Spravato® (esketamine) CIII nasal spray

SPRAVATO® REMS
Pharmacy Enrollment Form

janssen PHARMACEUTICAL COMPANIES of Johnson & Johnson

INSTRUCTIONS:

1. Review the *SPRAVATO® Prescribing Information* and the *SPRAVATO® REMS Program Overview*
2. Complete this form online at www.SPRAVATOrems.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091

If you are an Inpatient Pharmacy (support inpatient units, emergency department, etc.) and operate under the same DEA license and physical location with your Inpatient Healthcare Setting, your pharmacy will be considered certified once the Inpatient Healthcare Setting Enrollment form is completed/submitted, and you do not require a separate pharmacy enrollment form. This form is intended only for pharmacies that dispense to outpatient facilities.

Indicates Required Field

Pharmacy Information

Name of Pharmacy*:		
Pharmacy Address 1*:	Address Line 2:	
City*:	State*:	ZIP*:
Pharmacy Telephone Number*:	DEA License Number* (On file with distributor account)	DEA Expiration Date* (MM/DD/YYYY):

Pharmacy Type*(select all that apply) ☐ Community/Retail ☐ Specialty ☐ Other:_____

Your pharmacy information will be shared with Janssen's patient support and distribution partners, to allow your pharmacy to purchase product.

Pharmacy Shipping Address, if different from above

Pharmacy Address (address must match the DEA address associated with your Pharmacy's DEA License Number):	Address Line 2:	
City:	State:	ZIP:

Pharmacy Authorized Representative Information

First Name*:		Last Name*:	Title*:
Telephone Number*:	Ext:	Fax*:	Email Address*:

Pharmacy Alternate Contact

First Name:		Last Name:	
Telephone Number:	Ext:	Fax:	Email Address:

Pharmacy Authorized Representative Agreement

I am the Authorized Representative designated by my pharmacy to carry out the certification process and oversee implementation and coordinate the activities of the SPRAVATO® REMS. By completing this form, I agree, on behalf of the pharmacy, to comply with all REMS requirements:

I will:

- Review the SPRAVATO® Prescribing Information and REMS Program Overview.
- Enroll in the SPRAVATO® REMS by completing this *Pharmacy Enrollment Form* and submitting this form to the SPRAVATO® REMS.
- **Establish processes and procedures** and **train** all relevant staff involved in dispensing SPRAVATO® on the following:
  - SPRAVATO® can only be dispensed to a certified healthcare setting.
  - SPRAVATO® must never be dispensed directly to a patient for home use.
  - Before dispensing SPRAVATO®, verify the healthcare setting is certified.
  - Not distribute, transfer, loan, or sell SPRAVATO® except to certified dispensers.
  - If the authorized representative changes, have the new authorized representative re-certify the Pharmacy into the REMS by completing the *Pharmacy Enrollment Form*.
- Maintain records documenting staff's completion of training.
- Maintain records that all REMS processes and procedures are in place and are being followed.
- Maintain records of all shipments of SPRAVATO® received and dispensing information including patient name, dose, number of devices, and date dispensed.
- Comply with audits carried out by Janssen Pharmaceuticals, Inc., or third party acting on behalf of Janssen Pharmaceuticals, Inc., to ensure that all processes and procedures are in place and are being followed.

Authorized Representative Signature*:	**Date:**

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.

Phone: 1-855-382-6022 **www.SPRAVATOrems.com** **Fax: 1-877-778-0091**

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Reference ID: 4649523