

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.zulressoforms.com, by fax to 833-564-7243, or by email to information@zulressoforms.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) :

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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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