555 555-3434	smason@abc.com

Navigation: << < > >> <=> Page 1 of 11 | Total Records: 55

NEW DELEGATE

CONTINUE



4567890123

REMOVE ASSOCIATION

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".

First Name	Last Name	Phone	Email
LORETTA	MAYBLY	555 555-3434	lmaybly@hcs1.com
STEVE	MASON	555 555-3434	smason@abc.com



Page 1 of 11 | Total Records: 55

NEW DELEGATE

CONTINUE

Modify Delegate Information

*First Name

Loretta

*Last Name

Maybly

*Phone

555 555-3434

*Fax

555 555-9999

CANCEL

UPDATE

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".

First Name	Last Name	Phone	Email
LORETTA	MAYBLY	555 555-3434	lmaybly@hcs1.com
STEVE	MASON	555 555-3434	smason@abc.com



Page 1 of 11 | Total Records: 55

NEW DELEGATE

CONTINUE

Enter Delegate Information

*First Name

*Last Name

Healthcare Facility

*Phone

*Fax

*Email

CANCEL

ADD

Healthcare Settings

 ADD HEALTHCARE SETTING

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

 ADD/MODIFY DELEGATE

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) 555-9999

 lmably@hcs1.com

 REMOVE ASSOCIATION

 Steve Mason

 (555) 555-3434

 (555) 555-8888

 smason@hcs1.com

 REMOVE ASSOCIATION

 Molly Malone

 (555) 555-5656

 (555) 555-7777

 mmalone@hcs1.com

 REMOVE ASSOCIATION

Associated NPI #'S

 ADD NPI #

 2345678901

 REMOVE ASSOCIATION

 3456789012

 REMOVE ASSOCIATION

 4567890123

 REMOVE ASSOCIATION

Healthcare Setting 2

City, State Zip

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pha

ZULRESSO Add NPI

ZULRESSO Add National Provider Identifier (NPI #)

National Provider Identifier (NPI#)

CANCEL

SUBMIT

Molly Malone

(555) 555-5656

(555) 555-7777

mmal0ne@hcs1.com

REMOVE ASSOCIATION

2345678901

REMOVE ASSOCIATION

3456789012

REMOVE ASSOCIATION

4567890123

REMOVE ASSOCIATION

Healthcare Setting 2

Delegates

ADD/MODIFY DELEGATE

City, State Zip

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pharmacy: Yes

 Loretta Maybly

 (555) 555-1212

 (555) 555-9999

 lmably@hcs1.com

 REMOVE ASSOCIATION

 Steve Mason

 (555) 555-3434

 (555) 555-8888

 smason@hcs1.com

 REMOVE ASSOCIATION

 Molly Malone

 (555) 555-5656

 (555) 555-7777

 mmalone@hcs1.com

 REMOVE ASSOCIATION

Associated NPI #'S

 ADD NPI #

 2345678901

 REMOVE ASSOCIATION

 3456789012

 REMOVE ASSOCIATION

 4567890123

 REMOVE ASSOCIATION

 55678901234

 REMOVE ASSOCIATION

Healthcare Setting 2

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

ADD HEALTHCARE SETTING

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

ADD/MODIFY DELEGATE

Loretta Maybly

(555) 555-1212

(555) 555-9999

lmaybly@hcs1.com

REMOVE ASSOCIATION

Steve Mason

(555) 555-3434

(555) 555-8888

smason@hcs1.com

REMOVE ASSOCIATION

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

YES NO

ADD NPI #

2345678901

REMOVE ASSOCIATION

3456789012

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

ADD/MODIFY DELEGATE

Corey Pearson

Phone #: 555 555-1212

Fax #: 555 555-8888

Email: spearson@hcs1.com

REMOVE ASSOCIATION

Associated NPI #'S

ADD NPI #

There are no NPI#s associated with this Healthcare Setting