Spravato® (esketamine) CIII nasal spray

SPRAVATO® REMS

Patient Monitoring Form - Outpatient Use Only

For Healthcare Setting Use Place Patient Label or Barcode Here

INSTRUCTIONS:

This form is intended only for use by outpatient medical offices or clinics, **excluding emergency departments**. You must also submit the **Patient Enrollment Form** if this is the patient's first treatment session.

1. Monitor the patient for any signs of sedation, dissociation, or respiratory depression during the 2-hour monitoring period as a requirement of the REMS.
2. Complete all required fields on this form after **every** treatment session for **all outpatients** enrolled in the SPRAVATO® REMS.
3. Submit completed patient monitoring forms within **7 days** online at www.SPRAVATOrems.com.

**** Indicates Required Field***

Patient

First Name*:	MI:	Last Name*:	Birthdate* (MM/DD/YYYY):	Sex*: ☐ Male ☐ Female ☐ Other

Is this the patient's first treatment*? ☐ Yes ☐ No

If YES, is the patient enrolled*? ☐ Yes ☐ No

If NO is selected, please submit the **Patient Enrollment Form** at www.SpravatoREMS.com or by fax.

Concomitant Medication

Is the patient currently taking any of the following medication(s) that may cause sedation, dissociation, respiratory depression, or blood pressure changes (including but not limited to benzodiazepines, sedative hypnotics, opioids, psychostimulants)? ☐ Yes ☐ No

If yes, list medications here: _____

Monitoring Healthcare Provider

First Name*:	Last Name*:
Telephone*:	Email*:

Healthcare Setting Information (PRINT)

Healthcare Setting Name*:

Healthcare Setting Address 1*:	Healthcare Setting Address 2:

City*:	State*:	ZIP*:	Healthcare Setting DEA Number*:

Patient Treatment Session Information (Administration and Monitoring)

Treatment Date* (MM/DD/YYYY): _____

Dose Administered* ☐ 56 mg ☐ 84 mg ☐ Other: **Lot Number***: _____

Treatment Duration*
(Patient must be monitored for at least 2 hours)

Total treatment duration _____ **minutes** (from 1st device administration to completion of monitoring)

If not monitored for at least 2 hours, provide reason why:
_____

Monitoring of Vital Signs*:

Were vital signs in acceptable range prior to:

Administration? ☐ Yes ☐ No

Treatment session completion? ☐ Yes ☐ No

Monitoring of Pulse Oximetry*:

Was pulse oximetry at an acceptable level prior to administration? ☐ Yes ☐ No

During treatment? ☐ Yes ☐ No

At treatment session completion? ☐ Yes ☐ No;

If a Serious Adverse Event (SAE) occurred during the session, describe in the following section

Serious Adverse Events of Interest

For this SPRAVATO® REMS, a Serious Adverse Event (SAE) of interest is defined as any event involving **sedation, dissociation, respiratory depression, or hypertension** that results in death, hospitalization, disability/permanent damage, an important medical event+, or is life-threatening.

Did the patient experience a SAE of interest as defined above?

☐ Yes (describe in following section) ☐ No

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Patient

First Name*:	MI:	Last Name*:	Birthdate* (MM/DD/YYYY):	Sex*: ☐ Male ☐ Female ☐ Other

Monitoring Healthcare Provider

First Name*:	Last Name*:
Phone*:	Email:

Treatment Date (MM/DD/YYYY): _____

Serious Adverse Events of Interest – Additional Details (PRINT)

Janssen Pharmaceuticals, Inc., Safety Department will follow up to obtain more information about events reported in this table.
If needed, add additional pages to document SAEs.

Event Outcome (Check all that apply)	Event Timing	Description of Serious Adverse Event of Interest (include relevant details such as clinical course, therapeutic interventions, comorbidities, prescription/nonprescription medications)	Event Resolution
The SAE resulted in one or more of the following outcomes: ☐ Death ☐ Life-threatening ☐ Hospitalization ☐ Disability/permanent damage ☐ Important Medical Event+	Date of Event (MM/DD/YY): During treatment session? ☐ Yes ☐ No	☐ Sedation ☐ Dissociation ☐ Respiratory depression ☐ Hypertension Details: _____ _____ _____ _____	☐ Yes ☐ No ☐ Unknown If yes, time to resolution (min): _____
The SAE resulted in one or more of the following outcomes: ☐ Death ☐ Life-threatening ☐ Hospitalization ☐ Disability/permanent damage ☐ Important Medical Event+	Date of Event (MM/DD/YY): During treatment session? ☐ Yes ☐ No	☐ Sedation ☐ Dissociation ☐ Respiratory depression ☐ Hypertension Details: _____ _____ _____ _____ _____	☐ Yes ☐ No ☐ Unknown If yes, time to resolution (min): _____
The SAE resulted in one or more of the following outcomes: ☐ Death ☐ Life-threatening ☐ Hospitalization ☐ Disability/permanent damage ☐ Important Medical Event+	Date of Event (MM/DD/YY): During treatment session? ☐ Yes ☐ No	☐ Sedation ☐ Dissociation ☐ Respiratory depression ☐ Hypertension Details: _____ _____ _____ _____ _____	☐ Yes ☐ No ☐ Unknown If yes, time to resolution (min): _____

+Defined as any event that may jeopardize the patient or may require intervention to prevent one of the above outcomes.

Report other product quality complaints or adverse events that are not defined above to:

Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.