Spravato™ (esketamine) CIII nasal spray

SPRAVATO™ REMS
Patient Monitoring Form

INSTRUCTIONS

- Complete this form after every treatment session to record the administration and monitoring for all patients enrolled in the SPRAVATO™ REMS starting from the first dose
- Submit completed forms promptly by fax **(1-877-778-0091)** or online at **www.SPRAVATOrems.com**

**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 concomitant medication(s) that may cause sedation or blood pressure changes?

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

Healthcare Setting and Healthcare Provider Information (PRINT)

First Name*:	Last Name*:	
Telephone*:	Email*:	
Healthcare Setting Name*:		
Healthcare Setting Address 1*:	Healthcare Setting Address 2:	
City*:	State*:	ZIP*:

Treatment Session Information

Date*_____ MM/_____ DD/_____ YYYY

Actual Dose Administered* ☐ 28 mg ☐ 56 mg ☐ 84 mg

Time at Start of Administration (from 1st device use)*: _____:_____ AM/PM

Patient must be monitored for at least 2 hours

Time When Patient Completed Treatment Session*: _____:_____ AM/PM

I confirm vital signs (BP, HR, RR) were in an acceptable range **prior to SPRAVATO™ administration.*** ☐ Yes ☐ No

I confirm vital signs were in an acceptable range **prior to patient ready to leave.*** ☐ Yes ☐ No

BP Prior to Administration*	BP 40 Minutes Post Administration*	BP Prior to Patient Ready to Leave*
_____mmHg	_____mmHg	_____mmHg

Was the patient clinically ready to leave **prior to the required 2 hours?*** ☐ Yes ☐ No

If Yes, when was the patient ready to leave?*_____ minutes from start of administration.

If No, use the below sections to describe as appropriate.

Sedation and Dissociation

Did the patient experience sedation or dissociation?

Sedation* ☐ Yes ☐ No	If yes,* indicate onset of symptoms from start of administration. ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins ☐ Greater than 120 mins Did symptoms resolve within 2 hours of administration?* ☐ Yes ☐ No If greater than 2 hours, specify total time since start of administration.* _____
Dissociation* ☐ Yes ☐ No	If yes,* indicate onset of symptoms from start of administration. ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins ☐ Greater than 120 mins Did symptoms resolve within 2 hours of administration?* ☐ Yes ☐ No If greater than 2 hours, specify total time since start of administration.* _____

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Patient Information (PRINT)

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

Serious Adverse Events

Did the patient experience a serious adverse event during this treatment session or since the last treatment session? A serious adverse event is defined as any undesirable experience associated with the use of SPRAVATO™ that resulted in patient hospitalization, a disability or permanent damage, death, required medical intervention, or was life-threatening.

Serious Adverse Event	Occurrence	Date of Event (MM/DD/YYYY)	The Event Resulted in (check all that apply)	Did the event resolve?
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical intervention ☐ Life-threatening ☐ Death	☐ Yes ☐ No ☐ Unknown
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical intervention ☐ Life-threatening ☐ Death	☐ Yes ☐ No ☐ Unknown
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical intervention ☐ Life-threatening ☐ Death	☐ Yes ☐ No ☐ Unknown

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

Reporting of Other Events

For any other adverse event not captured above, healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.