Spravato® (esketamine) 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.

1. Complete all required fields on this form after **every** treatment session for **all outpatients** enrolled in the SPRAVATO® REMS.
2. Submit completed patient monitoring forms within **7 days**, online at www.SPRAVATOrems.com or by fax (1-877-778-0091).

** Indicates Required Field*

Patient Information (PRINT)

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

Concomitant Medication

Is the patient currently taking any of the following medication(s) that may cause sedation or blood pressure changes?

- Benzodiazepines* ☐ Yes ☐ No
- Non-benzodiazepine sedative hypnotics* ☐ Yes ☐ No
- Psychostimulants* ☐ Yes ☐ No
- Monoamine oxidase inhibitors (MAOIs)* ☐ Yes ☐ No

Healthcare Provider Conducting Patient Monitoring (PRINT)

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

Healthcare Setting Information (PRINT)

Healthcare Setting Name*:		
Healthcare Setting Address 1*:	Healthcare Setting Address 2:	
City*:	State*:	ZIP*:

Patient Treatment Session Information (Administration and Monitoring)

Treatment Date*	Date (MM/DD/YYYY): _____		
Dose Administered*	☐ 56 mg ☐ 84 mg ☐ Other:_____	**Lot Number:** _____	
Treatment Duration*	Total time _____**minutes** (from 1st device administration to completion of monitoring) **Patient must be monitored for at least 2 hours**		
REMS Evaluation Question*	*If there was not a 2-hour minimum monitoring requirement, when would this patient have been ready to leave/no longer require monitoring?* _____ ***minutes*** *from start of administration*		
Monitoring of Vital Signs*	Vital signs were in acceptable range **prior** to: • administration? ☐ Yes ☐ No • treatment session completion? ☐ Yes ☐ No		
Monitoring of Blood Pressure*	**Prior to administration** _____ /_____ mmHg	**40 mins post-administration** _____ /_____ mmHg	**Prior to treatment session completion** _____ /_____ mmHg

Did the patient experience Sedation and/or Dissociation

Sedation*: ☐ Yes ☐ No	**Dissociation***: ☐ Yes ☐ No
Onset of symptoms from start of administration* ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins ☐ >120 mins	**Onset of symptoms** from start of administration* ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins ☐ >120 mins
Resolution of symptoms within 2 hours?* ☐ Yes ☐ No Specify total time to resolution*: _____**minutes**	**Resolution of symptoms** within 2 hours?* ☐ Yes ☐ No Specify total time to resolution*: _____**minutes**
Medication(s) given for sedation?* ☐ Yes ☐ No •If YES, name and dose of medication(s): _____	**Medication(s) given for dissociation?*** ☐ Yes ☐ No •If YES, name and dose of medication(s): _____

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** Indicates Required Field*

Patient Information (PRINT)

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

Healthcare Provider Conducting Patient Monitoring (PRINT)

First Name*:	Last Name*:
Phone*:	Email:
Treatment Date (MM/DD/YYYY):	

Serious Adverse Events (PRINT)

A serious adverse event (SAE) for this SPRAVATO® REMS is defined as any event that results in/is:

- **Hospitalization**
- **Disability or permanent damage**
- **Death**
- **Life-threatening**
- **Important medical event**
  – defined as any event that may jeopardize the patient or may require intervention to prevent one of the above outcomes

*All non-serious adverse events or product quality complaints that are **not defined above**, should be reported to: Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.*

Did the patient experience a serious adverse event?* ☐ **Yes** ☐ **No** **If YES, describe below.**

Event resulted in the following: (check all that apply)	**Event Timing**	**Event Description** (Please list one event per row)	**Event Resolution**
☐ Hospitalization ☐ Disability or permanent damage ☐ Death ☐ Life-threatening ☐ Important Medical Event	☐ During treatment sessions ☐ Between treatment sessions Date of Event ______________ (MM/DD/YYYY)		☐ Yes ☐ No ☐ Unknown
☐ Hospitalization ☐ Disability or permanent damage ☐ Death ☐ Life-threatening ☐ Important Medical Event	☐ During treatment sessions ☐ Between treatment sessions Date of Event ______________ (MM/DD/YYYY)		☐ Yes ☐ No ☐ Unknown
☐ Hospitalization ☐ Disability or permanent damage ☐ Death ☐ Life-threatening ☐ Important Medical Event	☐ During treatment sessions ☐ Between treatment sessions Date of Event ______________ (MM/DD/YYYY)		☐ Yes ☐ No ☐ Unknown

Janssen Pharmaceuticals, Inc., Safety Department may follow up to obtain more information about these events.