SPRAVATO® REMS

Patient Enrollment Form - Outpatient Use Only

INSTRUCTIONS:

This form is intended only for use by outpatient medical offices or clinics, excluding emergency departments

1. Complete this form online at www.SPRAVATOrems.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091

This section is to be completed by the Prescriber

**** Indicates required field***

Healthcare Setting Information

Healthcare Setting Name*:		
Healthcare Setting DEA License Number* (associated with the Healthcare Setting address):		
Address 1*:	Address 2:	
City*:	State*:	ZIP*:
Phone*:	Fax*:	

Prescriber Information

First Name*:	Last Name*:	
Credentials*: ☐ Physician ☐ Physician Assistant ☐ Nurse ☐ Pharmacist ☐ Other _____ **Specialty*:** ☐ Psychiatry ☐ Internal Medicine ☐ Family Practice ☐ Other_____		Prescriber DEA License Number*:
Phone*:	Fax:	Email*:
Prescriber Signature*:		**Date*:**

Referring Healthcare Provider – if different from Prescriber

First Name:	Last Name:

Relevant Clinical Information

Has the patient previously been treated with ketamine or esketamine for major depressive disorder, treatment-resistant depression, pain syndromes, or any other condition?*	☐ Yes ☐ No

If YES, list all pre-existing conditions treated with ketamine or esketamine:

_____

_____

List all pre-existing medical and psychiatric conditions*:

_____

_____

List concomitant medications (e.g., adjunctive depression medications, sedative hypnotics, psychostimulants, monoamine oxidase inhibitors [MAOIs])*:

_____

_____

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

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This section is to be completed by the Patient

Your healthcare provider will help you complete this form and provide you with a copy.

**** Indicates required field***

Patient Information

First Name*:	MI:	Last Name*:	Birthdate*: (MM/DD/YYYY):	Sex*: ☐ Male ☐ Female ☐ Other
Email*: (Email is required for online enrollment only)			Phone Number*:	
Address 1*:			Address 2:	
City*:		State*:		ZIP*:

Patient Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:

- Enroll in the SPRAVATO® REMS by completing this *Patient Enrollment Form* with my healthcare provider. Enrollment information will be submitted to the SPRAVATO® REMS.
- Receive counseling on safety risks and the need for monitoring to observe for resolution of sedation and dissociation, and for any changes in vital signs.

During treatment, and after administration I will:

- Use the SPRAVATO® nasal spray myself under the direct observation of a healthcare provider.
- Be observed at the healthcare setting where I get SPRAVATO® for at least 2 hours after each treatment until the healthcare provider determines I am ready to leave the healthcare setting.

I understand:

- Sedation and dissociation can result from treatment with SPRAVATO® and I must stay after each treatment.
  Until these effects resolve, I may feel:
  - sleepy and/or
  - disconnected from myself, my thoughts, feelings and things around me.
- I should make arrangements to safely get home.
- I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO®.
- I should contact my doctor or inform him/her at my next visit if I believe I have a side effect or reaction from SPRAVATO®.
- In order to receive SPRAVATO® as an outpatient, I am required to be enrolled in the REMS, and my information will be stored in a database of all outpatients who receive SPRAVATO® in the United States.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me or my prescriber via phone, mail, fax, or email to support administration of the REMS.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may use, disclose, and share my personal health information for the purpose of the operations of the REMS, including enrolling me into the REMS and administering the REMS, coordinating the dispensing of SPRAVATO®, and releasing and disclosing my personal health information to the Food and Drug Administration (FDA), as necessary, and as otherwise required by law.

Patient Name (please print):	
Patient Signature*:	**Date*:**

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