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.zulressorems.com, by fax to 833-564-7243, or by email to information@zulressorems.com. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

PATIENT 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):
☐ American Indian or Alaska Native ☐ Black or African American ☐ Asian ☐ Native Hawaiian or Other Pacific Islander ☐ White

Delivery Information: ☐ Vaginal ☐ Caesarean

Live Birth: ☐ Yes ☐ No

History of:

Postpartum Depression (With Prior Pregnancy): ☐ Yes ☐ No

Major Depressive Disorder: ☐ Yes ☐ No

Hypertension: ☐ Yes ☐ No

Hypotension/Fainting: ☐ Yes ☐ No

Substance/Alcohol Abuse: ☐ Yes ☐ No

Is There Any Other Relevant Medical History? ☐ Yes ☐ No

If Yes, Sage Therapeutics, Inc. Drug Safety Department will contact the site to collect additional medical history.

Onset of Current Episode PPD Symptoms: ☐ During Pregnancy ☐ After Delivery

Concomitant Medications Currently Being Taken: ☐ Oral Antidepressants ☐ Benzodiazepines ☐ Opioids ☐ Hormonal Birth Control ☐ Other: _____

Were Clinical Labs Performed? ☐ Yes ☐ 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: ☐ Excessive Sedation ☐ Loss of Consciousness (LOC)

Event Onset Date (MM/DD/YYYY)		Event Onset Time (24-Hour Clock HH:MM) :
Did the Event Resolve? ☐ Yes ☐ 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? ☐ Less Than 5 Min ☐ 5-15 Min ☐ 15-30 Min ☐ 30 Min-1 Hour ☐ >1 Hour

Dose of ZULRESSO at Time of Event (mcg/kg/h)	Was the Event Witnessed? ☐ Yes ☐ No

Was Infusion Stopped Due to Event? ☐ Yes ☐ 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? ☐ Yes ☐ No

If Yes, When: Infusion Restart Date (MM/DD/YYYY) Infusion Restart Time (24-Hour Clock HH:MM) :

Reference ID: 4533046

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

Dose of ZULRESSO Restarted (mcg/kg/h)	Did the Patient Complete the Infusion? ☐ Yes ☐ No
Was There a Desaturation Event Noted on Pulse Oximetry? ☐ Yes ☐ 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? ☐ Yes ☐ No	Did the Event Result in an Injury? ☐ Yes ☐ No
What Was the Patient's Position at the Time of the Event? ☐ Supine ☐ Sitting ☐ Standing	
What Was the Patient's Activity at the Time of the Event? ☐ Eating/Drinking ☐ Awake ☐ Resting ☐ Sleeping ☐ Other: _____	
During the Event Indicate the Minimum Stimulus to Elicit a Response From the Patient: ☐ Voice ☐ Light Touch ☐ Deep Touch ☐ Pain ☐ Did Not Respond	
Within 2 Hours Prior to the Event Did the Patient Report Symptoms of: ☐ Somnolence ☐ Sedation ☐ Dizziness ☐ Vertigo ☐ Other: _____	
Did the Event Need Treatment? ☐ Yes ☐ 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? ☐ Yes ☐ 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.

Sage Therapeutics™

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Zulresso™ (brexanolone) injection IV for intravenous use