

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 833-564-7423, 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.

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		
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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		
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