

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**211371Orig1s000**

**REMS**

# 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: MM/YYYY

### 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:**

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#### 1. Healthcare settings that dispense ZULRESSO must:

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To become certified to dispense

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](#).
  5. Have the Authorized Representative successfully complete the [Healthcare Setting Knowledge Assessment](#) and submit it to the REMS Program.
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	<p>6. Have the Authorized Representative enroll in the REMS Program by completing the <a href="#">Healthcare Setting Enrollment Form</a> and submitting it to the REMS Program.</p> <p>7. Train all relevant staff involved in prescribing, dispensing, and administering ZULRESSO on the REMS Program requirements using the <a href="#">Training for Healthcare Settings</a>.</p> <p>8. Establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering ZULRESSO and ensure they are trained.</p> <p>9. Establish processes and procedures to enroll the patient in the REMS program.</p> <p>10. Establish processes and procedures to counsel the patient and verify the patient is enrolled in the REMS Program before administration.</p> <p>11. Establish processes and procedures to submit the <a href="#">Post Infusion Form</a> and <a href="#">Excessive Sedation and Loss of Consciousness Adverse Event Form</a> to the REMS Program.</p>
Before dispensing	12. Enroll the patient by completing and submitting the <a href="#">Patient Enrollment Form</a> to the REMS Program.
Before administering	<p>13. Verify the patient is enrolled through the processes and procedures established as a requirement of the REMS Program.</p> <p>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 <a href="#">Patient Information Guide</a>. Provide a copy of the material to the patient.</p>
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 <a href="#">Post Infusion Form</a>.</p> <p>19. Report excessive sedation or loss of consciousness to the REMS Program using the <a href="#">Excessive Sedation and Loss of Consciousness Adverse Event Form</a>.</p>

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To maintain certification to dispense	20. Have any new Authorized Representative enroll in the REMS Program by successfully completing the <a href="#">Healthcare Setting Knowledge Assessment</a> and the <a href="#">Healthcare Setting Enrollment Form</a> and submitting both to the REMS Program.
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At all times	21. Not distribute, transfer, loan, or sell ZULRESSO. 22. Maintain records documenting staff's completion of training. 23. Maintain records that all REMS processes and procedures are in place and are being followed. 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. 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.
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## 2. Patients who are prescribed ZULRESSO:

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

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## 3. Pharmacies that dispense ZULRESSO must:

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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. 2. Have the authorized representative review the <a href="#">Program Overview</a> . 3. Have the authorized representative enroll in the REMS Program by completing the <a href="#">Pharmacy Enrollment Form</a> 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.
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Before dispensing	6. Verify that the healthcare setting is certified through the processes and procedures established as a requirement of the REMS Program.
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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.

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#### **4. Wholesalers-distributors that distribute ZULRESSO must:**

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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.

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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.

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#### **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: <a href="#">Letter for Healthcare Providers</a> with attachment: <a href="#">Patient Information Guide</a> <ol style="list-style-type: none"> <li>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"> <li>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.</li> <li>b. Send a second email within 30 calendar days of the date of the first email sent if the first email is marked unopen.</li> </ol> </li> <li>2. Disseminate through field-based sales and medical representatives.</li> </ol>

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

1. Establish and maintain a [REMS Program Website](#), [www.ZULRESSOrems.com](http://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 1-844-472-4379 and [information@zulressorems.com](mailto: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, pharmacies, and wholesalers-distributors are able to enroll by email and fax and verify enrollment/certification status by calling 1-844-472-4379.
6. Ensure healthcare providers are able to enroll patients by email and fax.
7. Ensure healthcare providers are able to submit the [Post Infusion Form](#) and [Excessive Sedation and Loss of Consciousness Adverse Event Form](#) by email and fax.
8. 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.
9. Notify healthcare settings and pharmacies within 2 business days after they become certified in the REMS Program.
10. Provide public access to a database of certified healthcare settings and pharmacies.
11. Provide certified pharmacies access to the database of certified healthcare settings, enrolled patients, and authorized wholesalers-distributors.
12. Provide certified healthcare settings access to the database of certified pharmacies, enrolled patients, and authorized wholesalers-distributors.

13. Provide authorized wholesalers-distributors access to the database of certified pharmacies and healthcare settings.
14. 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.
15. 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:**

16. 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.
17. 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 submission of the [Patient Enrollment Form](#). 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.
18. 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.
19. 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.
20. Establish a plan for addressing noncompliance with REMS Program requirements.
21. 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.
22. Audit 10% but no less than 50 each of healthcare settings and pharmacies no later than 90 calendar days after they become certified 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.
23. 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.
24. 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:

1. [Training for Healthcare Settings](#)
2. [Healthcare Setting Knowledge Assessment](#)

Patient:

3. [Patient Information Guide](#)

Pharmacy:

4. [Program Overview](#)

**Patient Care Form**

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

**Communication Materials**

7. [Letter for Healthcare Providers](#)

**Other Materials**

8. [REMS Program Website](#)

# ZULRESSO™ REMS Certified Healthcare Setting Enrollment Form

## INSTRUCTIONS

Complete and fax this form to the ZULRESSO REMS at 833-564-7243 or email this form to [information@zulressorems.com](mailto: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)		
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](http://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)		
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)		
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)		
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)		
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](mailto: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"/>			

SIGN  
HERE

DATE  
HERE

Date (MM/DD/YYYY)

Please visit [www.zulressorems.com](http://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. Fax completed form to ZULRESSO REMS at 833-564-7243 or email to [information@zulressoems.com](mailto:information@zulressoems.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)		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)		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)		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)		National Provider Identifier (NPI #)	
Address			
City	State	ZIP	

Please visit [www.zulressoems.com](http://www.zulressoems.com) or call 844-472-4379 for more information about the ZULRESSO REMS.



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**Zulresso™**  
[brexanolone] injection (X)  
for intravenous use

# Table of Contents

- **Training for Healthcare Settings** 3–16
- **Ordering Instructions** 17–18
- **Resources** 19–20

# Training for Healthcare Settings

# What Is ZULRESSO™ (brexanolone) injection?

- ZULRESSO is indicated for the treatment of postpartum depression (PPD) in adults.
- Women should not be pregnant at the time of infusion.
- ZULRESSO is intended for dilution and administration as a continuous intravenous infusion.
- ZULRESSO is available only through the ZULRESSO REMS.

### **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](http://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.
- The Post Infusion Form is available at the ZULRESSO REMS website ([www.zulressorems.com](http://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](http://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](http://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](http://www.zulressoems.com) or call the ZULRESSO REMS at 844-472-4379. The resources below are available for download at [www.zulressoems.com](http://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

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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## INSTRUCTIONS

1. Review the ZULRESSO REMS Training.
2. Complete this Knowledge Assessment and ZULRESSO REMS Healthcare Setting Enrollment Form.
3. Fax both pages of the Knowledge Assessment questions and the Healthcare Setting Enrollment Form to 833-564-7243 or email them to [information@zulressorems.com](mailto: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](http://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



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## 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.

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### **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. You should not be pregnant when you get ZULRESSO.



### 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 dizzy or like you are going to pass out

• Possible side effects of ZULRESSO. See the

• Guide for more information or talk to your

• ther.



### 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 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](http://www.zulressorems.com) or call **844-472-4379**.

To report side effects, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Zulresso™**  
(brexanolone) injection   
for intravenous use

 **SAGE**  
THERAPEUTICS.

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Reference ID: 4405779

# 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 1-844-472-4379.

Visit [www.zulressorems.com](http://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 to the ZULRESSO REMS via fax to 833-564-7243 or email to [information@zulressorems.com](mailto: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 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](http://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](http://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 to the ZULRESSO REMS via fax to 833-564-7243 or email to [information@zulressorems.com](mailto:information@zulressorems.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: <input type="checkbox"/> Vaginal <input type="checkbox"/> Caesarean			Live Birth: <input type="checkbox"/> Yes <input type="checkbox"/> No		
History of:					
Postpartum Depression (With Prior Pregnancy): <input type="checkbox"/> Yes <input type="checkbox"/> No		Major Depressive Disorder: <input type="checkbox"/> Yes <input type="checkbox"/> No			
Hypertension: <input type="checkbox"/> Yes <input type="checkbox"/> No		Hypotension/Fainting: <input type="checkbox"/> Yes <input type="checkbox"/> No		Substance/Alcohol Abuse: <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 <sub>2</sub> 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 <sub>2</sub> 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](http://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](http://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: 1-844-564-7243 / E: [information@zulressorems.com](mailto: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](http://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. Contact a certified Healthcare Setting to initiate the patient admittance process.

Complete details about the ZULRESSO REMS can be found at [www.zulressorems.com](http://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](http://www.fda.gov/medwatch).

Sincerely,  
Sage Therapeutics, Inc.



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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 Providers

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 <http://www.fda.gov/medwatch>.

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[CERTIFY IN THE ZULRESSO REMS >](#)

[HOW TO ADMINISTER ZULRESSO >](#)



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# ZULRESSO REMS Healthcare Setting Enrollment

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

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



STEP 1

## Designate and Maintain

Identify an Authorized Representative. The Authorized Representative will carry out the certification process, 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](#).



TRAINING FOR HEALTHCARE SETTINGS



PRESCRIBING INFORMATION



STEP 3

## Complete

Complete the [ZULRESSO REMS Healthcare Setting Knowledge Assessment](#). All questions must be answered correctly to become certified.



HEALTHCARE SETTING KNOWLEDGE ASSESSMENT



STEP 4

## Complete

Complete the [ZULRESSO REMS Healthcare Setting Enrollment Form](#).



HEALTHCARE SETTING ENROLLMENT FORM



STEP 5

## Submit

Submit the completed [ZULRESSO REMS Healthcare Setting Enrollment Form](#).

Completed forms can be sent to the ZULRESSO REMS via email at [information@zulressorems.com](mailto: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.



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 <http://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 or emailed to the ZULRESSO REMS at [information@zulessorems.com](mailto:information@zulessorems.com).



## POST ADMINISTRATION REQUIREMENTS

### Post Infusion Form

The Post Infusion Form must be submitted to the ZULRESSO REMS after the completion of the infusion, if the patient 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
- 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 faxed to the ZULRESSO REMS at 833-564-7243 or emailed to [information@zulessorems.com](mailto:information@zulessorems.com).

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



[POST INFUSION FORM](#)



[ADVERSE EVENT FORM](#)

Requires a completed Post Infusion Form

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](#).

Forms can be sent to the ZULRESSO REMS via email at [information@zulressorems.com](mailto: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.



**PHARMACY ENROLLMENT FORM**



**STEP 4**  
**Establish**

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



**STEP 5**  
**Train**

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

Completed forms can be sent to the ZULRESSO REMS via email at [information@zulressorems.com](mailto: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.

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.

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# 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 or need help, call **844-472-4379** Monday – Friday 8AM–8PM ET.

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## 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 call the ZULRESSO REMS at 844-472-4379.

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



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# ZULRESSO REMS Forms and Resources

Below are downloadable resources to support the ZULRESSO REMS.



## Materials for Healthcare Settings

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

### Certification Materials

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

### Administration Materials

- PATIENT INFORMATION GUIDE
- PATIENT ENROLLMENT FORM
- POST INFUSION FORM
- ADVERSE EVENT FORM



## Materials for Pharmacies

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

- PROGRAM OVERVIEW FOR PHARMACIES
- PHARMACY ENROLLMENT FORM



## Materials for Patients

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

- PATIENT INFORMATION GUIDE



## Materials for Healthcare Providers

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

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

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



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