

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

211243Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document

SPRAVATO (esketamine hydrochloride) REMS Program

I. Administrative Information

Application Number: NDA 211243

Application Holder: Janssen Pharmaceuticals, Inc.

Initial REMS Approval: 3/2019

II. REMS Goal

The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO administration, and abuse and misuse of SPRAVATO by:

- Ensuring that SPRAVATO is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
- Ensuring pharmacies and healthcare settings that dispense SPRAVATO are certified
- Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
- Enrollment of all patients in a registry to further characterize the risks and support safe use

III. REMS Requirements

Janssen Pharmaceuticals, Inc. must ensure that healthcare settings, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare settings that dispense SPRAVATO must:

- | | |
|---------------------------------|--|
| To become certified to dispense | <ol style="list-style-type: none">1. Have a prescriber onsite during SPRAVATO administration and monitoring.2. Have healthcare provider(s) onsite to monitor patients.3. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting.4. Have the authorized representative review the SPRAVATO prescribing information.5. Have the authorized representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form and submitting it to the REMS Program.6. Train all relevant staff involved in prescribing, dispensing and administering SPRAVATO on 1) Patient self-administration under the supervision of a healthcare provider; and 2) Monitoring for resolution of sedation and dissociation and changes in vital signs for a minimum of 2 hours.7. Establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering SPRAVATO and ensure |
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they are trained on 1) Patient self-administration under the supervision of a healthcare provider; and 2) Monitoring for resolution of sedation and dissociation and changes in vital signs for a minimum of 2 hours.

8. Establish processes and procedures to enroll the patient in the REMS Program.
9. Establish processes and procedures to counsel the patient on the need for enrollment, monitoring, and risks of sedation and dissociation.
10. Establish processes and procedures to verify the patient is enrolled in the REMS Program before each administration and that SPRAVATO is not dispensed for use outside the certified healthcare setting.
11. Establish processes and procedures to complete and submit the [Patient Monitoring Form](#) after each administration within 7 calendar days.

Before treatment initiation (first dose)	<ol style="list-style-type: none"> 12. Counsel the patient on the risks and need for monitoring for resolution of sedation and dissociation and changes in vital signs. 13. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program.
Before administering	<ol style="list-style-type: none"> 14. Counsel the patient on the need for monitoring for resolution of sedation and dissociation, and changes in vital signs. 15. Verify the patient is enrolled in the REMS Program through the processes and procedures established as a requirement of the REMS Program.
During and after administering, for at least 2 hours	<ol style="list-style-type: none"> 16. Assess the patient for self-administration of SPRAVATO and resolution of sedation and dissociation, and changes in vital signs.
After administering, within 7 calendar days	<ol style="list-style-type: none"> 17. Document and submit to the REMS Program using the Patient Monitoring Form.
To maintain certification to dispense	<ol style="list-style-type: none"> 18. Have any new authorized representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form.
At all times	<ol style="list-style-type: none"> 19. Not dispense SPRAVATO for use outside the certified healthcare setting. 20. Not distribute, transfer, loan, or sell SPRAVATO. 21. Maintain records documenting staff's completion of training. 22. Maintain records that all processes and procedures are in place and are being followed. 23. Maintain records of all shipments of SPRAVATO received and dispensing information including patient name, dose, number of devices, and date administered.

24. Comply with audits carried out by Janssen Pharmaceuticals, Inc. or a third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.
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2. Patients who are prescribed SPRAVATO:

Before treatment initiation (first dose)	<ol style="list-style-type: none">1. Receive counseling from a healthcare provider on risks and the need for monitoring for resolution of sedation and dissociation.2. Enroll in the REMS Program by completing the Patient Enrollment Form with a healthcare provider. Enrollment information will be provided to the REMS Program.
During treatment, before each dose	<ol style="list-style-type: none">3. Receive counseling from a healthcare provider on the need for monitoring for resolution of sedation and dissociation.
During treatment, during and after administration for at least 2 hours	<ol style="list-style-type: none">4. Be monitored for taking SPRAVATO, resolution of sedation and dissociation, and changes in vital signs at the healthcare setting.

3. Pharmacies that dispense SPRAVATO must:

To become certified to dispense	<ol style="list-style-type: none">1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.2. Have the authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.3. Train all relevant staff involved in dispensing that SPRAVATO must only be dispensed to a certified healthcare setting.4. Establish processes and procedures to verify that a healthcare setting is certified in the REMS Program before dispensing SPRAVATO.
Before dispensing	<ol style="list-style-type: none">5. Verify that the healthcare setting is certified through the processes and procedures established as a requirement of the REMS Program.
At all times	<ol style="list-style-type: none">6. Not distribute, transfer, loan or sell SPRAVATO except to certified dispensers.7. Not dispense SPRAVATO for use outside a certified healthcare setting.8. Maintain records documenting staff's completion of training.9. Maintain records that all processes and procedures are in place and are being followed.10. Maintain records of all shipments of SPRAVATO received and dispensing information including patient name, dose, number of devices, and date dispensed.11. 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.

4. Wholesalers-distributors that distribute SPRAVATO must:

To be able to distribute	<ol style="list-style-type: none">1. Establish processes and procedures to ensure that SPRAVATO is distributed only to certified healthcare settings and certified pharmacies.2. Train all relevant staff involved in distributing on the REMS Program requirements.
At all times	<ol style="list-style-type: none">3. Distribute only to certified healthcare settings and certified pharmacies.4. Maintain and submit records of all shipments of SPRAVATO.5. Comply with audits carried out by Janssen Pharmaceuticals, Inc. or a third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

To inform healthcare providers about the REMS Program and the risks and safe use of SPRAVATO, Janssen Pharmaceuticals, Inc. must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plans
Healthcare providers likely to prescribe, dispense, and/or administer SPRAVATO	<p>REMS Letter: REMS Letter for Healthcare Providers with attachment Fact Sheet.</p> <ol style="list-style-type: none">1. Email within 60 calendar days of the date SPRAVATO is first commercially distributed<ol style="list-style-type: none">a. Send by mail within 30 calendar days of the date the email was sent if a healthcare provider's email address is not available or the email is undeliverable.b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened.c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.

To support REMS Program operations, Janssen Pharmaceuticals, Inc. must:

1. Establish and maintain a REMS Program website, www.SPRAVATOREMS.com. The REMS Program website must include the capability to complete healthcare setting and pharmacy certification online, patient enrollment online, the capability to provide patient monitoring information online, and to print the Prescribing Information, Medication Guide and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS program website. The REMS program website must not link back to the promotional product website(s).
2. Make the REMS program website fully operational and all REMS materials available through the website and coordinating center by the date SPRAVATO is first commercially distributed.
3. Establish and maintain a REMS coordinating center for REMS participants at 1-855-382-6022.

4. Establish and maintain a validated and secure database of all REMS participants who are enrolled and/or certified in the REMS Program.
5. Ensure healthcare settings and pharmacies are able to enroll and certify in the REMS Program online or by fax.
6. Ensure healthcare providers are able to enroll patients by fax and online.
7. Ensure healthcare settings are able to submit the [Patient Monitoring Form](#) by fax and online.
8. Notify healthcare settings and pharmacies within 7 calendar days after they become certified in the REMS.
9. Provide the [Healthcare Setting Enrollment Form](#) and [Pharmacy Enrollment Form](#) and Prescribing Information to REMS participants who (1) attempt to dispense SPRAVATO and are not yet certified, or (2) inquire about how to become certified.
10. Provide public access to a database of certified healthcare settings and pharmacies.
11. Provide certified pharmacies access to the database of certified healthcare settings and enrolled patients.
12. Provide certified healthcare settings access to the database of certified pharmacies and enrolled patients.
13. Provide authorized wholesalers-distributors access to a database of certified pharmacies and healthcare settings.
14. Establish and maintain a registry which includes a reporting and collection system for all patients to provide information on the incidence of adverse outcomes from sedation, dissociation.
15. Ensure that once a report suggestive of adverse outcomes from sedation or dissociation is received, Janssen Pharmaceuticals, Inc. follows up with the healthcare provider to obtain all required data for the registry.

To ensure REMS participants' compliance with the REMS program, Janssen Pharmaceuticals, Inc. must:

16. Notify healthcare settings if [Patient Monitoring Forms](#) have not been received by the REMS Program in the last 60 calendar days from the date of submission of the [Patient Enrollment Form](#).
17. Ensure every 60 calendar days from the date of submission of the [Patient Enrollment Form](#) that all expected monitoring forms are received for each patient.
18. Verify annually that the authorized representative's name and information correspond to the authorized healthcare setting or pharmacy. If the authorized representative changes at any time, the healthcare setting or pharmacy must be required to re-certify with a new authorized representative.
19. Maintain adequate records to demonstrate that REMS requirements have been met, including but not limited to records of: drug distribution and dispensing; certification of healthcare settings and pharmacies; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.
20. Establish a plan for addressing non-compliance with the REMS Program requirements.
21. Monitor pharmacies, healthcare settings, and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

22. Audit 10% or 50 (whichever is greater) healthcare settings, 10% or 50 (whichever is greater) pharmacies, and data from all wholesalers-distributors that have ordered/dispensed SPRAVATO at 12 months from date of first commercial distribution and annually thereafter to ensure that all REMS processes are in place, functioning and support the REMS requirements. To be audited, healthcare setting must have received at least one shipment of SPRAVATO in the past 12 months and not have been previously audited in the past 3 years.
23. Take reasonable steps to improve implementation of and compliance with the requirements in the SPRAVATO REMS Program based on monitoring and evaluation of the SPRAVATO REMS Program.

IV. REMS Assessment Timetable

Janssen Pharmaceuticals, Inc. must submit REMS assessments at 6 months and 12 months and annually thereafter from the date of initial approval of the REMS (03/04/2019). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Janssen Pharmaceuticals, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the SPRAVATO REMS:

Enrollment Forms

Healthcare Setting:

1. [Healthcare Setting Enrollment Form](#)

Patient:

2. [Patient Enrollment Form](#)

Pharmacy:

3. [Pharmacy Enrollment Form](#)

Patient Care Forms

4. [Patient Monitoring Form](#)

Communication Materials

5. [REMS Letter for Healthcare Providers](#)
6. [Fact Sheet](#)

Other Materials

7. [REMS Program Website](#)

SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Healthcare Setting, enroll by following these 3 steps:

STEP 1: REVIEW	STEP 2: COMPLETE AND SIGN	STEP 3: SUBMIT
<ul style="list-style-type: none"> ➤ Designate an Authorized Representative ➤ The Authorized Representative must review the following: <ul style="list-style-type: none"> • Prescribing Information 	<ul style="list-style-type: none"> ➤ The Authorized Representative must complete the Healthcare Setting Enrollment Form ➤ If the designated Authorized Representative changes, the new Authorized Representative must enroll and complete these 3 steps 	<ul style="list-style-type: none"> ➤ Submit the Healthcare Setting Enrollment Form either: <ul style="list-style-type: none"> • Online at www.SPRAVATorems.com. or <ul style="list-style-type: none"> • Print and fax completed form to 1-877-778-0091

**Indicates Required Field*

Healthcare Setting Information			
Healthcare Setting Name*:			
Healthcare Setting Address 1*:		Address Line 2:	
City*:	State*:	ZIP*:	
Facility DEA License Number* (On file with distributor account):		DEA License Expiration Date (MM/DD/YYYY)*:	
Healthcare Setting Type*: <input type="checkbox"/> Group Practice <input type="checkbox"/> Hospital <input type="checkbox"/> Independent Practice <input type="checkbox"/> Long Term Care <input type="checkbox"/> Mental Health Facility <input type="checkbox"/> Outpatient Clinic (select all that apply) <input type="checkbox"/> Other: _____			
Does your healthcare setting intend to purchase SPRAVATO™ from a specialty distributor (i.e., buy and bill)?* <input type="checkbox"/> Yes <input type="checkbox"/> No			
For each additional healthcare setting where SPRAVATO™ will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, you will need to complete page 3.			
Your healthcare setting information will be shared with Janssen's patient support and distribution partners, to allow your healthcare setting to purchase product. Your healthcare setting information (name, location and phone number) will be listed on a location finder, as a certified healthcare setting, available to healthcare professionals and patients seeking treatment with SPRAVATO™. If you do not want your information listed, please call SPRAVATO™ REMS at 1-855-382-6022.			

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.

Authorized Representative Information			
First Name*:	MI:	Last Name*:	
Credentials*: <input type="checkbox"/> Physician <input type="checkbox"/> Physician Assistant <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other: _____			
Telephone Number*:	EXT:	Fax*:	Email Address*:
Alternate Contact			
First Name:	Last Name:		
Telephone Number:	EXT:	Fax:	Email Address:
Healthcare Setting Authorized Representative Agreement			
<p>I am the Authorized Representative designated by my Healthcare Setting to oversee implementation and coordinate the activities of the SPRAVATO™ REMS. By signing this form, I agree, on behalf of myself and my Healthcare Setting, to comply with the following requirements:</p> <p>I will:</p> <ul style="list-style-type: none"> Review the SPRAVATO™ Prescribing Information. Enroll in the SPRAVATO™ REMS by completing this <i>Healthcare Setting Enrollment Form</i> and submitting this form to the SPRAVATO™ REMS. Have a prescriber onsite during SPRAVATO™ administration and monitoring. Have a healthcare provider(s) onsite to monitor each patient for at least 2 hours following administration of SPRAVATO™ for resolution of sedation and dissociation, and changes in vital signs. Train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO™ and establish processes and procedures to ensure that the following take place in my Healthcare Setting: <ul style="list-style-type: none"> A healthcare provider counsels the patient on the need for enrollment, monitoring, and risks of sedation and dissociation, and changes in vital signs prior to receiving SPRAVATO™. All patients are enrolled in the SPRAVATO™ REMS by completing and submitting the <i>Patient Enrollment Form</i>. Verify the patient is enrolled in the REMS before dispensing SPRAVATO™ for patient self-administration. The patient self-administers SPRAVATO™ under the direct supervision of a healthcare provider. A healthcare provider monitors every patient for at least 2 hours for resolution of sedation and dissociation and changes in vital signs after every dose. A <i>Patient Monitoring Form</i> is submitted to the SPRAVATO™ REMS for every patient within 7 calendar days following administration of every dose. SPRAVATO™ is not dispensed for use outside the Healthcare Setting. Have any new Authorized Representative enroll in the REMS by completing the <i>Healthcare Setting Enrollment Form</i>. Do not distribute, transfer, loan, or sell SPRAVATO™. Maintain records documenting staff's completion of training. Maintain records that all processes and procedures are in place and are being followed. Maintain records on all shipments of SPRAVATO™ received and dispensing information including the patient name, dose, number of devices and date administered. Comply with audits carried out by Janssen Pharmaceuticals, Inc. or a third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed. 			
Name (please print):			
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.

Use this form to add each additional healthcare setting location for which the same Authorized Representative will be responsible.

Additional Healthcare Setting			
Authorized Representative First Name:		MI:	Last Name*:
Authorized Representative Email:			
Healthcare Setting Name*:			
Healthcare Setting Address 1*:		Address Line 2:	
City*:	State*:	ZIP*:	
Facility DEA License Number* (On file with distributor account):			DEA License Expiration Date* (MM/DD/YYYY):
Healthcare Setting Type*: <input type="checkbox"/> Group Practice <input type="checkbox"/> Hospital <input type="checkbox"/> Independent Practice <input type="checkbox"/> Long Term Care <input type="checkbox"/> Mental Health Facility <input type="checkbox"/> Outpatient Clinic (select all that apply): <input type="checkbox"/> Other: _____			
Does this facility intend to purchase SPRAVATO™ directly from a wholesaler or distributor?* <input type="checkbox"/> Yes <input type="checkbox"/> No			
Alternate Contact Information			
First Name:		Last Name:	
Phone Number:	EXT:	Fax:	
Email Address:			
<p>Your healthcare setting information will be shared with Janssen's patient support and distribution partners, to allow your healthcare setting to purchase product. Your healthcare setting information (name, location and phone number) will be listed on a location finder, as a certified healthcare setting, available to healthcare professionals and patients seeking treatment with SPRAVATO™. If you do not want your information listed, please call SPRAVATO™ REMS at 1-855-382-6022.</p>			

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.

SPRAVATO™ is available only through the SPRAVATO™ REMS, a restricted distribution program. Only healthcare settings, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive SPRAVATO™. Your healthcare provider will help you complete this form and provide you with a copy.

Prescribers and patients: Please complete this form online at www.SPRAVATOREMS.com or, once completed, fax it to the REMS at 1-877-778-0091

** Indicates Required Field*

Healthcare Setting Information			
Healthcare Setting Name*:			
Healthcare Setting DEA#*(on file with distributor account):			
Address 1*:		Address 2:	
City*:		State*:	ZIP*:
Phone*:		Fax*:	
Prescribing Physician			
First Name*:		Last Name*:	
Credentials*: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other Specialty*: <input type="checkbox"/> Psychiatry <input type="checkbox"/> Internal Medicine <input type="checkbox"/> Family Practice <input type="checkbox"/> Other(specify) _____			Prescriber DEA#*:
Phone*:	Fax*:	Email*:	
Signature*:			Date*:
Referring Physician – if different than Prescribing Physician			
First Name:		Last Name:	
Phone:			

Relevant Clinical Information	
Has the patient previously been treated with ketamine for treatment-resistant depression, pain syndromes or any other condition?*	<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES, list all pre-existing conditions treated with ketamine:	
List all pre-existing medical and psychiatric conditions:	
List concomitant medications (e.g., adjunctive depression medications, sedative hypnotics, psychostimulants, monoamine oxidase inhibitors (MAOIs))	

This section is to be completed by the Patient

Patient Information				
First Name*:	MI:	Last Name*:	Birthdate*: (MM/DD/YYYY):	Sex*: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> 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:				
<u>Before my treatment begins, I will:</u>				
<ul style="list-style-type: none"> • Enroll in the SPRAVATO™ REMS by completing this <i>Patient Enrollment Form</i> with my healthcare provider. Enrollment information will be provided to the REMS. • Agree to receive counseling on the risks and the need for monitoring for resolution of sedation and dissociation, and for any changes in my vital signs. 				
<u>During treatment I will:</u>				
<ul style="list-style-type: none"> • 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. 				
<u>I understand:</u>				
<ul style="list-style-type: none"> • Sedation and dissociation can result from treatment with SPRAVATO™ and I must stay after each treatment. Until these effects resolve, I may feel: <ul style="list-style-type: none"> - sleepy and/or - disconnected from myself, my thoughts, feelings and things around me. • I should make arrangements to safely leave the healthcare setting and 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™, I am required to be enrolled in the REMS, and my information will be stored in a database of all patients who receive SPRAVATO™ in the United States. • Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me 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:				
Patient Signature*:			Date*:	

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SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Pharmacy, enroll by following these 3 steps:

STEP 1: REVIEW	STEP 2: COMPLETE AND SIGN	STEP 3: SUBMIT
<ul style="list-style-type: none"> ➤ Designate an Authorized Representative ➤ Authorized Representative review the following: <ul style="list-style-type: none"> • Prescribing Information • Fact Sheet • Medication Guide • Instruction for Use 	<ul style="list-style-type: none"> ➤ The Authorized Representative must complete the <i>Pharmacy Enrollment Form</i> ➤ If the Authorized Representative changes, the new Authorized Representative must complete and sign a new <i>Pharmacy Enrollment Form</i> 	<ul style="list-style-type: none"> ➤ Submit the <i>Pharmacy Enrollment Form</i> either: <ul style="list-style-type: none"> • Online at www.SPRAVATOREMS.com. or • Print and fax completed form to 1-877-778-0091

* Indicates Required Field

Pharmacy Information			
Name of Pharmacy*:			
Pharmacy Address 1*:		Address Line 2:	
City*:	State*:	ZIP*:	
DEA License Number* (On file with distributor account):		DEA Expiration Date* (MM/DD/YYYY):	
Pharmacy Type*:(select all that apply) <input type="checkbox"/> Clinic <input type="checkbox"/> Hospital <input type="checkbox"/> Inpatient <input type="checkbox"/> Long-term care <input type="checkbox"/> Mental Health Facility <input type="checkbox"/> Outpatient <input type="checkbox"/> Specialty <input type="checkbox"/> 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 than above			
Pharmacy Address: (address must match the DEA address associated with your Pharmacy's DEA number)		Address Line 2:	
City:	State:	ZIP:	
Pharmacy Authorized Representative Information			
First Name*:	Last Name*:	Title*:	
Telephone Number*:	EXT:	Fax*:	Email Address*:
Alternate Contact			
First Name:		Last Name:	
Phone Number:	EXT:	Fax:	
Pharmacy Authorized Representative Agreement			
I am the Authorized Representative designated by my pharmacy to oversee implementation and coordinate the activities of the SPRAVATO™ REMS. By signing this form, I agree, on behalf of myself and pharmacy, to comply with the following requirements:			
I will:			
<ul style="list-style-type: none"> • Enroll in the SPRAVATO™ REMS by completing this <i>Pharmacy Enrollment Form</i> and submitting this form to the SPRAVATO™ REMS. • Train all relevant staff involved in dispensing SPRAVATO™ on the following: <ul style="list-style-type: none"> - SPRAVATO™ can only be dispensed to a certified healthcare setting. - SPRAVATO™ must never be dispensed directly to a patient for home use. • Establish processes and procedures to verify that a healthcare setting is certified before dispensing SPRAVATO™ • Before dispensing SPRAVATO™, verify the healthcare setting is certified using the established processes and procedures. • Not distribute, transfer, loan or sell SPRAVATO™ except to certified dispensers. • 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.

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*:	Middle Initial:	Last Name*:	Birthdate* (MM/DD/YYYY):
Concomitant Medication			
Is the patient currently taking any of the following concomitant medication(s) that may cause sedation or blood pressure changes?			
• benzodiazepines	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
• non-benzodiazepine sedative hypnotics	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
• psychostimulants	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
• monoamine oxidase inhibitors (MAOIs)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Healthcare Setting and Healthcare Provider Information (PRINT)			
First Name*:	Last Name*:		
Phone*:	Email*:		
Healthcare Setting Name*:			
Healthcare Setting Address 1*:		Healthcare Setting Address 2:	
City*:	State*:	ZIP*:	
Treatment Session Information			
Date ____ MM/ ____ DD/ ____ YYYY		Dose ____ 28 mg ____ 56 mg ____ 84 mg	
Time at start of administration: ____:____ AM / PM	Patient must be monitored for at least 2 hours		Time of discharge: ____:____ AM/PM
<input type="checkbox"/> I confirmed vital signs (BP, HR, RR) were in an acceptable range prior to SPRAVATO™ administration.			
<input type="checkbox"/> I confirmed vital signs were in an acceptable range prior to patient discharge.			
BP prior to administration	BP 40 minutes post administration	BP prior to discharge	
____ mmHg	____ mmHg	____ mmHg	
Was the patient clinically ready for discharge prior to the required 2 hours? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If Yes, when was the patient ready for discharge? ____ 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 <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, indicate onset of symptoms from start of administration <input type="checkbox"/> 1-29 mins <input type="checkbox"/> 30-59 mins <input type="checkbox"/> 60-89 mins <input type="checkbox"/> 90-120 mins Did symptom resolve within 2 hours of administration? <input type="checkbox"/> Yes <input type="checkbox"/> No If greater than 2 hours, specify total time since administration _____		
Dissociation <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, indicate onset of symptoms from start of administration <input type="checkbox"/> 1-29 mins <input type="checkbox"/> 30-59 mins <input type="checkbox"/> 60-89 mins <input type="checkbox"/> 90-120 mins Did symptom resolve within 2 hours of administration? <input type="checkbox"/> Yes <input type="checkbox"/> No If greater than 2 hours, specify total time since administration _____		

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 one which is 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?
	<input type="checkbox"/> During this treatment session <input type="checkbox"/> Since the last treatment session		<input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Medical Intervention <input type="checkbox"/> Life threatening <input type="checkbox"/> Death	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
	<input type="checkbox"/> During this treatment session <input type="checkbox"/> Since the last treatment session		<input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Medical Intervention <input type="checkbox"/> Life threatening <input type="checkbox"/> Death	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
	<input type="checkbox"/> During this treatment session <input type="checkbox"/> Since the last treatment session		<input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Medical Intervention <input type="checkbox"/> Life threatening <input type="checkbox"/> Death	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.



FDA-REQUIRED REMS SAFETY INFORMATION

SUBJECT: SPRAVATO™: Risk of serious adverse outcomes resulting from sedation and dissociation, and abuse and misuse

March 4, 2019

Dear Healthcare Provider:

The purpose of this letter is to inform you about the serious risks associated with the use of SPRAVATO™ (esketamine) nasal spray, approved by the FDA on March 4, 2019 for treatment-resistant depression in adults.

The FDA has determined that a REMS is necessary to ensure that the benefits of SPRAVATO™ outweigh the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™.

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration. SPRAVATO™ must never be dispensed directly to a patient for home use.

What are the SPRAVATO™ REMS requirements?

- SPRAVATO™ is available only through a limited distribution program that is part of the SPRAVATO™ REMS.
- All healthcare settings and pharmacies must be certified in the SPRAVATO™ REMS before they can purchase, dispense, or supervise administration of SPRAVATO™.
- All patients must be enrolled in the SPRAVATO™ REMS before they can receive SPRAVATO™.

Please see the attached non-promotional **SPRAVATO™ REMS Fact Sheet** for more information.

How can I obtain more information to become a certified healthcare setting and/or pharmacy, or to refer patients for treatment?

Please visit www.SPRAVATorems.com for more information about how your healthcare setting or pharmacy can be certified in the SPRAVATO™ REMS.



Where can I find more information about the SPRAVATO™ REMS?

- Visit www.SPRAVATOREMS.com to access the following materials:
 - SPRAVATO™ REMS Healthcare Setting Enrollment Form
 - SPRAVATO™ REMS Pharmacy Enrollment Form
 - SPRAVATO™ REMS Patient Enrollment Form
 - SPRAVATO™ REMS Patient Monitoring Form
 - SPRAVATO™ REMS Fact Sheet
 - SPRAVATO™ Prescribing Information
 - SPRAVATO™ Medication Guide
 - SPRAVATO™ Instructions for Use
- For additional information or questions about the SPRAVATO™ REMS, call 1-855-382-6022.
- Call Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736) for any clinical or medical questions related to SPRAVATO™.

Indication

SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression in adults.

Reporting Adverse Events and Product Quality Complaints

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.

Sincerely,

Michelle Kramer, MD, MPH
Vice President, Medical Affairs
Janssen Pharmaceutical, Inc

Enclosed: *SPRAVATO™ Prescribing Information*
SPRAVATO™ Medication Guide
SPRAVATO™ REMS Fact Sheet

SPRAVATO™ REMS Fact Sheet

What is the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. The FDA has determined that a REMS is necessary to ensure that the benefits of SPRAVATO™ outweigh the potential risks.

The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™ by:

- Ensuring that SPRAVATO™ is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
- Ensuring pharmacies and healthcare settings that dispense SPRAVATO™ are certified
- Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
- Enrollment of all patients in the REMS (registry) to further characterize the risks and support safe use

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration. SPRAVATO™ must never be dispensed directly to a patient for home use.

What are the SPRAVATO™ REMS requirements?

SPRAVATO™ is available only through a limited distribution program that is part of the SPRAVATO™ REMS. All healthcare settings and pharmacies are required to enroll in the SPRAVATO™ REMS via a designated authorized representative before they can purchase product from a distributor, dispense, or supervise administration of SPRAVATO™. All patients must also be enrolled in the SPRAVATO™ REMS before they can receive SPRAVATO™.

How can healthcare settings and/or pharmacies obtain SPRAVATO™ for patients?

To order, dispense, prescribe, and/or supervise administration of SPRAVATO™, the healthcare setting and/or pharmacy must be certified in the SPRAVATO™ REMS.

To become certified, the healthcare setting or pharmacy must:

1. Designate an “authorized representative” to complete the **SPRAVATO™ REMS Healthcare Setting Enrollment Form** and/or **SPRAVATO™ REMS Pharmacy Enrollment Form** and submit it to the SPRAVATO™ REMS.
2. Healthcare settings and pharmacies must establish appropriate policies and procedures, and train relevant staff involved in the prescribing, dispensing and administering, and handling of SPRAVATO™ to ensure that product is delivered/dispensed directly to a healthcare provider at the site of care and not dispensed directly to a patient to take home.
3. Healthcare settings must further establish policies and procedures and train relevant staff on the following steps to comply with REMS requirements:
 - a. Counsel and enroll patients in the SPRAVATO™ REMS

- b. Ensure that administration of SPRAVATO™ is under the direct observation by a healthcare provider
- c. Ensure that patients are monitored by a healthcare provider for at least 2 hours post-administration
- d. Report relevant information back to the SPRAVATO™ REMS using the *Patient Monitoring Form*

Once certified as a healthcare setting and/or pharmacy, SPRAVATO™ may be obtained:

For a healthcare setting and/or pharmacy: By ordering SPRAVATO™ directly through a distributor/wholesaler

Once your healthcare setting and/or pharmacy is certified, you may obtain a list of distributors/wholesalers to purchase product by contacting the SPRAVATO™ REMS at 1-855-382-6022.

For a healthcare setting: Through a certified pharmacy

Once your healthcare setting is certified, you may obtain a list of REMS certified pharmacies by contacting the SPRAVATO™ REMS at 1-855-382-6022.

Where can I find more information about the SPRAVATO™ REMS?

- Visit www.SPRAVATOREMS.com to access the following materials:
 - SPRAVATO™ REMS Healthcare Setting Enrollment Form
 - SPRAVATO™ REMS Pharmacy Enrollment Form
 - SPRAVATO™ REMS Patient Enrollment Form
 - SPRAVATO™ REMS Patient Monitoring Form
 - SPRAVATO™ REMS Letter for Healthcare Providers
 - SPRAVATO™ Prescribing Information
 - SPRAVATO™ Medication Guide
 - SPRAVATO™ Instructions for Use
- For additional information or questions about the SPRAVATO™ REMS, call 1-855-382-6022.
- Call Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736) for any clinical or medical questions related to SPRAVATO™.

How should SPRAVATO™ be stored and handled?

- Once SPRAVATO™ is delivered for a named-patient or is obtained for a healthcare setting's bulk supply, it should be kept in a secure place per State and Federal Drug Enforcement Agency (DEA) laws and regulations for controlled substances.
- Product dispensed for a specific named-patient must be administered within 14 days after receipt by the healthcare setting per DEA requirements. Unused named-patient products must be appropriately disposed of as per State and Federal regulations and may not be returned to the general inventory of the healthcare setting or pharmacy.
- Janssen offers a SPRAVATO™ disposal program, if your healthcare setting is not equipped to do so. Contact 1-800-JANSSEN for more information.

Reporting Adverse Events and Product Quality Complaints

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.

SPRAVATO™ REMS

(Risk Evaluation and Mitigation Strategy)

What is the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy)?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product.

The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™ by:

- Ensuring that SPRAVATO™ is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
- Ensuring pharmacies and healthcare settings that dispense SPRAVATO™ are certified
- Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
- Enrollment of all patients in a registry to further characterize the risks and support safe use

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. SPRAVATO™ must never be dispensed directly to a patient for home use.

Program Requirements



Healthcare Setting

Healthcare Settings must be certified in the SPRAVATO™ REMS in order to treat patients with SPRAVATO™

[Healthcare Setting Certification ▶](#)



Pharmacy

Pharmacies must be certified in the SPRAVATO™ REMS in order to dispense SPRAVATO™

[Pharmacy Certification ▶](#)



Patient

Patients must be enrolled in the SPRAVATO™ REMS in order to receive SPRAVATO™ treatment

[Patient Enrollment ▶](#)

SPRAVATO™ Indication

SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment for treatment-resistant depression (TRD) in adults.

SPRAVATO™ is only available through select distribution channels.

If you have any questions about the SPRAVATO™ REMS or need help with certification or enrollment, call 1-855-382-6022 Monday – Friday 8AM – 8PM ET



Healthcare Settings

SPRAVATO™ REMS Healthcare Setting Enrollment

Healthcare settings must be certified in the SPRAVATO™ REMS in order to prescribe product. **SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. SPRAVATO™ must never be dispensed directly to a patient for home use.**

How does my Healthcare Setting become certified in the SPRAVATO™ REMS?



Step 1: Designate an Authorized Representative to oversee implementation and compliance with the REMS requirements



Step 2: Review the following materials:

- SPRAVATO™ REMS Fact Sheet
- SPRAVATO™ Medication Guide
- SPRAVATO™ Prescribing Information
- SPRAVATO™ Instructions for Use



Step 3: Complete and submit the SPRAVATO™ REMS Healthcare Setting Enrollment Form to the REMS

[Online](#) | [By Fax](#)

PDFs for Download: Resources for Healthcare Settings

SPRAVATO™ REMS Healthcare Setting Enrollment Form

SPRAVATO™ REMS Fact Sheet

SPRAVATO™ REMS Patient Enrollment Form

SPRAVATO™ Prescribing Information

SPRAVATO™ REMS Patient Monitoring Form

SPRAVATO™ Medication Guide

SPRAVATO™ REMS Letter for Healthcare Providers

SPRAVATO™ Instructions for Use



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For SPRAVATO™ REMS Program information contact:

Phone: 1-855-382-6022

Fax: 1-877-778-0091

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.

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Pharmacies

SPRAVATO™ REMS Pharmacy Enrollment

Pharmacies must be certified in the SPRAVATO™ REMS to be able to receive and dispense/fulfill medication orders for SPRAVATO™.

How does my Pharmacy become certified in the SPRAVATO™ REMS?



Step 1: Designate an Authorized Representative to oversee implementation and compliance of the SPRAVATO™ REMS requirements



Step 2: Review the following materials:

- SPRAVATO™ REMS Fact Sheet
- SPRAVATO™ Medication Guide
- SPRAVATO™ Prescribing Information
- SPRAVATO™ Instructions for Use



Step 3: Complete and submit the SPRAVATO™ REMS Pharmacy Enrollment Form to the REMS

[Online](#) | [By Fax](#)

PDFs for Download: Resources for Pharmacies

[SPRAVATO™ REMS Pharmacy Enrollment Form](#)

[SPRAVATO™ Prescribing Information](#)

[SPRAVATO™ REMS Letter for Healthcare Providers](#)

[SPRAVATO™ Medication Guide](#)

[SPRAVATO™ REMS Fact Sheet](#)

[SPRAVATO™ Instructions for Use](#)



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Patients

What is the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy)?

Because of the risks associated with SPRAVATO™, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS). As part of the REMS, your doctor will discuss the risks of misuse, abuse, sedation (feeling sleepy), dissociation (feeling disconnected from yourself, including thoughts, feelings, and things around you) while on SPRAVATO™ with you. Both you and your doctor must sign the Patient Enrollment Form for you to receive SPRAVATO™. Your doctor will provide a copy of the signed form to the SPRAVATO™ REMS.

How do I enroll in the SPRAVATO™ REMS?

If your healthcare provider and you have both agreed that SPRAVATO™ is the appropriate treatment for you, you will need to enroll in the SPRAVATO™ REMS in order to receive treatment with SPRAVATO™.

These are the steps to take in partnership with your healthcare provider:

1

Step 1: Read the SPRAVATO™ Medication Guide and Instructions for Use. Your healthcare provider will review specific risk and safety information for SPRAVATO™ with you and describe how to use the product

2

Step 2: Ask your healthcare provider any questions you have about taking SPRAVATO™ and about the SPRAVATO™ REMS

3

Step 3: Make sure you understand:

A. How to enroll and take part in the SPRAVATO™ REMS

B. The benefits and risks of SPRAVATO™

C. That each time you receive SPRAVATO™:

- You will need to use SPRAVATO™ nasal spray yourself under direct observation of a healthcare provider in a healthcare setting, such as a doctor's office, clinic, or hospital
- You will be monitored by a healthcare provider for at least 2 hours; the healthcare provider will then decide when you are ready to leave the healthcare setting
- After treatment with SPRAVATO™, **do not** drive, operate heavy machinery, or do anything where you need to be completely alert until the next day following a restful sleep

4

Step 4: Together with your healthcare provider complete and sign the SPRAVATO™ REMS Patient Enrollment Form

Your healthcare provider will fill out most of the enrollment form for you and will send the form to SPRAVATO™ REMS

PDFs for Download: Resources for Patients

[SPRAVATO™ Medication Guide](#)

[SPRAVATO™ Instructions for Use](#)



Contact Us



Phone: [1-855-382-6022](tel:1-855-382-6022)



Fax: [1-877-778-0091](tel:1-877-778-0091)

Hours of Operation: Monday — Friday 8:00 AM — 8:00 PM ET

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For SPRAVATO™ REMS
Program information contact:

Phone: 1-855-382-6022

Fax: 1-877-778-0091

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Resources



Healthcare Setting Resources for SPRAVATO™ REMS

SPRAVATO™ REMS Healthcare Setting Enrollment Form

SPRAVATO™ REMS Fact Sheet

SPRAVATO™ REMS Patient Enrollment Form

SPRAVATO™ Prescribing Information

SPRAVATO™ REMS Patient Monitoring Form

SPRAVATO™ Medication Guide

SPRAVATO™ REMS Letter for Healthcare Providers

SPRAVATO™ Instructions for Use



Pharmacy Resources for SPRAVATO™ REMS

SPRAVATO™ REMS Pharmacy Enrollment Form

SPRAVATO™ Prescribing Information

SPRAVATO™ REMS Letter for Healthcare Providers

SPRAVATO™ Medication Guide

SPRAVATO™ REMS Fact Sheet

SPRAVATO™ Instructions for Use



Patient Resources for SPRAVATO™ REMS

SPRAVATO™ Medication Guide

SPRAVATO™ Instructions for Use



SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy)

What is the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy)?

A REMS (Risk Evaluation and Mitigation Strategy) is a program designed to manage known or potential serious risks associated with a drug. The goal of the REMS is to mitigate the risks associated with the administration, and abuse and misuse of the drug.

- Ensuring that SPRAVATO™ is only administered in a healthcare setting that monitors these patients
- Ensuring pharmacies and health care providers are certified to dispense and administer SPRAVATO™
- Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
- Enrollment of all patients in a registry to further characterize the risks and support safe use

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. SPRAVATO™ must never be dispensed directly to a patient for home use.

By clicking "Continue" you will exit the SPRAVATO™ REMS website.

Cancel ▶ Continue ▶

Program Requirements



Healthcare Setting

Healthcare Settings must be certified in the SPRAVATO™ REMS in order to treat patients with SPRAVATO™

Healthcare Setting Certification ▶



Pharmacy

Pharmacies must be certified in the SPRAVATO™ REMS in order to dispense SPRAVATO™

Pharmacy Certification ▶



Patient

Patients must be enrolled in the SPRAVATO™ REMS in order to receive SPRAVATO™ treatment

Patient Enrollment ▶

SPRAVATO™ Indication

SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment for treatment-resistant depression (TRD) in adults.

SPRAVATO™ is only available through select distribution channels.

If you have any questions about the SPRAVATO™ REMS or need help with certification or enrollment, call 1-855-382-6022 Monday – Friday 8AM – 8PM ET



For SPRAVATO™ REMS Program information contact:
Phone: 1-855-382-6022
Fax: 1-877-778-0091

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Login

Your username is the email address you registered with when you created your account online or is the username supplied to you via email if your account was created for you.

[Forgot Username](#)

LOGIN

OR

Don't have an online account?

Register

To create your web account for the SPRAVATO[™] REMS, please complete the fields below. The email address you specify must be unique with the SPRAVATO[™] REMS website, and will be used as your username to log in to the site.

*First Name

*Last Name

*Phone Number

*Fax Number

*Email Address

*Credentials

- Physician Physician Assistant Nurse Practitioner Pharmacist
 Nurse Other

SUBMIT

If you have questions about the SPRAVATO[™] REMS or need help enrolling,
call 1-855-382-6022
Monday – Friday, 8:00 AM – 8:00 PM ET

Login

Your username is the email address you registered with when you created your account online or is the username supplied to you via email if your account was created for you.

[Forgot Username](#)

LOGIN

OR

Don't have an online account?

Register

To create your web account for the SPRAVATO[™] REMS, please complete the fields below. The email address you specify must be unique with the SPRAVATO[™] REMS website, and will be used as your username to log in to the site.

* First Name

* Last Name

* Phone Number

* Fax Number

* Email Address

* Credentials

- Physician Physician Assistant Nurse Practitioner Pharmacist
 Nurse Other

* Credentials Other

SUBMIT

If you have questions about the SPRAVATO[™] REMS or need help enrolling,
call 1-855-382-6022
Monday – Friday, 8:00 AM – 8:00 PM ET

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

[Privacy Policy](#) [Terms of Use](#)

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.

Account Submitted Successfully

Thank you for submitting your information to create your web account for the SPRAVATO[™] REMS.

A confirmation of this submission has been sent to the email address provided. You can expect to receive 2 emails, one contains your username and the second contains your temporary password. Please login with the username provided. You will then be prompted to update your password.

If you do not receive the emails within the next few hours, or would like to update your enrollment information at any time, please contact the SPRAVATO[™] REMS at 1-855-382-6022.

[LOGIN](#)

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

[Privacy Policy](#) [Terms of Use](#)

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.

Login

Your username is the email address you registered with when you created your account online or is the username supplied to you via email if your account was created for you.

[Forgot Username](#)

LOGIN

OR

Don't have an online account?

Register

To create your web account for the SPRAVATO[™] REMS, please complete the fields below. The email address you specify must be unique with the SPRAVATO[™] REMS website, and will be used as your username to log in to the site.

* First Name

* Last Name

* Phone Number

* Fax Number

* Email Address

* Credentials

- Physician Physician Assistant Nurse Practitioner Pharmacist
 Nurse Other

SUBMIT

If you have questions about the SPRAVATO[™] REMS or need help enrolling,
call 1-855-382-6022
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Phone: 1-855-382-6022
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Login



Please enter your password

* Password:

CANCEL

NEXT

Login

Your username is the email address you used when you created your account online or the username supplied to you via email if you were created for you.

User Name

[Forgot Username](#)

LOGIN

SPRAVATO[™] REMS, please complete the fields unique with the SPRAVATO[™] REMS before logging in to the site.

* First Name

* Last Name

* Phone Number

* Fax Number

Change Password ✕

Your password has expired and must be changed.

*New Password: ⓘ

*Re-type new Password:

CANCEL

NEXT

Login

Your username is the email address you used when you created your account or the username supplied to you via email if your account was created for you.

User Name

[Forgot Username](#)

REMS, please complete the fields unique with the SPRAVATOTM REMS login to the site.

* Last Name

* Phone Number

* Fax Number

Login

Your username is the email address you registered with when you created your account online or is the username supplied to you if your account was created for you.

User Name

[Forgot Username](#)

LOG

Update Profile



* Security Caption:

* Security Question

* Answer

-- Please Select --

▼ Answer

-- Please Select --

▼ Answer

-- Please Select --

▼ Answer

CANCEL

NEXT

REMS, please complete the fields below. The email address you use on the REMS website, and will be used as your username to log in to the

SUBMIT

Review Materials



If you have not previously reviewed the material below, please review now by clicking on the link. The document will open up in a new window for you to review.

SPRAVATO™ REMS Materials

- [Prescribing Information](#)

NEXT

SPRAVATO™ REMS Healthcare Setting Enrollment Form

SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Healthcare Settings and Pharmacies that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.



To become a SPRAVATO™ REMS certified Healthcare Setting, enroll by following these 3 steps:

STEP 1: REVIEW	STEP 2: COMPLETE AND SIGN	STEP 3: SUBMIT
<ul style="list-style-type: none">Designate an Authorized RepresentativeThe Authorized Representative must review the following:<ul style="list-style-type: none">Prescribing Information	<ul style="list-style-type: none">The Authorized Representative must complete the Healthcare Setting Enrollment FormIf the designated Authorized Representative changes, the new Authorized Representative must enroll and complete these 3 steps	<ul style="list-style-type: none">Submit the Healthcare Setting Enrollment Form either:<ul style="list-style-type: none">Online at: www.SPRAVATOrems.comorPrint and fax completed form to 1-877-778-0091

**Indicates Required Field*

Healthcare Setting Information

* Facility DEA License Number (on file with distributor account)

CONTINUE

SPRAVATO™ REMS Healthcare Setting Enrollment Form

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*Indicates Required Field

Healthcare Setting Information

* Facility DEA License Number (on file with distributor account)

* DEA License Expiration Date (MM/DD/YYYY)

* Healthcare Setting Name

* Healthcare Setting Address 1

Address Line 2

* City

* State

* ZIP

* Healthcare Setting Type (select all that apply)
 Group Practice Hospital Independent Practice Long Term Care
 Mental Health Facility Outpatient Clinic Other

* Does your healthcare setting intend to purchase SPRAVATO™ from a specialty distributor (i.e., buy and bill)?
 Yes No

To add additional healthcare setting locations where SPRAVATO™ will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, click below. Must complete for all locations.

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

Your healthcare setting information (name, location and phone number) will be listed on a location finder, as a certified healthcare setting, available to healthcare professionals and patients seeking treatment with SPRAVATO™. If you do not want your information listed please call SPRAVATO™ REMS at 1-855-382-6022.

Authorized Representative Information

* First Name MI * Last Name

* Credentials
 Physician Physician Assistant Nurse Practitioner Pharmacist Nurse
 Other

* Telephone Number EXT * Fax

* Email Address

Alternate Contact

First Name Last Name

Telephone Number EXT Fax

Email Address

Healthcare Setting Authorized Representative

I am the Authorized Representative designated by my Healthcare Setting to oversee implementation and coordinate the activities of the SPRAVATO™ REMS. By signing this form, I agree, on behalf of myself and my Healthcare Setting, to comply with the following requirements:

I will:

- Review the SPRAVATO™ REMS Prescribing Information.
- Enroll in the SPRAVATO™ REMS by completing this *Healthcare Setting Enrollment Form* and submitting this form to the SPRAVATO™ REMS.
- Have a prescriber onsite during SPRAVATO™ administration and monitoring
- Have a healthcare provider(s) onsite to monitor each patient for at least 2 hours following administration of SPRAVATO™ for resolution of sedation and dissociation, and changes in vital signs.
- Train** all relevant staff involved in prescribing, dispensing, and administering SPRAVATO™ and **establish processes and procedures** to ensure that the following take place in my Healthcare Setting:
 - A healthcare provider counsels the patient on the need for enrollment, monitoring, and risks of sedation and dissociation, and changes in vital signs prior to receiving SPRAVATO™.
 - All patients are enrolled in the SPRAVATO™ REMS by completing and submitting the *Patient Enrollment Form*.
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 - SPRAVATO™ is not dispensed for use outside the Healthcare Setting.
- Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*.
- Do not distribute, transfer, loan, or sell SPRAVATO™.
- Maintain records documenting staff's completion of training.
- Maintain records that all processes and procedures are in place and are being followed.
- Maintain records on the shipments of SPRAVATO™ received and dispensing information including the patient name, dose, number of devices and date administered.
- Comply with audits carried out by Janssen Pharmaceuticals, Inc. or a third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

* Signature:

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*Facility DEA License Number (on file with distributor account)

*DEA License Expiration Date (MM/DD/YYYY)

*Healthcare Setting Name

*Healthcare Setting Address 1

Address Line 2

*City

*State

*ZIP

*Healthcare Setting Type (select all that apply)
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 Mental Health Facility Outpatient Clinic Other

*Other Healthcare Setting Type

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SPRAVATO[™] REMS Healthcare Setting Certification



The following Healthcare Setting(s) is now certified in the SPRAVATO[™] REMS.

HCS 1



The certification of the following Healthcare Setting(s) in the SPRAVATO[™] REMS is pending.

If you have any questions, please contact the SPRAVATO[™] REMS Coordinating Center at 1-855-382-6022.

HCS 3

[ADD ANOTHER HEALTHCARE SETTING](#)

Pharmacy Online Enrollment Coming Soon!

In order to enroll your pharmacy in the SPRAVATO[™] REMS, please complete the *Pharmacy Enrollment Form* and submit it to the SPRAVATO[™] REMs via fax at 1-877-778-0091.

If you have any questions, please contact the SPRAVATO[™] REMS Coordinating Center at 1-855-382-6022.

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

[Privacy Policy](#) [Terms of Use](#)

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.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TIFFANY R FARCHIONE
03/05/2019 06:23:27 PM