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
Most Recent REMS Update: 6/2019

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:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have a prescriber onsite during SPRAVATO administration and monitoring.</td>
<td></td>
</tr>
<tr>
<td>2. Have healthcare provider(s) onsite to monitor patients.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
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<tr>
<td>4. Have the authorized representative review the SPRAVATO prescribing information.</td>
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</tr>
<tr>
<td>5. Have the authorized representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form and submitting it to the REMS Program.</td>
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</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>7. Establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering SPRAVATO and ensure</td>
<td></td>
</tr>
</tbody>
</table>
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 SPRAVATÒ 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.

<table>
<thead>
<tr>
<th>Before treatment initiation (first dose)</th>
<th>12. Counsel the patient on the risks and need for monitoring for resolution of sedation and dissociation and changes in vital signs.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Before administering</th>
<th>14. Counsel the patient on the need for monitoring for resolution of sedation and dissociation, and changes in vital signs.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15. Verify the patient is enrolled in the REMS Program through the processes and procedures established as a requirement of the REMS Program.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>During and after administering, for at least 2 hours</th>
<th>16. Assess the patient for self-administration of SPRAVATÒ and resolution of sedation and dissociation, and changes in vital signs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>After administering, within 7 calendar days</td>
<td>17. Document and submit to the REMS Program using the Patient Monitoring Form.</td>
</tr>
<tr>
<td>To maintain certification to dispense</td>
<td>18. Have any new authorized representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>At all times</th>
<th>19. Not dispense SPRAVATÒ for use outside the certified healthcare setting.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20. Not distribute, transfer, loan, or sell SPRAVATÒ.</td>
</tr>
<tr>
<td></td>
<td>21. Maintain records documenting staff’s completion of training.</td>
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<tr>
<td></td>
<td>22. Maintain records that all processes and procedures are in place and are being followed.</td>
</tr>
<tr>
<td></td>
<td>23. Maintain records of all shipments of SPRAVATÒ received and dispensing information including patient name, dose, number of devices, and date administered.</td>
</tr>
</tbody>
</table>
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.

### 2. Patients who are prescribed SPRAVATO:

<table>
<thead>
<tr>
<th>Before treatment initiation (first dose)</th>
<th>1. Receive counseling from a healthcare provider on risks and the need for monitoring for resolution of sedation and dissociation.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>During treatment, before each dose</td>
<td>3. Receive counseling from a healthcare provider on the need for monitoring for resolution of sedation and dissociation.</td>
</tr>
<tr>
<td>During treatment, during and after administration for at least 2 hours</td>
<td>4. Be monitored for taking SPRAVATO, resolution of sedation and dissociation, and changes in vital signs at the healthcare setting.</td>
</tr>
</tbody>
</table>

### 3. Pharmacies that dispense SPRAVATO must:

<table>
<thead>
<tr>
<th>To become certified to dispense</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Have the authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.</td>
</tr>
<tr>
<td></td>
<td>3. Train all relevant staff involved in dispensing that SPRAVATO must only be dispensed to a certified healthcare setting.</td>
</tr>
<tr>
<td></td>
<td>4. Establish processes and procedures to verify that a healthcare setting is certified in the REMS Program before dispensing SPRAVATO.</td>
</tr>
<tr>
<td>Before dispensing</td>
<td>5. Verify that the healthcare setting is certified through the processes and procedures established as a requirement of the REMS Program.</td>
</tr>
<tr>
<td>At all times</td>
<td>6. Not distribute, transfer, loan or sell SPRAVATO except to certified dispensers.</td>
</tr>
<tr>
<td></td>
<td>7. Not dispense SPRAVATO for use outside a certified healthcare setting.</td>
</tr>
<tr>
<td></td>
<td>8. Maintain records documenting staff’s completion of training.</td>
</tr>
<tr>
<td></td>
<td>9. Maintain records that all processes and procedures are in place and are being followed.</td>
</tr>
<tr>
<td></td>
<td>10. Maintain records of all shipments of SPRAVATO received and dispensing information including patient name, dose, number of devices, and date dispensed.</td>
</tr>
<tr>
<td></td>
<td>11. 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.</td>
</tr>
</tbody>
</table>
4. Wholesalers-distributors that distribute SPRAVATO must:

<table>
<thead>
<tr>
<th>To be able to distribute</th>
<th>1. Establish processes and procedures to ensure that SPRAVATO is distributed only to certified healthcare settings and certified pharmacies.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Train all relevant staff involved in distributing on the REMS Program requirements.</td>
</tr>
<tr>
<td>At all times</td>
<td>3. Distribute only to certified healthcare settings and certified pharmacies.</td>
</tr>
<tr>
<td></td>
<td>4. Maintain and submit records of all shipments of SPRAVATO.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Target Audience</th>
<th>Communication Materials &amp; Dissemination Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare providers likely to prescribe, dispense, and/or administer SPRAVATO</td>
<td>REMS Letter: <a href="#">REMS Letter for Healthcare Providers with attachment Fact Sheet</a>.</td>
</tr>
<tr>
<td></td>
<td>1. Email within 60 calendar days of the date SPRAVATO is first commercially distributed</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.</td>
</tr>
</tbody>
</table>

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. 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**
- Designate an Authorized Representative
- The Authorized Representative must review the following:
  - Prescribing Information

**STEP 2: COMPLETE AND SIGN**
- 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

**STEP 3: SUBMIT**
- Submit the Healthcare Setting Enrollment Form either:
  - Online at www.SPRAVATOrems.com
  - 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*: ____________________________

Healthcare Setting Telephone Number*: ____________________________

Healthcare Setting Website URL: ____________________________

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

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

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

If your healthcare setting is an independent (private) practice, or group practice, or outpatient clinic, how does your practice intend to acquire SPRAVATO™ for patients? (Select only one option)

- □ By sending a patient-specific prescription for SPRAVATO™ CIII (controlled substance) to a REMS certified pharmacy, have that pharmacy deliver patient-name product to your practice, and follow all required State and Federal DEA laws and regulations.

  OR

- □ By acquiring SPRAVATO™ CIII (controlled substance) as bulk supply directly from a Janssen qualified specialty distributor, and follow all required State and Federal DEA laws and regulations.

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.

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

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Reference ID: 4454144
**SPRAVATO™ REMS**  
Healthcare Setting Enrollment Form

*Indicates required field*

### Authorized Representative Information

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>MI:</th>
<th>Last Name*:</th>
</tr>
</thead>
</table>

### Credentials*:

- [ ] Physician  
- [ ] Physician Assistant  
- [ ] Nurse Practitioner  
- [ ] Pharmacist  
- [ ] Nurse  
- [ ] Other: ____________________________

<table>
<thead>
<tr>
<th>Telephone Number*:</th>
<th>EXT:</th>
<th>Fax*:</th>
<th>Email Address*:</th>
</tr>
</thead>
</table>

### Alternate Contact

<table>
<thead>
<tr>
<th>First Name:</th>
<th>Last Name:</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Telephone Number:</th>
<th>EXT:</th>
<th>Fax:</th>
<th>Email Address:</th>
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</table>

### Healthcare Setting Authorized Representative Agreement

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™ 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.
  - 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 Patient Monitoring Form 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 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 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):

<table>
<thead>
<tr>
<th>Authorized Representative Signature*:</th>
<th>Date*:</th>
</tr>
</thead>
</table>

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.
**Indicates required field**

### Additional Healthcare Setting

<table>
<thead>
<tr>
<th>Authorized Healthcare Setting</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorized Representative First Name*:</td>
<td>MI:</td>
</tr>
<tr>
<td>Authorized Representative Email:</td>
<td></td>
</tr>
<tr>
<td>Healthcare Setting Name*:</td>
<td></td>
</tr>
<tr>
<td>Healthcare Setting Address 1*:</td>
<td>Address Line 2:</td>
</tr>
<tr>
<td>City*:</td>
<td>State*:</td>
</tr>
<tr>
<td>Healthcare Setting Telephone Number*:</td>
<td>Healthcare Setting Website URL:</td>
</tr>
<tr>
<td>Facility DEA License Number* (on file with distributor account):</td>
<td>DEA License Expiration Date (MM/DD/YYYY)*:</td>
</tr>
</tbody>
</table>

### Healthcare Setting Type* (select all that apply):

- [ ] Hospital
- [ ] Mental Health Facility
- [ ] Long Term Care
- [ ] Outpatient Clinic
- [ ] Independent Practice
- [ ] Group Practice
- [ ] Other: ________________________________

*If your healthcare setting is an independent (private) practice, or group practice, or outpatient clinic, how does your practice intend to acquire SPRAVATO™ for patients? (Select only one option)*

- [ ] By sending a patient-specific prescription for SPRAVATO™ CIII (controlled substance) to a REMS certified pharmacy, have that pharmacy deliver patient-name product to your practice, and follow all required State and Federal DEA laws and regulations.

**OR**

- [ ] By acquiring SPRAVATO™ CIII (controlled substance) as bulk supply directly from a Janssen qualified specialty distributor, and follow all required State and Federal DEA laws and regulations.

### Alternate Contact Information

<table>
<thead>
<tr>
<th>First Name:</th>
<th>Last Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone Number:</td>
<td>EXT:</td>
</tr>
</tbody>
</table>

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.
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

<table>
<thead>
<tr>
<th>Healthcare Setting Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Setting Name*:</td>
</tr>
<tr>
<td>Healthcare Setting DEA#:</td>
</tr>
</tbody>
</table>

| Address 1*: Address 2: |
| City*: State*: ZIP*: |
| Phone*: Fax*: |

<table>
<thead>
<tr>
<th>Prescribing Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*: Last Name*:</td>
</tr>
<tr>
<td>Credentials*:</td>
</tr>
<tr>
<td>Psychiatry</td>
</tr>
<tr>
<td>MD</td>
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<tr>
<td>DO</td>
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<tr>
<td>NP</td>
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<td>PA</td>
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<tr>
<td>Other</td>
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<tr>
<td>Specialty*:</td>
</tr>
<tr>
<td>Internal Medicine</td>
</tr>
<tr>
<td>Family Practice</td>
</tr>
<tr>
<td>Other(specify):</td>
</tr>
<tr>
<td>Prescriber DEA#:</td>
</tr>
<tr>
<td>Phone*: Fax*: Email*:</td>
</tr>
<tr>
<td>Signature*: Date*:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Referring Physician – if different than Prescribing Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name: Last Name:</td>
</tr>
<tr>
<td>Phone:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relevant Clinical Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the patient previously been treated with ketamine for treatment-resistant depression, pain syndromes or any other condition?*</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If YES, list all pre-existing conditions treated with ketamine:</th>
</tr>
</thead>
<tbody>
<tr>
<td>List all pre-existing medical and psychiatric conditions:</td>
</tr>
<tr>
<td>List concomitant medications (e.g., adjunctive depression medications, sedative hypnotics, psychostimulants, monoamine oxidase inhibitors (MAOIs))</td>
</tr>
<tr>
<td>Reference ID: 4454144</td>
</tr>
</tbody>
</table>
This section is to be completed by the Patient

**Patient Information**

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>MI:</th>
<th>Last Name*:</th>
<th>Birthdate*: (MM/DD/YYYY):</th>
<th>Sex*: □ M □ F □ Other</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Email*:</th>
<th>Phone Number*:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Email is required for online enrollment only)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Address 1*:</td>
<td>Address 2*:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>City*:</td>
<td>State*:</td>
</tr>
</tbody>
</table>

**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 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.

**During treatment 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 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:**

<table>
<thead>
<tr>
<th>Patient Signature*:</th>
<th>Date*:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
SPRAVATO™ REMS
Pharmacy Enrollment Form

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**
- Designate an Authorized Representative
- The Authorized Representative must review the following:
  - Prescribing Information
  - Fact Sheet
  - Medication Guide
  - Instructions for Use

**STEP 2: COMPLETE AND SIGN**
- The Authorized Representative must complete the Pharmacy Enrollment Form
- If the Authorized Representative changes, the new Authorized Representative must complete and sign a new Pharmacy Enrollment Form

**STEP 3: SUBMIT**
- Submit the Pharmacy Enrollment Form either:
  - Online at www.SPRAVATOrems.com
  - Print and fax completed form to 1-877-778-0091

* Indicates required field

**Pharmacy Information**

<table>
<thead>
<tr>
<th>Name of Pharmacy*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Address 1*: Address Line 2:</td>
</tr>
<tr>
<td>City*: State*: ZIP*:</td>
</tr>
<tr>
<td>Pharmacy Telephone Number*: DEA License Number* (On file with distributor account): DEA Expiration Date* (MM/DD/YYYY):</td>
</tr>
</tbody>
</table>

**Pharmacy Type** (select all that apply):
- Clinic
- Hospital
- Inpatient
- Long-term Care
- Mental Health Facility
- Outpatient
- 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 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: |
| Telephone 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:
- Enroll in the SPRAVATO™ REMS by completing this Pharmacy Enrollment Form and submitting this form to the SPRAVATO™ REMS.
- 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.
  - 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.

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

<table>
<thead>
<tr>
<th>First Name*</th>
<th>MI:</th>
<th>Last Name*</th>
<th>Birthdate* (MM/DD/YYYY):</th>
<th>Sex*: □ Male □ Female □ Other</th>
</tr>
</thead>
</table>

### Concomitant Medication

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

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

### Healthcare Setting and Healthcare Provider Information (PRINT)

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>Last Name*:</th>
<th>Telephone*:</th>
<th>Email*:</th>
<th>Healthcare Setting Name*:</th>
<th>Healthcare Setting Address 1*:</th>
<th>Healthcare Setting Address 2*:</th>
<th>City*:</th>
<th>State*:</th>
<th>ZIP*:</th>
</tr>
</thead>
</table>

### Treatment Session Information

<table>
<thead>
<tr>
<th>Date* MM/DD/YYYY</th>
<th>Actual Dose Administered*</th>
<th>Patient must be monitored for at least 2 hours</th>
<th>Time When Patient Completed Treatment Session* AM/PM</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>BP Prior to Administration* mmHg</th>
<th>BP 40 Minutes Post Administration* mmHg</th>
<th>BP Prior to Patient Ready to Leave* mmHg</th>
</tr>
</thead>
</table>

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.*__________
**Indicates required field**

### Patient Information (PRINT)

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>MI:</th>
<th>Last Name*:</th>
<th>Birthdate* (MM/DD/YYYY):</th>
<th>Sex*:</th>
<th>□ Male □ Female □ Other</th>
</tr>
</thead>
</table>

### 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.

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

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.
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 XX, YY 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
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.

Reference ID: 4454144
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
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?

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

2. **Step 2: Review the following materials:**
   - SPRAVATO™ REMS Fact Sheet
   - SPRAVATO™ Prescribing Information
   - SPRAVATO™ Instructions for Use
   - SPRAVATO™ Medication Guide

3. **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
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?

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

2. Step 2: Review the following materials:
   - SPRAVATO™ Fact Sheet
   - SPRAVATO™ Prescribing Information
   - SPRAVATO™ Medication Guide
   - SPRAVATO™ Instructions for Use

3. 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
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:

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.

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

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 full night's sleep.

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
Fax: 1-877-778-0091

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

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For SPRAVATO™ REMS Program information contact:  
Phone: 1-855-392-0022  
Fax: 1-817-775-2032

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Distributed by: Janssen Pharmaceuticals, Inc., Titusville, NJ 08096

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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, managed by the manufacturer, to manage known or potential serious risks associated with a given drug. The goal of the REMS is to mitigate the risks and help ensure that the benefits of the drug outweigh the risks for patients.

Guiding Principles:

• Ensuring that SPRAVATO™ is dispensed or administered in a healthcare setting that monitors these patients.
• Ensuring that SPRAVATO™ is dispensed or administered only to patients who understand the risks and have been properly monitored.
• Ensuring that each patient is informed about the serious adverse outcomes resulting from discontinuation and withdrawal 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.

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

Legal Terms of Use | Privacy Policy

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7746) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

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Distributed by: Janssen Pharmaceuticals, Inc., Titusville, NJ 08560

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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.

* I am a
  - [ ] Healthcare Setting
  - [ ] Prescribing Physician
  - [ ] Pharmacy

Healthcare Setting Authorized Representative Information

* First Name

* Last Name

* Phone Number

* Fax Number

* Email Address

* Credentials
  - [ ] Physician
  - [ ] Physician Assistant
  - [ ] Nurse Practitioner
  - [ ] Pharmacist
  - [ ] Nurse
  - [ ] Other

* Credentials Other
  - Other

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

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*I am a
  ○ Healthcare Setting
  ○ Prescribing Physician
  ○ Pharmacy

Prescribing Physician
Healthcare Setting Information
*Certified Healthcare Setting DEA #

Prescribing Physician Information
*First Name

* Last Name

*Phone Number

*Fax Number

*Email Address

*Prescriber DEA #

*Credentials
  ○ MD
  ○ DO
  ○ NP
  ○ PA
  ○ Other

*Specialty
  ○ Psychiatry
  ○ Internal Medicine
  ○ Family Practice
  ○ 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

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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.

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

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

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.

*I am a
  ○ Healthcare Setting  ○ Prescribing Physician  ○ Pharmacy

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: 1-877-778-0031
www.SPRAVATOrems.com

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.
Change Password

Your password has expired and must be changed.

* New Password:

* Re-type new Password:

[Cancel] [Next]
Update Profile

*Security Caption:

*Security Question

--- Please Select ---

--- Please Select ---

--- Please Select ---

Answer

Answer

Answer

CANCEL NEXT
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

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

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.

Reference ID: 4454144
SPRAVATO™ REMS
Healthcare Setting Enrollment Form

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:

<table>
<thead>
<tr>
<th>STEP 1: REVIEW</th>
<th>STEP 2: COMPLETE AND SIGN</th>
<th>STEP 3: SUBMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Designate an Authorized Representative&lt;br&gt;• The Authorized Representative must review the following:&lt;br&gt;  • Prescribing Information</td>
<td>• The Authorized Representative must complete the Healthcare Setting Enrollment Form&lt;br&gt;• If the designated Authorized Representative changes, the new Authorized Representative must enroll and complete these 3 steps</td>
<td>• Submit the Healthcare Setting Enrollment Form either:&lt;br&gt;  • Online at: <a href="http://www.SPRAVATOREms.com">www.SPRAVATOREms.com</a>&lt;br&gt;  OR&lt;br&gt;  • Print and fax completed form to 1-877-778-0091</td>
</tr>
</tbody>
</table>

*Indicates Required Field

Healthcare Setting Information

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

CONTINUE

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

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.
## Healthcare Setting Enrollment Form

### IMPORTANT: 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 three steps:

**STEP 1: COMPLETE THE BAD SIGN**
- Designate an Authorized Representative
- The Authorized Representative must review the following:
  - Prescribing Information
- Submit the Healthcare Setting Enrollment Form.

**STEP 2: SUBMIT**
- The Authorized Representative must complete the Healthcare Setting Enrollment Form.
- If the designated Authorized Representative changes, the new Authorized Representative must enroll and complete the form 3 times.
- Submit the Healthcare Setting Enrollment Form via:
  - On-line at www.SPRAVATO.com
  - Print and fax form to 1-847-776-0991.

### Indicates Required Field

- *Facility DEA License Number (on file with distributor associate)
- *DEA License Expiration Date (MM/DD/YYYY)
- *Facility Name
- *Facility Setting Address 1
- *City
- *State
- *ZIP
- *Facility Setting Type (select all that apply)
- Hospital
- Retail
- Independent Practice
- Group Practice
- Other

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, click below.

**ADD ANOTHER HEALTHCARE SETTING**

Your healthcare setting information will be shared with prescriber, patient support, and distributor systems, 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 1-855-460-4622.

### Authorized Representative Information

**First Name:**

**Last Name:**

**Date of Birth:**

**Gender:**

**Telephone Number:**

**Email Address:**

**Alternate Contact:**

**First Name:**

**Last Name:**

**Telephone Number:**

**Email Address:**

### Healthcare Setting Authorized Representative

- Sign up as Authorized Representative designated by your Healthcare Setting to review implementation and coordinate the activities of the SPRAVATO™ REMS. By signing this form, I represent, on behalf of myself and my Healthcare Setting, to comply with the following requirements:
- Read and 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 pharmacy or community drugstore during SPRAVATO™ administration and monitoring.
- Have a healthcare provider available to monitor each patient for at least 2 hours following administration of SPRAVATO™ for resolution of side effects and discontinuation, and changes in vital signs.
- Trade of relevant staff involved in prescribing, dispensing, and administering SPRAVATO™ and establishing processes and procedures to ensure that the following take place in your Healthcare Setting:
  - A healthcare provider consults the patient in the healthcare setting, monitors and reports adverse effects, and discontinues SPRAVATO™.
  - All patients are enrolled in the SPRAVATO™ REMS by completing and submitting the Patient Enrollment Form. SPRAVATO™ is not dispensed from the healthcare setting.
- The patient self-administers SPRAVATO™ under the direct supervision of a healthcare provider.
- A designated healthcare provider monitors each patient for at least 2 hours following administration of SPRAVATO™ for resolution of side effects and discontinuation, and changes in vital signs every 6 hours.
- A Patient Information Form is submitted to the SPRAVATO™ REMS for each patient within 7 calendar days following administration of every dose.
- SPRAVATO™ is not dispensed from the healthcare setting.
- Have a non-overlapping Authorized Representative enrolled in the REMS.
- Do not distribute, forward, share or sell SPRAVATO™.
- Maintain accurate and complete documentation of training.
- Maintain records of all processes and procedures in place and how they are implemented.
- Maintain records on the shipments of SPRAVATO™ received and dispensing information including the patient name, dose, number of doses and date administered.
- Only eligible patients are harmed by SPRAVATO™. Only eligible patients are harmed by SPRAVATO™.

**Signature:**

**Date:**

**Contact Information:**

**Phone:**

**Fax:**

**Email:**

**Website:**
SPRATIVO™ REMS
Healthcare Setting Enrollment Form

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

To become an SPRATIVO™ REMS certified Healthcare Setting, send in by following these 7 steps:

STEP 1: START

**Indicates Required Field**

**Healthcare Setting Information**

- **Facility (DEA License Number) (contains drug with distributor account):**
- **DEA License Expiration Date (MM/DD/YYYY):**
- **Healthcare Setting Name:**
- **Address Information:**
  - **Address Line 1:**
  - **City:**
  - **State:**
  - **Zip Code:**
- **Healthcare Setting Telephone Number:**
- **Healthcare Setting Type:**
  - [ ] Hospital
  - [ ] Mental Health Facility
  - [ ] Long Term Care
  - [ ] Outpatient Clinic
  - [ ] Independent Practice
  - [ ] Emphasis Practice
  - [ ] Other

**Other Healthcare Setting Information:**

If your healthcare setting is an independent (private practice, or group practice), or a sphagnum field, how does your practiceo intend to accommodate SPRATIVO™ for patients?

- By enrolling in the patient identification program for SPRATIVO™ CR (sphagnum field practice), you consent to our REMS certification program. Your pharmacy, if necessary patients, patient system and procedures, and other DEA laws and regulations.

- By enrolling in SPRATIVO™ CR (sphagnum field practice) on behalf of the pharmacy, will be sent to a near-qualified specialty distributor, and all enrolled must be added to the DEA (EMIS) regulations.

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# SPRAVATÔ™ REMS Healthcare Setting Enrollment Form

**SPRAVATÔ™ REMS** may be required through the SPRAVATÔ™ REMS Risk Evaluation and Mitigation Strategy. OnlyPharmacies enrolled in healthcare settings that are certified in the SPRAVATÔ™ REMS can receive SPRAVATÔ™.

## Healthcare Setting Information

- **Reference ID**: 4454144

<table>
<thead>
<tr>
<th><strong>Field</strong></th>
<th><strong>Value</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility ID Number</td>
<td>(e.g., 526732)</td>
</tr>
<tr>
<td>Location</td>
<td>(e.g., 123 Main St, Suite A, Los Angeles, CA 90001)</td>
</tr>
<tr>
<td>Address Line 1</td>
<td>123 Main St, Suite A</td>
</tr>
<tr>
<td>Address Line 2</td>
<td>Los Angeles, CA 90001</td>
</tr>
<tr>
<td>City</td>
<td>Los Angeles</td>
</tr>
<tr>
<td>State</td>
<td>CA</td>
</tr>
<tr>
<td>ZIP Code</td>
<td>90001</td>
</tr>
<tr>
<td>Phone Number</td>
<td>(e.g., 555-1234)</td>
</tr>
<tr>
<td>E-mail Address</td>
<td>(e.g., <a href="mailto:info@healthcaresetting.com">info@healthcaresetting.com</a>)</td>
</tr>
</tbody>
</table>

## Healthcare Setting Information

- **Facility ID Number**: (e.g., 526732)
- **Location**: 123 Main St, Suite A, Los Angeles, CA 90001
- **Address Line 1**: 123 Main St, Suite A
- **Address Line 2**: Los Angeles, CA 90001
- **City**: Los Angeles
- **State**: CA
- **ZIP Code**: 90001
- **Phone Number**: (e.g., 555-1234)
- **E-mail Address**: (e.g., info@healthcaresetting.com)

For each additional healthcare setting where SPRAVATÔ™ will be delivered, dispensed, and administered within your healthcare system for which an SPA (safety and professional administration) is applicable, use the information provided below.

## Additional Healthcare Setting Information

- **Facility ID Number**: (e.g., 526732)
- **Location**: 123 Main St, Suite A, Los Angeles, CA 90001
- **Address Line 1**: 123 Main St, Suite A
- **Address Line 2**: Los Angeles, CA 90001
- **City**: Los Angeles
- **State**: CA
- **ZIP Code**: 90001
- **Phone Number**: (e.g., 555-1234)
- **E-mail Address**: (e.g., info@healthcaresetting.com)

## Healthcare Setting Information

- **Facility ID Number**: (e.g., 526732)
- **Location**: 123 Main St, Suite A, Los Angeles, CA 90001
- **Address Line 1**: 123 Main St, Suite A
- **Address Line 2**: Los Angeles, CA 90001
- **City**: Los Angeles
- **State**: CA
- **ZIP Code**: 90001
- **Phone Number**: (e.g., 555-1234)
- **E-mail Address**: (e.g., info@healthcaresetting.com)

## Healthcare Setting Information

- **Facility ID Number**: (e.g., 526732)
- **Location**: 123 Main St, Suite A, Los Angeles, CA 90001
- **Address Line 1**: 123 Main St, Suite A
- **Address Line 2**: Los Angeles, CA 90001
- **City**: Los Angeles
- **State**: CA
- **ZIP Code**: 90001
- **Phone Number**: (e.g., 555-1234)
- **E-mail Address**: (e.g., info@healthcaresetting.com)

## Healthcare Setting Information

- **Facility ID Number**: (e.g., 526732)
- **Location**: 123 Main St, Suite A, Los Angeles, CA 90001
- **Address Line 1**: 123 Main St, Suite A
- **Address Line 2**: Los Angeles, CA 90001
- **City**: Los Angeles
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- **Facility ID Number**: (e.g., 526732)
- **Location**: 123 Main St, Suite A, Los Angeles, CA 90001
- **Address Line 1**: 123 Main St, Suite A
- **Address Line 2**: Los Angeles, CA 90001
- **City**: Los Angeles
- **State**: CA
- **ZIP Code**: 90001
- **Phone Number**: (e.g., 555-1234)
- **E-mail Address**: (e.g., info@healthcaresetting.com)
SPRAVATO™ REMS Healthcare Setting Certification

⚠ Action Needed

☐ Healthcare Setting

The Healthcare Setting is now certified in the SPRAVATO™ REMS.

[Healthcare Setting #1 Name]

Please check your email for next steps.

You selected to acquire SPRAVATO™ as bulk supply directly from a Janssen qualified specialty distributor. Please click below to continue.

CONTINUE TO PHARMACY ENROLLMENT

☐ Healthcare Setting

The Healthcare Setting is now certified in the SPRAVATO™ REMS.

[Healthcare Setting #4 Name]

Please check your email for next steps.

You selected to acquire SPRAVATO™ as bulk supply directly from a Janssen qualified specialty distributor. Please click below to continue.

CONTINUE TO PHARMACY ENROLLMENT

✓ Complete

☐ Healthcare Setting

The Healthcare Setting is now certified in the SPRAVATO™ REMS.

[Healthcare Setting #2 Name]

Please check your email for next steps.

Pending

☐ Healthcare Setting

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

[Healthcare Setting #3 Name]

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

ADD ANOTHER HEALTHCARE SETTING

Phone: 1-800-382-6022
Fax: 1-877-778-0091
www.SPRAVATOrems.com

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 Pharmacy Enrollment Form

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:

<table>
<thead>
<tr>
<th>STEP 1: REVIEW</th>
<th>STEP 2: COMPLETE AND SIGN</th>
<th>STEP 3: SUBMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Designate an Authorized Representative</td>
<td>• The Authorized Representative must complete the Pharmacy Enrollment Form</td>
<td>• Submit the Pharmacy Enrollment Form either:</td>
</tr>
<tr>
<td>• Authorized Representative must review the following:</td>
<td></td>
<td>• Online at <a href="http://www.SPRAVATOREMS.com">www.SPRAVATOREMS.com</a>:</td>
</tr>
<tr>
<td>• Prescribing Information</td>
<td>• If the Authorized Representative changes, the new Authorized Representative must complete and sign a new Pharmacy Enrollment Form</td>
<td>• OR</td>
</tr>
<tr>
<td>• Patient Sheet</td>
<td></td>
<td>• Print and fax completed form to 1-877-779-0991</td>
</tr>
<tr>
<td>• Medication Guide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Instructions for Use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Indicates Required Field.

## Pharmacy Information

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

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

- **Shipping Address - Same as 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:**
- **Fax:**
- **Email Address:**

## Alternate Contact

- **First Name:**
- **Last Name:**
- **Telephone Number:**
- **Fax:**

## Pharmacy Authorized Representative Agreement

I, 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:

- Enroll in the SPRAVATO™ REMS by completing this Pharmacy Enrollment Form and submitting this form to the SPRAVATO™ REMS.
- Train relevant staff involved in dispensing SPRAVATO™ on the following:
  - SPRAVATO™ cannot 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.
- Notify hospitals, clinics, or other health care facilities to which SPRAVATO™ is distributed.
- 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 doses 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.

*Signature:*
SPRATVATO™ REMS Pharmacy Enrollment Form

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

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

**STEP 1: REVIEW**
- Designate an Authorized Representative
- Authorized Representative must review the following:
  - Prescribing Information
  - Fact Sheet
  - Medication Guide
  - Instructions for Use

**STEP 2: COMPLETE AND SIGN**
- The Authorized Representative must complete the Pharmacy Enrollment Form
- If the Authorized Representative changes, the new Authorized Representative must complete and sign a new Pharmacy Enrollment Form

**STEP 3: SUBMIT**
- Submit the Pharmacy Enrollment Form either:
  - Online at www.SPRATVATOREMS.com
  - OR
  - Print and fax completed form to 1-877-776-0091

* Indicates Required Field.

**Pharmacy Information**
- DEA License Number (On file with distributor account) [ ]
- DEA Expiration Date: [ ] 1/2021
- Name of Pharmacy: ABC Healthcare Setting
- Pharmacy Address 1: 405 Main Street
- Address Line 2: [ ]
- City: [ ] State: [ ] Zip: [ ]
- Phone: [ ] Pharmacy Telephone Number: [ ]
- Pharmacy Type (check off that apply):
  - Clinic
  - Hospital
  - Independent
  - Mental Health Facility
  - Outpatient
  - Specialty
  - Other
- Other Pharmacy Type: [ ]

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**
- Shipping Address - Same as above

**Pharmacy Authorized Representative Information**
- First Name: [ ] Last Name: [ ] Title: [ ]
- Telephone Number: [ ] Fax: [ ]
- Email Address: [ ]

Alternate Contact
- First Name: [ ] Last Name: [ ]
- Telephone Number: [ ] Fax: [ ]

**Pharmacy Authorized Representative Agreement**

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

I will:
- Enroll in the SPRATVATO™ REMS by completing this Pharmacy Enrollment form and submitting this form to the SPRATVATO™ REMS.
- Train all relevant staff in dispensing SPRATVATO™ on the following:
  - SPRATVATO™ can only be dispensed to a certified healthcare setting.
  - SPRATVATO™ 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 SPRATVATO™.
- Before dispensing SPRATVATO™, verify the healthcare setting is certified using the established processes and procedures.
- Maintain all documentation of training made available by Janssen Pharmaceuticals, Inc. and third-party entities acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.
- Maintain records of all shipments of SPRATVATO™ 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 entities acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

*Signature*:

**Phone:** 1-800-262-1022
**Fax:** 1-877-776-0091
**www.JanssenDerm.com**

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRATVATO™ 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 Healthcare Setting Certification

Action Needed

Healthcare Setting

The Healthcare Setting is now certified in the SPRAVATO™ REMS.

[Healthcare Setting #4 Name]

Please check your email for next steps.
You selected to acquire SPRAVATO™ as bulk supply directly from a Janssen qualified specialty distributor. Please tick below to continue.

Complete

Healthcare Setting

The Healthcare Setting is now certified in the SPRAVATO™ REMS.

[Healthcare Setting #1 Name]
(associated with [Pharmacy #1 Name])

Please check your email for next steps.

Pharmacy

The Pharmacy is now certified in the SPRAVATO™ REMS.

[Pharmacy #1 Name]
(associated with [Healthcare Setting #1 Name])

Pending

Healthcare Setting Enrollment

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

[Healthcare Setting #3 Name]

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

ADD ANOTHER HEALTHCARE SETTING
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
- REMS Fact Sheet
- Medication Guide
- Instructions for Use

NEXT
SPRAVATO™ REMS Pharmacy Enrollment Form

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**STEP 1: REVIEW**
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- Authorized Representative must review the following:
  - Prescribing Information
  - Fact Sheet
  - Medication Guide
  - Instructions for Use

**STEP 2: COMPLETE AND SIGN**
- The Authorized Representative must complete the Pharmacy Enrollment Form
- If the Authorized Representative changes, the new Authorized Representative must complete and sign a new Pharmacy Enrollment Form

**STEP 3: SUBMIT**
- Submit the Pharmacy Enrollment Form either:
  - Online at: www.SPRAVATOrems.com
  - OR
  - Print and fax completed form to 1-877-778-0091

* Indicates Required Field.

Pharmacy Information

* DEA License Number (On file with distributor account)

CONTINUE

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

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 Pharmacy Enrollment Form

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™.

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**STEP 1: REVIEW**
- Designate an Authorized Representative
- Authorized Representative must review the following:
  - Prescribing Information
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  - Medication Guide
  - Instructions for Use

**STEP 2: COMPLETE AND SIGN**
- The Authorized Representative must complete the Pharmacy Enrollment Form
- If the Authorized Representative changes, the new Authorized Representative must sign and complete a new Pharmacy Enrollment Form

**STEP 3: SUBMIT**
- Submit the Pharmacy Enrollment Form either:
  - Online at www.SPRAVATOREMS.com
  - OR
  - Print and fax completed form to 1-877-778-0001.

* Indicates Required Field.

## Pharmacy Information

- **DEA License Number (On file with distributor account)**
  - [ ]
- **DEA Expiration Date:**
  - [ ]
- **Name of Pharmacy**
  - [ ]
- **NPI:**
  - [ ]
- **State:**
  - [ ]
- **Address Line 1:**
  - [ ]
- **Address Line 2:**
  - [ ]
- **City:**
  - [ ]
- **ZIP:**
  - [ ]
- **Phone:**
  - [ ]
- **Fax:**
  - [ ]
- **Other Pharmacy Type:**
  - [ ]

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

- **Shipping Address - Same as above**

## Pharmacy Authorized Representative Information

- **First Name:**
  - [ ]
- **Last Name:**
  - [ ]
- **Title:**
  - [ ]
- **Telephone Number:**
  - [ ]
- **Fax:**
  - [ ]
- **Email Address:**
  - [ ]

## Alternate Contact

- **First Name:**
  - [ ]
- **Last Name:**
  - [ ]
- **Telephone Number:**
  - [ ]
- **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:
- Enroll in the SPRAVATO™ REMS by completing this Pharmacy Enrollment Form and submitting this form to the SPRAVATO™ REMS.
- Train all relevant staff involved in dispensing SPRAVATO™ on the following:
  - SPRAVATO™ can only be dispensed to a certified healthcare setting.
  - SPRAVATO™ cannot 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.
- Track distributors, transport, loan or sell SPRAVATO™ except to certified dispensers.
- Maintain records documenting staffs 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.

*Signature:*

**CONTINUE**

**CANCEL**
SPRAVATO™ REMS Pharmacy Certification

Complete

Pharmacy

The Pharmacy is now certified in the SPRAVATO™ REMS.

[Pharmacy Name]

Please check your email for next steps.

CONTINUE
My Patients

Below is a list of your patients.

Patient Listing

- Download the list to spreadsheet format by clicking the Excel icon just above the column headers.
- Search/Filter the list by entering information in the textbox below any column header.
- Sort the list by clicking on any column header.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>Date of Birth</th>
<th>REMS Status</th>
<th>Most Recent Ship Date</th>
<th>PMF Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert</td>
<td>Smith</td>
<td>123 Main Street</td>
<td>Philadelphia</td>
<td>PA</td>
<td>19042</td>
<td>1/1/2000</td>
<td>Certified</td>
<td>5/23/2018</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mary</td>
<td>Connors</td>
<td>3 Broadway</td>
<td>Blue Bell</td>
<td>PA</td>
<td>19042</td>
<td>1/1/2000</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you would like to submit a Patient Monitoring Form, but cannot find the patient in the grid below, please click here.

Submit a Patient Monitoring Form
# Patient Monitoring Form

## Patient Information

- **First Name:** Peggy
- **Middle Initial:**
- **Last Name:** Sun
- **Birthday:** 1/1/2000
- **Sex:** F

## Concomitant Medication

<table>
<thead>
<tr>
<th>Medication Type</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzodiazepines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-benzodiazepine sedative hypnotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychostimulants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monoamine oxidase inhibitors (MAOIs)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Healthcare Setting and Healthcare Provider Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Name</strong></td>
<td>Jon</td>
</tr>
<tr>
<td><strong>Last Name</strong></td>
<td>Ben</td>
</tr>
<tr>
<td><strong>Telephone</strong></td>
<td>555-353-1212</td>
</tr>
<tr>
<td><strong>Email</strong></td>
<td><a href="mailto:john@asr.com">john@asr.com</a></td>
</tr>
<tr>
<td><strong>Healthcare Setting Name</strong></td>
<td>ABC Healthcare</td>
</tr>
<tr>
<td><strong>Healthcare Setting Address 1</strong></td>
<td>123 Main Street</td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>New York</td>
</tr>
<tr>
<td><strong>State</strong></td>
<td>NY</td>
</tr>
<tr>
<td><strong>ZIP</strong></td>
<td>10001</td>
</tr>
</tbody>
</table>

## 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):**
  - 2:00 PM

## Patient must be monitored for at least 2 hours

- **Time When Patient Completed Treatment Session:**
  - 4:00 PM

- **Confirm vital signs (BP, HR, RR) were in an acceptable range prior to SPRAVATO™ administration:**
  - Yes
  - No

- **Confirm vital signs were in an acceptable range prior to patient ready to leave:**
  - Yes
  - No

- **BP Prior to Administration (mmHg):**
- **BP 40 Minutes Post Administration (mmHg):**
- **BP Prior to Patient Ready to Leave (mmHg):**

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

## Sedation and Dissociation

- **Sedation:**
  - Yes
  - No

- **Dissociation:**
  - Yes
  - No

## 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.

<table>
<thead>
<tr>
<th>Event</th>
<th>Occurrence</th>
<th>Date of Event (MM/DD/YYYY)</th>
<th>The event resulted in (check all that apply)</th>
<th>Did the event resolve?</th>
</tr>
</thead>
</table>

## 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-JANSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).
Patient Monitoring Form

Patient Information

First Name: Peggy
Middle Initial: M
Last Name: Sue

Concomitant Medication

Is the patient currently taking any of the following concomitant medications that may cause sedation or blood pressure changes?

- Benzodiazepines
  - Yes
  - No
- Non-benzodiazepine sedative hypnotics
  - Yes
  - No
- Psychostimulants
  - Yes
  - No
- Antihypertensive agents (MAOIs)
  - Yes
  - No

Healthcare Setting and Healthcare Provider Information

- *First Name*
- Telephone
- Healthcare Setting Name:
- Healthcare Setting Address 1:
- City:
- State:
- ZIP:

Treatment Session Information

- Date (MM/DD/YYYY): [MM/DD/YYYY]
- Time of Administration (by: device used): [PM] [AM]
- Administration: [28 mg] [56 mg] [84 mg]

Patient must be monitored for at least 2 hours

- Time When Patient Completed Treatment Session: [PM] [AM]
- BP Prior to Administration (now): [ ] [ ]
- BP 40 Minutes Post Administration (now): [ ] [ ]
- BP Prior to Patient Read to Leave (now): [ ] [ ]

Sedation and Dissociation

Did the patient experience sedation or dissociation?

- Sedation
  - Yes
  - No
- Did symptoms resolve within 2 hours of administration?
  - Yes
  - No
  - greater than 120 mins

Serious Adverse Events

Did the patient experience any serious adverse events 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 required medical intervention, prevented the administration of the medication, or was life-threatening.

- Serious Adverse Event
- Occurrence
- Date of Event (MM/DD/YYYY)
- The event resulted in... [ ] [ ] [ ] [ ]
- Did the event require... [ ] [ ] [ ] [ ]

ADD SERIOUS ADVERSE EVENT

Janssen Pharmaceuticals, Inc. Safety Department may follow up with a telephone call 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 (1-800-528-7736) or the FDA at 1-888-FDA-1080 or online at www.fda.gov/medwatch.
SPRAVATO® REMS
Patient Enrollment Form

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.

*Indicates Required Field

Healthcare Setting Information

Healthcare Setting Name:
Address: 150144d Street
City: Boston
Phone Number: 855 955 1322

Prescribing Physician

*First Name: Jane
*Last Name: Doe
*Credentials: MD, NP, PA, Other
*Specialty: Psychiatry
*Email: jdoe@abc.com
*Telephone: 609 1000 1234

Referred Physician - if different than Prescribing Physician

First Name: John
Last Name: Smith

Relevant Clinical Information

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

List all pre-existing medical and psychiatric conditions:

List concurrent medications (e.g., antidepressant depression medications, sedative hypnotics, psychostimulants, monoamine oxidase inhibitors (MAOIs)):

Patient Information

*First Name: John
*Last Name: Doe
*Address: 123 Doe St
City: Boston
*Zip: 02112
*Email: jdoe@abc.com

Patient Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:

* Go to the SPRAVATO® Room by completing this Patient Enrollment Form with my healthcare provider. Enrollment information will be provided to the REMS.

* Agree to not consuming alcohol or Illicit drugs (e.g., marijuana) on the day of treatment and the need to monitor for resolution of sedation and dissociation, and for any changes in my sex sign.

During treatment, 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.

* Not drive a motor vehicle or operate heavy machinery for the rest of the day on which I receive SPRAVATO®.

* Not call my doctor or other healthcare provider at my next visit if I believe I have a side effect or reaction from SPRAVATO®.

* Not use the SPRAVATO® device to inject any medication other than ketamine and all information will be stored in a database of patients who receive SPRAVATO® in the United States.

* Not inject ketamine into my bloodstream or intranasally. I agree to be monitored and observed by my healthcare provider for the purpose of monitoring the REMS, including recording events and monitoring the REMS, coordinating periodic reviews of SPRAVATO® safety, and improving and disclosing any personal health information to the medical and Drug Administration (FDA), as necessary, and as otherwise required by law.

Patient Acknowledgment

* Is a patient currently available to complete patient signature during online enrollment? Yes No

Prescriber Confirmation

In order to sign this form electronically, please enter your usename and password.

Username: *Password: *
### Change Healthcare Setting

Please click on the Healthcare Setting name to select, then click "Continue".

<table>
<thead>
<tr>
<th>DEA#</th>
<th>HCS Name</th>
<th>City</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>11111</td>
<td>Healthcare Facility Name1</td>
<td>Philadelphia</td>
<td>PA</td>
</tr>
<tr>
<td>22222</td>
<td>Healthcare Facility Name2</td>
<td>NY</td>
<td>NY</td>
</tr>
</tbody>
</table>

*Indicates Required Field

### Healthcare Setting Information

- **Healthcare Setting DEA# (on file with distributor account):** 12345
- **Healthcare Setting Name:**
  - Address 1: 100 Main Street
  - City: Molven
  - Phone Number: 555 555-1212
- **Address 2:**
  - State: PA
  - Email: abc@abc.com
  - ZIP: 19542

### Prescribing Physician

- **Reference ID:** 4454144
SPRAVATO™ REMS Patient Enrollment Form

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.

Healthcare Setting Information

Healthcare Setting Name: [Name of healthcare setting]
Address: [Address information]
City: [City]
State: [State]
ZIP: [ZIP code]
Phone: [Phone number]
Email: [Email address]

Prescribing Physician

*First Name: [First name]
*Last Name: [Last name]
*Credentials: [MD] [NP] [PA] [PNP] [Other]
Specialty: [Psychiatry] [Internal Medicine] [Family Practice] [Other]
Specialty Other: [Other specialty]
*Phone: [Phone number]
*Email: [Email address]

Referring Physician - if different than Prescribing Physician

Referring Physician: [Name of referring physician]
Fix: [Fax number]

Referring Physician - Same as Prescribing Physician

Relevant Clinical Information

Has the patient previously been treated with ketamine for treatment-resistant depression, pain syndromes or any other condition? [Yes] [No]
List all pre-existing conditions treated with ketamine:
List all pre-existing medical and psychiatric conditions:
List concomitant medications (e.g., antidepressive medication, sedative hypnotics, psychotomimetics, monoamine oxidase inhibitors [MAOIs]):

Patient Information

*First Name: [First name]
*Last Name: [Last name]
*Gender: [Male] [Female] [Other]
*Address 1: [Address]
*Address 2: [Address]
*City: [City]
*State: [State]
*ZIP: [ZIP code]
*Email: [Email address]
*Phone: [Phone number]

Patient Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:
- Review the SPRAVATO™ REMS and consent to participate. The Patient Enrollment Form with my healthcare provider. Informational materials will be provided to the patient.
- Agree to receive counseling on the risks and the need for monitoring for resolution of auditory and dissociative, and for any changes in my vital signs.
- During treatment, I will:
- Not use the SPRAVATO™ product until prescribed by a healthcare professional.
- Abide by the healthcare setting’s rules for treatment with SPRAVATO™ for at least 3 hours after each treatment until the healthcare provider determines I am ready to leave the healthcare setting.
- Undertaken:
- I agree to allow the healthcare setting and my healthcare provider to monitor the patient’s response to treatment.
- I should not drive or be heavy machinery for the first of this day on which I receive SPRAVATO™.
- I should contact my doctor or employer if I feel unwell during treatment 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.
- I am aware of the potential for the reporting of adverse events to the REMS and the importance of reporting such events to the REMS.
- I agree to report any serious adverse event to my healthcare provider and the REMS.

Patient Acknowledgement

Is patient currently available to complete patient signature during online enrollment? [Yes] [No]

Prescriber Confirmation

In order to sign this form electronically, please re-enter your username and password.

Username: [Username]
Password: [Password]

CANCELSUBMIT TO REMS
A new document from SPRAVATO REMS is available for you to sign.

You will be given the opportunity to:

- Preview the document.
- Send feedback or questions to SPRAVATO REMS.
- Decline signing and send feedback to SPRAVATO REMS.
- Sign the document electronically using AssureSign.
Review the terms and conditions below and check the checkbox indicating your agreement to receive and sign this document electronically. Click Start Signing when you are ready to sign.

By checking the box below, I agree that the electronic digitized signatures I apply on the following document are representations of my signature and are legally valid and binding as if I had signed the document with ink on paper in accordance with the Uniform Electronic Transactions Act (UETA) and the Electronic Signatures in Global and National Commerce Act (E-SIGN) of 2000.

AssureSign complies with requirements and standards of the Electronic Signatures In Global and National Commerce Act (E-SIGN Act) effective October 1, 2000, the Uniform Electronic Transaction Act (UETA), and the Government Paperwork Elimination Act (GPEA).

☐ I have read and agree to the terms and conditions

Start Signing
Adopt a Signature

Provide your name by drawing with touch, mouse, or stylus.
Signature

By clicking "Adopt Signature", I agree that the signature and initials above will be the electronic representation of my signature and initials for all purposes when I use them to sign documents. Applying them to a document is legally equivalent to signing with a pen on paper.

Adopt Signature
All Information Entered

You have entered all requested information and signatures.

When ready, click Finish to complete this step of the document signing process.

Finish
A new document from SPRAVATO REMS is available for you to sign.

You will be given the opportunity to:

- Preview the document
- Send feedback or questions to SPRAVATO REMS.
- Decline signing and send feedback to SPRAVATO REMS.
- Sign the document electronically using AssureSign.

**Username:** abc@abc.com

**Note - Please check your email for the password**

**Password**

[Input field]

[Submit button]

Reference ID: 4454144
Welcome

Agree to Terms

Sign

Done

Review the terms and conditions below and check the checkbox indicating your agreement to receive and sign this document electronically. Click **Start Signing** when you are ready to sign.

By checking the box below, I agree that the electronic digitized signatures I apply on the following document are representations of my signature and are legally valid and binding as if I had signed the document with ink on paper in accordance with the Uniform Electronic Transactions Act (UETA) and the Electronic Signatures in Global and National Commerce Act (E-SIGN) of 2000.

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☑ I have read and agree to the terms and conditions

[Start Signing]
Adopt a Signature

Provide your name by drawing with touch, mouse, or stylus.

Signature

By clicking “Adopt Signature”, I agree that the signature and initials above will be the electronic representation of my signature and initials for all purposes when I use them to sign documents. Applying them to a document is legally equivalent to signing with a pen on paper.

Adopt Signature
All Information Entered

You have entered all requested information and signatures. When ready, click Finish to complete this step of the document signing process.

[Back] Finish

Patient Information

First Name: Mary
Last Name: Smith
Email: abc@abc.com
Phone Number: 555-555-1212
Address 1: 100 Main St
City: Philadelphia
State: PA
Zip: 90099

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. Important information will be provided to the REMS.
- Agree to receive counseling as the need for monitoring for sedation, dissociation, and any changes in my vital signs.

During my treatment I will:
- Use the SPRAVATO nasal spray under the direct observation of a healthcare provider.
- Be observed at the healthcare setting where I get SPRAVATO at least six weeks after my first treatment until the healthcare provider determines I am ready to leave the healthcare setting.

I understand:
- Sedation and dissociation can result from misuse of SPRAVATO and I must stay away from each treatment. Until these effects resolve, I may feel:
  - sleepy
  - disconnected from myself, surroundings, and things around me.
  - should make arrangements to have someone accompany me to the healthcare setting and get home.
  - should not drive or other responsibility for the workday or week
  - should not work, drive, or perform any other responsibility for the rest of the day on which I receive SPRAVATO.
  - should contact my doctor or pharmacist prior to my next visit if I believe I am having 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 and 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: Mary Smith
Patient Signature: [Signature]

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
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