I. Administrative Information

Application Number: NDA 211,243
Application Holder: Janssen Pharmaceuticals, Inc.
Initial REMS Approval: 3/2019
Most recent REMS Update: 1/2022

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 patients are informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring.
- Enrolling all patients who receive treatment in an outpatient healthcare setting 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 for outpatient use must:

   | To become certified to dispense | 1. Have a prescriber onsite during SPRAVATO administration and monitoring. |
   |  | 2. Have healthcare provider(s) onsite to monitor patients. |
   |  | 3. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting. |
   |  | 4. Have the authorized representative review the SPRAVATO prescribing information and REMS Program Overview. |
   |  | 5. Have the authorized representative enroll in the REMS Program by completing the Outpatient Healthcare Setting Enrollment Form and submitting it to the REMS Program. |
   |  | 6. Establish processes and procedures to enroll the patient in the REMS Program. |
   |  | 7. Establish processes and procedures to counsel the patient on the need for enrollment, monitoring, and risks of sedation and dissociation, and changes in vital signs. |
8. Establish processes and procedures to verify the patient is enrolled in the REMS Program before each administration and that SPRAVATO is not dispensed for use outside the certified healthcare setting.

9. Establish processes and procedures to complete and submit the Patient Monitoring Form after each administration within 7 calendar days.

10. Train all relevant staff involved in prescribing, dispensing and administering SPRAVATO on 1) Counseling the patient on the need for monitoring and risks of sedation and dissociation, and changes in vital signs; 2) Patient administration under the supervision of a healthcare provider; and 3) Monitoring for resolution of sedation and dissociation and changes in vital signs for a minimum of 2 hours.

11. Establish processes and procedures to identify all staff involved in prescribing, dispensing, and administering SPRAVATO and ensure they are trained on 1) Counseling the patient on the need for monitoring and risks of sedation and dissociation, and changes in vital signs; 2) Patient administration under the supervision of a healthcare provider; 3) Monitoring for resolution of sedation and dissociation and changes in vital signs for a minimum of 2 hours.

<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>13. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program.</td>
<td></td>
</tr>
<tr>
<td>Before administering</td>
<td>14. Counsel the patient on the need for monitoring for resolution of sedation and dissociation, and changes in vital signs.</td>
</tr>
<tr>
<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>
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</tr>
<tr>
<td>During and after administering, for at least 2 hours</td>
<td>16. Assess the patient for administration of SPRAVATO and resolution of sedation and dissociation, and changes in vital signs.</td>
</tr>
<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 Outpatient Healthcare Setting Enrollment Form.</td>
</tr>
<tr>
<td>At all times</td>
<td>19. Not dispense SPRAVATO for use outside the certified healthcare setting.</td>
</tr>
<tr>
<td></td>
<td>20. Not distribute, transfer, loan, or sell SPRAVATO.</td>
</tr>
<tr>
<td></td>
<td>21. Maintain records documenting staff’s completion of training.</td>
</tr>
</tbody>
</table>
22. Maintain records that all processes and procedures are in place and are being followed.

23. Maintain records of all shipments of SPRAVATO received and dispensing information including patient name, dose, number of devices, and date administered.

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

2. Healthcare settings that dispense SPRAVATO for inpatient use (including emergency departments within certified healthcare settings) must:

<table>
<thead>
<tr>
<th>To become certified to dispense</th>
<th>1. Have a prescriber onsite during SPRAVATO administration and monitoring.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Have healthcare provider(s) onsite to monitor patients.</td>
</tr>
<tr>
<td></td>
<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>
</tr>
<tr>
<td></td>
<td>4. Have the authorized representative review the SPRAVATO prescribing information and REMS Program Overview.</td>
</tr>
<tr>
<td></td>
<td>5. Have the authorized representative enroll in the REMS Program by completing and submitting the Inpatient Healthcare Setting Enrollment Form.</td>
</tr>
<tr>
<td></td>
<td>6. Establish processes and procedures to counsel the patient on the need for monitoring and risks of sedation and dissociation, and changes in vital signs.</td>
</tr>
<tr>
<td></td>
<td>7. Establish processes and procedures to verify SPRAVATO is not dispensed for use outside the certified healthcare setting.</td>
</tr>
<tr>
<td></td>
<td>8. Train all relevant staff involved in prescribing, dispensing and administering SPRAVATO on 1) Counseling the patient on the need for monitoring, risks of sedation and dissociation, changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities; 2) Patient administration under the supervision of a healthcare provider; and 3) Monitoring for resolution of sedation and dissociation and changes in vital signs for a minimum of 2 hours.</td>
</tr>
</tbody>
</table>

| Before administering | 9. Counsel the patient on the need for monitoring for resolution of sedation and dissociation, and changes in vital signs and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities. |

| During and after administering, for at least 2 hours | 10. Assess the patient for administration of SPRAVATO and resolution of sedation and dissociation, and changes in vital signs. |
To maintain certification to dispense

11. Have any new authorized representative enroll in the REMS Program by completing the Inpatient Healthcare Setting Enrollment Form.

At all times

12. Not dispense SPRAVATO for use outside the certified healthcare setting.

13. Not distribute, transfer, loan, or sell SPRAVATO.

14. Maintain records documenting staff’s completion of training.

15. Maintain records that all processes and procedures are in place and are being followed.

16. Maintain records of all shipments of SPRAVATO received and dispensing information including patient name, dose, number of devices, and date administered.

17. 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.

3. Patients who are prescribed SPRAVATO:

Before treatment initiation (first dose)

1. Receive counseling from a healthcare provider on risks and the need for monitoring for resolution of sedation and dissociation, and changes in vital signs.

2. For outpatients: Enroll in the REMS Program by completing the Patient Enrollment Form with a healthcare provider. Enrollment information will be provided to the REMS Program.

During treatment, before each dose

3. Receive counseling from a healthcare provider on the need for monitoring for resolution of sedation and dissociation; and change in vital signs.

During treatment, during and after administration for at least 2 hours

4. Be monitored for taking SPRAVATO, resolution of sedation and dissociation, and changes in vital signs at the healthcare setting.

4. Pharmacies that dispense SPRAVATO must:

To become certified to dispense

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.

2. Have the authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.

3. Establish processes and procedures to verify that a healthcare setting is certified in the REMS Program before dispensing SPRAVATO.

4. Train all relevant staff involved in dispensing that SPRAVATO must only be dispensed to a certified healthcare setting.

Before dispensing

5. Verify that the healthcare setting is certified through the processes and procedures established as a requirement of the REMS Program.
### 5. 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>

**Janssen Pharmaceuticals, Inc. must provide training to health care settings that dispense SPRAVATO.**

The training includes the following educational material: REMS Program Overview. The training must be provided online and in hardcopy format by mail or fax.

**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.

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 in outpatient healthcare settings are able to enroll patients by fax and online.

7. Ensure outpatient 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 Outpatient Healthcare Setting Enrollment Form, Inpatient Healthcare Setting Enrollment Form, Pharmacy Enrollment Form, REMS Program Overview 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.

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 treated in outpatient healthcare settings, to provide information on the incidence of adverse outcomes from sedation and 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 outpatient 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 15% or 50 healthcare settings (whichever is greater), 15% or 50 pharmacies (whichever is greater), 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 from the date of initial approval of the REMS and annually thereafter. 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. Outpatient Healthcare Setting Enrollment Form
2. Inpatient Healthcare Setting Enrollment Form

Patient:

3. Patient Enrollment Form

Pharmacy:

4. Pharmacy Enrollment Form

**Training and Educational Materials**

Healthcare Setting:

5. REMS Program Overview

Pharmacy:

6. REMS Program Overview

**Patient Care Forms**

7. Patient Monitoring Form

**Other Materials**

8. REMS Program Website
SPRAVATO® REMS
Outpatient Healthcare Setting Enrollment Form

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

* Indicates Required Field

<table>
<thead>
<tr>
<th>Healthcare Setting Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Setting Name*:</td>
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<tr>
<td>Healthcare Setting Address 1*:</td>
</tr>
<tr>
<td>City*:</td>
</tr>
<tr>
<td>Healthcare Setting Telephone Number*:</td>
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<tr>
<td>Healthcare Setting Website URL:</td>
</tr>
<tr>
<td>DEA License Number* (associated with the Healthcare Setting address):</td>
</tr>
<tr>
<td>Name of DEA License Holder (if different from Healthcare Setting Name):</td>
</tr>
<tr>
<td>DEA License Expiration Date (MM/DD/YYYY)*:</td>
</tr>
</tbody>
</table>

Healthcare Setting Type*: □ Mental Health Facility □ 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 all that apply)
□ 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.
□ By acquiring SPRAVATO® CIII (controlled substance) as bulk supply directly from a SPRAVATO® REMS-qualified 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
© Janssen Pharmaceuticals, Inc. 2020 08/20
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 all REMS Requirements:

I will:

• Review the SPRAVATO® Prescribing Information and REMS Program Overview.
• Enroll in the SPRAVATO® REMS by completing this 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.
• Establish processes and procedures and train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO® to ensure that the following takes place in my Healthcare Setting:
  - Prior to the patient receiving SPRAVATO®, a healthcare provider counsels the patient on the need for enrollment, monitoring, risks of sedation and dissociation, and changes in vital signs.
  - All patients are enrolled in the SPRAVATO® REMS by completing and submitting the Patient Enrollment Form with their prescriber.
  - Verify the patient is enrolled in the REMS before dispensing SPRAVATO® for patient administration.
  - The patient 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 days following administration of every dose.
  - Notify the SPRAVATO® REMS in advance if patient treatment will be transferred from one REMS-certified Healthcare Setting to another REMS-certified Healthcare Setting.
  - SPRAVATO® is not dispensed for use outside the Healthcare Setting.
  - If the authorized representative changes, have the new authorized representative re-certify the Outpatient Healthcare Setting into the REMS by completing the Outpatient Healthcare Setting Enrollment Form.
  - 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 of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date administered.
• Comply with audits carried out by Janssen Pharmaceuticals, Inc., or a third party acting on behalf of Janssen Pharmaceuticals, Inc., to ensure that all processes and procedures are in place and are being followed.

Name (please print):

Authorized Representative Signature*:

Date*: 

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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
**SPRAVATO® REMS**

Outpatient Healthcare Setting Enrollment Form

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

* Indicates Required Field

<table>
<thead>
<tr>
<th>Additional Healthcare Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorized Representative First Name*:</td>
</tr>
<tr>
<td>Authorized Representative Email:</td>
</tr>
<tr>
<td>Healthcare Setting Name *:</td>
</tr>
<tr>
<td>Healthcare Setting Address 1*:</td>
</tr>
<tr>
<td>City*:</td>
</tr>
<tr>
<td>ZIP*:</td>
</tr>
<tr>
<td>Healthcare Setting Telephone Number*:</td>
</tr>
<tr>
<td>DEA License Number* (associated with the Healthcare Setting address):</td>
</tr>
<tr>
<td>DEA License Expiration Date (MM/DD/YYYY)*:</td>
</tr>
</tbody>
</table>

**Healthcare Setting Type**:  
- Mental Health Facility
- 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 all that apply)

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

<table>
<thead>
<tr>
<th>Additional Alternate Contact Information</th>
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<tbody>
<tr>
<td>First Name:</td>
</tr>
<tr>
<td>Telephone Number:</td>
</tr>
<tr>
<td>Fax:</td>
</tr>
</tbody>
</table>

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

Your healthcare setting information (name, location, and phone number) will be listed on a location finder, as a certified outpatient 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.

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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
Inpatient Healthcare Setting Enrollment Form

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

As an Inpatient Healthcare Setting (with inpatient units, emergency department, etc.), your Inpatient Pharmacy, operating under the same Drug Enforcement Administration (DEA) license and physical location, will be considered certified once this form is completed/submitted. **A separate pharmacy enrollment is not required.**

* Indicates Required Field

### Healthcare Setting Information

<table>
<thead>
<tr>
<th>Healthcare Setting Name*:</th>
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</thead>
<tbody>
<tr>
<td>Healthcare Setting Address 1*: Address Line 2:</td>
</tr>
<tr>
<td>City*: State*: ZIP*:</td>
</tr>
<tr>
<td>Healthcare Setting Telephone Number*: Healthcare Setting Website URL:</td>
</tr>
<tr>
<td>DEA License Number* (associated with the Healthcare Setting address): Name of DEA License Holder (if different from Healthcare Setting Name): DEA License Expiration Date (MM/DD/YYYY)*:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Healthcare Setting Type*: (select all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Hospital-Emergency Department ☐ Hospital-Inpatient ☐ Mental Health Facility</td>
</tr>
<tr>
<td>☐ Other: ____________________________</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.**

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.
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 all REMS requirements:

I will:

• Review the SPRAVATO® Prescribing Information and REMS Program Overview.
• Enroll in the SPRAVATO® REMS by completing this 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.

• Establish processes and procedures and train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO® to ensure that the following takes place in my Healthcare Setting:
  - A healthcare provider counsels the patient prior to receiving SPRAVATO® on the need for monitoring due to risks of sedation and dissociation, changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.
  - The patient 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.
  - SPRAVATO® is not dispensed for use outside the Healthcare Setting.
  - If the authorized representative changes, have the new authorized representative re-certify the Inpatient Healthcare Setting into the REMS by completing the Inpatient Healthcare Setting Enrollment Form.
  - 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 of 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.

Healthcare Setting and Pharmacy Authorized Representative Agreement

Name (please print):

Authorized Representative Signature*: Date*:
**INSTRUCTIONS:**
This form is intended only for use by outpatient medical offices or clinics, **excluding emergency departments**

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

**This section is to be completed by the Prescriber**

* Indicates required field

### Healthcare Setting Information

<table>
<thead>
<tr>
<th>Healthcare Setting Name*:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Setting DEA License Number* (associated with the Healthcare Setting address):</td>
</tr>
<tr>
<td>Address 1*: Address 2:</td>
</tr>
<tr>
<td>City*: State*: ZIP*:</td>
</tr>
<tr>
<td>Phone*: Fax*:</td>
</tr>
</tbody>
</table>

### Prescriber Information

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>Last Name*:</th>
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<tbody>
<tr>
<td>Credentials*:</td>
<td>Prescriber DEA License Number*:</td>
</tr>
<tr>
<td>Physician</td>
<td>Physician Assistant</td>
</tr>
<tr>
<td>Specialty*:</td>
<td>Psychiatry</td>
</tr>
<tr>
<td>Phone*: Fax: Email*:</td>
<td></td>
</tr>
<tr>
<td>Prescriber Signature*: Date*:</td>
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</tbody>
</table>

### Referring Healthcare Provider – if different from Prescriber

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

### Relevant Clinical Information

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

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

________________________________________________________________________

List all pre-existing medical and psychiatric conditions*:

________________________________________________________________________

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

________________________________________________________________________

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

This section is to be completed by the Patient

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

* Indicates required field

Patient Information

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

<table>
<thead>
<tr>
<th>Email*: (Email is required for online enrollment only)</th>
<th>Phone Number*:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address 1*:</th>
<th>Address 2:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>City*:</th>
<th>State*:</th>
<th>ZIP*:</th>
</tr>
</thead>
</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 submitted to the SPRAVATO® REMS.
- Receive counseling on safety risks and the need for monitoring to observe for resolution of sedation and dissociation, and for any changes in vital signs.

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

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

Patient Name (please print):

Patient Signature*: Date*:

This section is to be completed by the Patient

Your healthcare provider will help you complete this form and provide you with a copy.
SPRAVATO® REMS
Pharmacy Enrollment Form

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

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

* Indicates Required Field

Pharmacy Information

Name of Pharmacy*:

Pharmacy Address 1*:

Address Line 2:

City*:

State*:

ZIP*:

Pharmacy Telephone Number*:

DEA License Number* (On file with distributor account)

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

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

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

Pharmacy Shipping Address, if different from above

Pharmacy Address (address must match the DEA address associated with your Pharmacy’s DEA License Number):

Address Line 2:

City:

State:

ZIP:

Pharmacy Authorized Representative Information

First Name*:

Last Name*:

Title*:

Telephone Number*:

Ext:

Fax*:

Email Address*:

Pharmacy Alternate Contact

First Name:

Last Name:

Telephone Number:

Ext:

Fax:

Email Address:

Pharmacy Authorized Representative Agreement

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

I will:

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

Authorized Representative Signature*:

Date:

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

Phone: 1-855-382-6022 www.SPRAVATOrems.com Fax: 1-877-778-0091
© Janssen Pharmaceuticals, Inc. 2020 08/20
SPRAVATO® REMS Program Overview
(Risk Evaluation and Mitigation Strategy)

This overview describes the SPRAVATO® REMS requirements and responsibilities of inpatient healthcare settings, outpatient healthcare settings, pharmacies, and patients.

If you have any questions regarding the SPRAVATO® REMS, please visit www.SPRAVATOrems.com or call 1-855-382-6022

Spravato®
( esketamine) nasal spray

Reference ID:
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 U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

SPRAVATO® is available only through a restricted distribution program called the SPRAVATO® REMS because of 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 use only in a certified Healthcare Setting.

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 the SPRAVATO® REMS work?

Before Prescribing/Dispensing SPRAVATO®
- Inpatient Healthcare Setting Certification
  [covers hospital inpatient, inpatient pharmacy, and emergency departments]

Before Starting SPRAVATO® for each Patient
- Counsel the patient on the risks and need for monitoring for resolution of sedation and dissociation, and changes in vital signs.

During SPRAVATO® Treatment
- Supervise patient administration of SPRAVATO®.
- Monitor each patient for at least 2 hours following administration of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs.
- Report all suspected adverse events to the SPRAVATO® REMS.
- Enroll the patient using the Patient Enrollment Form.

- Counsel the patient on the risks and need for monitoring for resolution of sedation and dissociation, and changes in vital signs.

- Supervise patient administration of SPRAVATO®.
- Monitor each patient for at least 2 hours following administration of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs.
- Submit the Patient Monitoring Form.

- Verify that the healthcare setting is certified through the processes and procedures established as a requirement of the SPRAVATO® REMS.

- Receive counseling from a healthcare provider on the need for monitoring for resolution of sedation and dissociation, and changes in vital signs.

- Administer SPRAVATO® under the direct supervision of a healthcare provider.
- Be observed for at least 2 hours after each treatment of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs at the healthcare setting.
What are the Requirements of the SPRAVATO® REMS?

• In order for patients to receive SPRAVATO®, healthcare settings, pharmacies, and patients must comply with all requirements of the SPRAVATO® REMS

INPATIENT HEALTHCARE SETTING REQUIREMENTS

Become Certified*:

1. Designate an Authorized Representative to oversee implementation and coordinate the activities of the SPRAVATO® REMS

2. Review the following materials:
   - SPRAVATO® Prescribing Information
   - SPRAVATO® REMS Program Overview (this document)

3. Have the Authorized Representative complete and submit the Inpatient Healthcare Setting Enrollment Form at www.SPRAVATOrems.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091

4. Once submitted, you will be notified of certification in the SPRAVATO® REMS and you will receive information on additional requirements necessary to order and receive SPRAVATO®

Before treating a patient:

1. Establish processes and procedures and train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO®

2. Have a healthcare provider counsel the patient prior to receiving SPRAVATO® on the need for monitoring due to risks of sedation and dissociation, changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.

At All Times:

1. Ensure relevant staff are trained and follow all established processes and procedures to comply with SPRAVATO® REMS requirements†

2. Have a prescriber onsite during SPRAVATO® administration and monitoring

3. Have a healthcare provider monitor every patient for at least 2 hours for resolution of sedation and dissociation and changes in vital signs after every dose

4. Ensure SPRAVATO® is not dispensed for use outside the Healthcare Setting

5. Maintain records documenting staff completion of training

6. Maintain records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date administered

7. 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

†To review all SPRAVATO® REMS Inpatient Healthcare Setting requirements see the Inpatient Healthcare Setting Enrollment Form

*As an Inpatient Healthcare Setting (with inpatient units, emergency department, etc.), your Inpatient Pharmacy, operating under the same Drug Enforcement Administration (DEA) license and physical location, will be considered certified once the Inpatient Healthcare Setting Enrollment Form is completed/submitted. A separate pharmacy enrollment is not required.
OUTPATIENT HEALTHCARE SETTING REQUIREMENTS

Become Certified:

1. **Designate** an Authorized Representative to oversee implementation and coordinate the activities of the SPRAVATO® REMS
2. **Review** the following materials:
   - SPRAVATO® Prescribing Information
   - SPRAVATO® REMS Program Overview (this document)
3. Have the Authorized Representative **complete** and **submit** the *Outpatient Healthcare Setting Enrollment Form* at [www.SPRAVATOrems.com](http://www.SPRAVATOrems.com), or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091.
4. Once submitted, you will be notified of certification in the SPRAVATO® REMS and you will receive information on additional requirements necessary to order and receive SPRAVATO®

Before treating a patient:

1. **Establish** processes and procedures and train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO® to comply with all SPRAVATO® REMS requirements
2. Have a healthcare provider **counsel** the patient prior to receiving SPRAVATO® on the need for enrollment, monitoring, risks of sedation and dissociation, and changes in vital signs
3. Have a prescriber **enroll** the patient by completing and submitting the *Patient Enrollment Form* to the SPRAVATO® REMS
4. **Verify** the patient is enrolled in the SPRAVATO® REMS before dispensing SPRAVATO® for patient administration

At All Times:

1. **Ensure** relevant staff are trained and follow all established processes and procedures to comply with all SPRAVATO® REMS requirements*
2. Have a **prescriber onsite** during SPRAVATO® administration and monitoring
3. Have the patient **administer** SPRAVATO® under the direct supervision of a healthcare provider
4. 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 after every dose
5. **Document** and **submit** a *Patient Monitoring Form* for every patient within 7 days following administration of every dose of SPRAVATO®
6. **Notify** the SPRAVATO® REMS in advance if patient treatment will be transferred from one REMS-certified Healthcare Setting to another REMS-certified Healthcare Setting
7. **Ensure** SPRAVATO® is not dispensed for use outside the Healthcare Setting
8. **Maintain** records documenting staff completion of training
9. **Maintain** records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date administered
10. **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

*To review all SPRAVATO® REMS Outpatient Healthcare Setting requirements see the *Outpatient Healthcare Setting Enrollment Form*
PHARMACY REQUIREMENTS - FOR OUTPATIENT DISPENSING ONLY

Become Certified:

1. **Designate** an Authorized Representative to oversee implementation and coordinate the activities of the SPRAVATO® REMS

2. **Review** the following materials:
   - SPRAVATO® Prescribing Information
   - SPRAVATO® REMS Program Overview (this document)

3. Have the Authorized Representative **complete** and **submit** the Pharmacy Enrollment Form at www.SPRAVATOrems.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091

4. Once submitted, you will be notified of certification in the SPRAVATO® REMS and you will receive information on additional requirements necessary to order and receive SPRAVATO®

Before Dispensing:

1. **Establish** processes and procedures and train all relevant staff involved in dispensing SPRAVATO® to comply with all SPRAVATO® REMS requirements

2. **Verify** the healthcare setting is certified before dispensing SPRAVATO®

At All Times:

1. **Ensure** relevant staff are trained and follow all established processes and procedures to comply with all SPRAVATO® REMS requirements*

2. **Ensure** SPRAVATO® is never dispensed directly to a patient for home use

3. **Ensure** SPRAVATO® is only dispensed to a certified healthcare setting

4. **Maintain** records documenting staff’s completion of training

5. **Maintain** records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date dispensed

6. **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

*To review all SPRAVATO® REMS Pharmacy requirements see the Pharmacy Enrollment Form
PATIENT REQUIREMENTS

Before Treatment:

1. **Receive** counseling from a healthcare provider on risks and the need for monitoring for resolution of sedation and dissociation, and changes in vital signs.

2. **Outpatient Only:**
   - **Enroll** in the SPRAVATO® REMS Program by completing the *Patient Enrollment Form* with a healthcare provider. Enrollment information will be provided to the SPRAVATO® REMS Program.

During Treatment:

1. **Administer** SPRAVATO® nasal spray under the direct observation of a healthcare provider.

2. **Be observed** at the healthcare setting where SPRAVATO® is received for at least 2 hours after each treatment until the healthcare provider determines the patient is ready to leave the healthcare setting.

At All Times*:

1. **Make arrangements** to safely get home after receiving SPRAVATO®, if leaving the healthcare setting.

2. **Do not** drive or use heavy machinery for the rest of the day after receiving SPRAVATO®.

3. **Contact the healthcare provider** or inform the healthcare provider at the next visit if a side effect or reaction from SPRAVATO® occurs.

*To review all SPRAVATO® REMS requirements for patients receiving SPRAVATO® in an Outpatient Healthcare Setting, see the *Patient Enrollment Form*.
Contact the SPRAVATO® REMS

Phone: 1-855-382-6022
Fax: 1-877-778-0091
Hours of Operation: Monday- Friday 8:00 AM - 8:00 PM ET
Visit 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.

Please see the Prescribing Information for more information.

SPRAVATO® is a registered trademark of Janssen Pharmaceuticals, Inc.
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# INSTRUCTIONS:
This form is intended only for use by outpatient medical offices or clinics, excluding emergency departments.

1. Complete all required fields on this form after every treatment session for all outpatients enrolled in the SPRAVATO® REMS.
2. Submit completed patient monitoring forms within 7 days, online at www.SPRAVATOrems.com or by fax (1-877-778-0091).

* 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</th>
<th>Female</th>
<th>Other</th>
</tr>
</thead>
</table>

## Concomitant Medication

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

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

## Healthcare Provider Conducting Patient Monitoring (PRINT)

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>Last Name*:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone*:</td>
<td>Email*:</td>
</tr>
</tbody>
</table>

## Healthcare Setting Information (PRINT)

<table>
<thead>
<tr>
<th>Healthcare Setting Name*:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Setting Address 1*:</td>
</tr>
<tr>
<td>Healthcare Setting Address 2*:</td>
</tr>
<tr>
<td>City*:</td>
</tr>
</tbody>
</table>

## Patient Treatment Session Information (Administration and Monitoring)

<table>
<thead>
<tr>
<th>Treatment Date*</th>
<th>Date (MM/DD/YYYY):</th>
<th>Lot Number*:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dose Administered*</th>
<th>56 mg</th>
<th>84 mg</th>
<th>Other:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Treatment Duration*</th>
<th>Total time _____ minutes (from 1st device administration to completion of monitoring)</th>
</tr>
</thead>
</table>

**Patient must be monitored for at least 2 hours**

## REMS Evaluation Question*

If there was not a 2-hour minimum monitoring requirement, when would this patient have been ready to leave/no longer require monitoring? _______ minutes from start of administration

## Monitoring of Vital Signs*

Vital signs were in acceptable range prior to:

- **administration**: Yes / No
- **treatment session completion**: Yes / No

## Monitoring of Blood Pressure*

<table>
<thead>
<tr>
<th>Prior to administration</th>
<th>40 mins post-administration</th>
<th>Prior to treatment session completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>mmHg</td>
<td>mmHg</td>
<td>mmHg</td>
</tr>
</tbody>
</table>

## Did the patient experience Sedation and/or Dissociation

<table>
<thead>
<tr>
<th>Sedation*:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Onset of symptoms from start of administration*</th>
<th>1-29 mins</th>
<th>30-59 mins</th>
<th>60-89 mins</th>
<th>90-120 mins</th>
<th>&gt;120 mins</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Resolution of symptoms within 2 hours*</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Specify total time to resolution*: _______ minutes

<table>
<thead>
<tr>
<th>Medication(s) given for sedation*</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- If YES, name and dose of medication(s): ____________________________

<table>
<thead>
<tr>
<th>Medication(s) given for dissociation*</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- If YES, name and dose of medication(s): ____________________________

**Phone: 1-855-382-6022**

© Janssen Pharmaceuticals, Inc. 11/2021
**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</th>
<th>Female</th>
<th>Other</th>
</tr>
</thead>
</table>

**Healthcare Provider Conducting Patient Monitoring (PRINT)**

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Last Name*</th>
<th>Phone*</th>
<th>Email*</th>
</tr>
</thead>
</table>

| Treatment Date (MM/DD/YYYY): |

**Serious Adverse Events (PRINT)**

A serious adverse event (SAE) for this SPRAVATO® REMS is **defined** as any event that results in/is:

- Hospitalization
- Disability or permanent damage
- Death
- Life-threatening
- Important medical event

-- defined as any event that may jeopardize the patient or may require intervention to prevent one of the above outcomes

All non-serious adverse events or product quality complaints that are **not defined above**, should be reported to:

Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**Did the patient experience a serious adverse event?**

☐ Yes  ☐ No  ☐ If YES, describe below.

<table>
<thead>
<tr>
<th>Event resulted in the following: (check all that apply)</th>
<th>Event Timing</th>
<th>Event Description (Please list one event per row)</th>
<th>Event Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Hospitalization</td>
<td>☐ During treatment sessions</td>
<td>___________________________________________________________________________</td>
<td>☐ Yes ☐ No ☐ Unknown</td>
</tr>
<tr>
<td>☐ Disability or permanent damage</td>
<td>☐ Between treatment sessions</td>
<td>_________________________________________________________________________</td>
<td>☐ Yes ☐ No ☐ Unknown</td>
</tr>
<tr>
<td>☐ Death</td>
<td>Date of Event (MM/DD/YYYY)</td>
<td>_________________________________________________________________________</td>
<td>☐ Yes ☐ No ☐ Unknown</td>
</tr>
<tr>
<td>☐ Life-threatening</td>
<td></td>
<td>_________________________________________________________________________</td>
<td>☐ Yes ☐ No ☐ Unknown</td>
</tr>
<tr>
<td>☐ Important Medical Event</td>
<td></td>
<td>_________________________________________________________________________</td>
<td>☐ Yes ☐ No ☐ Unknown</td>
</tr>
</tbody>
</table>

| ☐ Hospitalization                                      | ☐ During treatment sessions | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |
| ☐ Disability or permanent damage                        | ☐ Between treatment sessions | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |
| ☐ Death                                                | Date of Event (MM/DD/YYYY) | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |
| ☐ Life-threatening                                      |                                                              | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |
| ☐ Important Medical Event                               |                                                              | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |

| ☐ Hospitalization                                      | ☐ During treatment sessions | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |
| ☐ Disability or permanent damage                        | ☐ Between treatment sessions | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |
| ☐ Death                                                | Date of Event (MM/DD/YYYY) | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |
| ☐ Life-threatening                                      |                                                              | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |
| ☐ Important Medical Event                               |                                                              | _________________________________________________________________________ | ☐ Yes ☐ No ☐ Unknown |

Janssen Pharmaceuticals, Inc., Safety Department may follow up to obtain more information about these events.
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 U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

SPRAVATO® (esketamine) nasal spray CII is available only through a restricted distribution program called the SPRAVATO® REMS because of 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 use only in a certified Healthcare Setting.

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

- **Inpatient Healthcare Setting**
  
  Inpatient Healthcare Settings must be certified in the SPRAVATO® REMS in order to treat patients with SPRAVATO®

- **Outpatient Healthcare Setting**

- **Pharmacy**

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

- **Patient**

  Patients must be enrolled in the SPRAVATO® REMS in order to receive SPRAVATO® treatment in an Outpatient Healthcare Setting

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 (TRD) in adults.
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

SPRAVATO® is only available through select restricted 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 Inpatient Healthcare Setting Enrollment

Inpatient Healthcare Settings must be certified in the SPRAVATO® REMS in order to treat patients with SPRAVATO®.

SPRAVATO® is intended for patient administration under the direct observation of a healthcare provider, due to risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO administration, and abuse and misuse of SPRAVATO. SPRAVATO® is intended for use only in a certified Healthcare Setting.

Inpatient Healthcare Settings are NOT required to enroll patients or submit Patient Monitoring Forms to the SPRAVATO® REMS.

As an Inpatient Healthcare Setting (with inpatient units, emergency department, etc.), your Inpatient Pharmacy, operating under the same Drug Enforcement Administration (DEA) license and physical location, will be considered certified once the Inpatient Healthcare Setting Enrollment Form is completed/submitted. A separate pharmacy enrollment is not required.

Inpatient Healthcare Settings are required to report all suspected adverse events to the SPRAVATO® REMS at 1-855-382-4022.

How does my Inpatient 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® Prescribing Information
   - SPRAVATO® REMS Program Overview

3. **Step 3**: Complete and submit the SPRAVATO® REMS Inpatient Healthcare Setting Enrollment Form to the REMS.
   - [Online]
   - [Fax]

PDFs for Download: Resources for Inpatient Healthcare Settings

- SPRAVATO® REMS Inpatient Healthcare Setting Enrollment Form
- SPRAVATO® REMS Program Overview
- SPRAVATO® Prescribing Information
SPRAVATO® REMS Outpatient Healthcare Setting Enrollment

Outpatient 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, due to risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO® administration, and abuse and misuse of SPRAVATO®. SPRAVATO® is intended for use only in a certified Healthcare Setting.

SPRAVATO® REMS Outpatient Healthcare Settings are required to enroll patients prior to patient treatment and submit Patient Monitoring Forms after each patient treatment to the SPRAVATO® REMS.

Outpatient Healthcare Setting Enrollment is intended only for outpatient medical offices and clinics. Emergency departments within hospitals are certified through the Inpatient Healthcare Setting enrollment.

How does my Outpatient 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® Prescribing Information
   - SPRAVATO® REMS Program Overview

3. Step 3: Complete and submit the SPRAVATO® REMS Outpatient Healthcare Setting Enrollment Form to the REMS.

   Online | Fax

PDFs for Download: Resources for Outpatient Healthcare Settings

SPRAVATO® REMS Outpatient Healthcare Setting Enrollment Form
SPRAVATO® Prescribing Information
SPRAVATO® REMS Patient Enrollment Form
SPRAVATO® REMS Program Overview
SPRAVATO® REMS Patient Monitoring Form

Legal Terms of Use | Privacy Policy

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen at 1-800-332-1176 or the FDA at 1-888-FDA-1088 or online at www.fda.gov/medwatch.

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By Janssen Pharmaceuticals, Inc., Titusville, NJ 08096

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SPRÄVATO® REMS Pharmacy Enrollment - for Outpatient Dispensing Only

Pharmacies must be certified in the SPRÄVATO® REMS to be able to receive and dispense SPRÄVATO®.

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

How does my Pharmacy become certified in the SPRÄVATO® REMS?

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

2. **Step 2:** Review the following materials:
   - SPRÄVATO® Prescribing Information
   - SPRÄVATO® REMS Program Overview

3. **Step 3:** Complete and submit the SPRÄVATO® REMS Pharmacy Enrollment Form to the REMS.
   - [Online](#)
   - [By Fax](#)

PDFs for Download: Resources for Pharmacies

- SPRÄVATO® REMS Pharmacy Enrollment Form
- SPRÄVATO® Prescribing Information
- SPRÄVATO® REMS Program Overview
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 healthcare provider 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 healthcare provider must sign the Patient Enrollment Form for you to receive SPRAVATO® in an outpatient medical office or clinic, excluding emergency departments. Your healthcare provider 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® in an outpatient medical office or clinic, excluding emergency departments.

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

1. Step 1: 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 an outpatient medical office or clinic, excluding emergency departments.
      • You will be monitored by a healthcare provider for at least 2 hours; the healthcare provider will then decide when you are ready to leave the healthcare setting.
      • After treatment with SPRAVATO®, do not drive, operate heavy machinery, or do anything where you need to be completely alert until the next day following a restful sleep.

2. Step 2: Together with your healthcare provider complete and sign the SPRAVATO® REMS Patient Enrollment Form:
   • Your healthcare provider will fill out most of the form for you and will send the form to SPRAVATO® REMS.

3. Step 3: Ask your healthcare provider any questions you have about taking SPRAVATO® and about the SPRAVATO® REMS.

For SPRAVATO® REMS Program information contact:
Phone: 1-855-580-4202
Fax: 1-877-770-4949

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen at 1-888-JANSSEN (1-888-526-7736) or the FDA 1-888-FDA-2394 or online at www.fda.gov/medwatch.

This site is published by Janssen Pharmaceuticals, Inc., which is solely responsible for its contents. This site is intended for use by healthcare professionals in the United States and Puerto Rico. Janssen Pharmaceuticals, Inc. recognizes that the internet is a global communications medium; however, laws, regulations, requirements, and medical practice for pharmaceutical products vary from country to country. The prescribing information included here may not be appropriate for use outside the United States and Puerto Rico.

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Legal Terms of Use | Privacy Policy

Reference ID: 4649523
Contact the SPRAVATO® REMS

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.
Inpatient Healthcare Setting Resources for SPRAVATO® REMS

- SPRAVATO® REMS Inpatient Healthcare Setting Enrollment Form
- SPRAVATO® Prescribing Information
- SPRAVATO® REMS Program Overview

Outpatient Healthcare Setting Resources for SPRAVATO® REMS

- SPRAVATO® REMS Outpatient Healthcare Setting Enrollment Form
- SPRAVATO® REMS Program Overview
- SPRAVATO® Prescribing Information
- SPRAVATO® REMS Patient Enrollment Form
- SPRAVATO® REMS Patient Monitoring Form

Pharmacy Resources for SPRAVATO® REMS

- SPRAVATO® REMS Pharmacy Enrollment Form
- SPRAVATO® Prescribing Information
- SPRAVATO® REMS Program Overview
Login
Your username was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 1-855-382-6022.

User Name

Forgot Username

Login

OR

Don't have an online account?

Register
To create your online account for the SPRAVATO® REMS, please start by completing the fields below.

* I am a
  - Healthcare Setting
  - Prescriber
  - 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: 1-877-778-0091
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 was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 1-855-382-6022.

Forgot Username

OR

Don't have an online account?

Register
To create your online account for the SPRAVATO® REMS, please start by completing the fields below.

* I am a
  - Healthcare Setting
  - Prescriber
  - Pharmacy

Healthcare Setting Authorized Representative Information

* First Name

* Last Name

* Telephone Number

* Fax Number

* Email Address

* Credentials
  - Physician
  - Physician Assistant
  - Nurse
  - Pharmacist
  - Other

* Credentials Other
  - Other

SUBMIT

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

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

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
Account Submitted Successfully

Thank you for submitting your information to create your web account for the SPRAVATO® REMS.

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

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

LOGIN
Register

To create your online account for the SPRAVATO® REMS, please start by completing the fields below.

* I am a
  - Healthcare Setting
  - Prescriber
  - 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

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 was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 855-382-6022.

User Name

Forget Username

LOGIN

Password:

I am a

○ Healthcare Setting  ○ Prescriber  ○ Pharmacy

CANCEL  NEXT

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

Healthcare providers should report all adverse events and product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN (1-800-526-7736).
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 --

Answer

-- Please Select --

Answer

-- Please Select --

Answer

CANCEL

NEXT
Healthcare Setting Type to Certify

Please click on the corresponding button below to certify as an Inpatient Healthcare Setting or an Outpatient Healthcare Setting.

If you wish to certify multiple healthcare settings as the same designated authorized representative, you will be prompted to enroll another inpatient or outpatient healthcare setting after completing this first enrollment.

Inpatient Healthcare Settings
As an Inpatient Healthcare Setting (with inpatient units, emergency department, etc.), your Inpatient Pharmacy, operating under the same Drug Enforcement Administration (DEA) license and physical location, will be considered certified once this form is completed/submitted. A separate pharmacy enrollment is not required.

Outpatient Healthcare Settings
This form is intended only for Outpatient Medical Offices and Clinics. Emergency departments within hospitals are certified through the Inpatient Healthcare Setting enrollment.

CERTIFY INPATIENT HEALTHCARE SETTING

CERTIFY OUTPATIENT HEALTHCARE SETTING
Review Materials

If you have not yet reviewed the materials below, please review now by clicking on each link. Each document will open in a new window.

**SPRAVATO® REMS Materials**

- SPRAVATO® Prescribing Information
- SPRAVATO® REMS Program Overview

NEXT
SPRAVATO® REMS
Inpatient Healthcare Setting Enrollment Form

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

As an Inpatient Healthcare Setting (with inpatient units, emergency department, etc.), your Inpatient Pharmacy, operating under the same Drug Enforcement Administration (DEA) license and physical location, will be considered certified once this form is completed/submitted. A separate pharmacy enrollment is not required.

*Indicates Required Field

Healthcare Setting Information

*DEA License Number (associated with the Healthcare Setting address)

CONTINUE
SPRAVATO® REMS
Inpatient Healthcare Setting Enrollment Form

Instructions:
1. Review the SPRAVATO® Prescribing Information and the SPRAVATO® REMS Program Overview.
2. Complete this form online at www.SPRAVATO.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-770-0081.

As an Inpatient Healthcare Setting (with inpatient units, emergency department, etc.), your Inpatient Pharmacy, operating under the same Drug Enforcement Administration (DEA) license and physical location, will be considered certified once this form is completed and approved. A separate pharmacy enrollment is not required.

Healthcare Setting Information

- DEA License Number (associated with the Healthcare Setting address)
  - Name of DEA License Holder (if different from Healthcare Setting name)
  - DEA License Expiration Date (MM/DD/YYYY)
- Healthcare Setting Name
- Healthcare Setting Address
- City: [ ]
- State: [ ]
- Zip: [ ]
- Healthcare Setting Telephone Number
- Healthcare Setting Website URL
- Healthcare Setting Type:
  - Hospital, Emergency Department
  - Hospital, inpatient
  - Other

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 1-855-365-4003.

Healthcare Setting and Pharmacy Authorized Representative Information

- First Name
- Last Name
- Credentials:
  - Physician
  - Physician Assistant
  - Nurse
  - Pharmacist
  - Other
- Telephone Number
- Email Address

Healthcare Setting and Pharmacy Alternate Contact

- First Name
- Last Name
- Telephone Number
- Email Address

Healthcare Setting and Pharmacy 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 all REMS requirements.

I will:
- Review the SPRAVATO® Prescribing Information and REMS Program Overview.
- Enroll in the SPRAVATO® REMS by completing this form and submitting this form to the SPRAVATO® REMS.
- Have a procedure in place during SPRAVATO® administration and monitoring.
- Have a healthcare provider(s) able to monitor each patient for at least 2 hours following administration of SPRAVATO® for a resolution of restlessness and dissociation, and changes in vital signs.
- Establish processes and procedures and task all relevant staff involved in prescribing, dispensing, and administering SPRAVATO® as necessary to ensure that the following take place in my Healthcare Setting:
  - A healthcare provider monitors the patient prior to administering SPRAVATO® and on the day following administration for signs of restlessness and dissociation, changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.
  - The patient administers SPRAVATO® under the direct supervision of a healthcare provider.
  - A healthcare provider monitors each patient for at least 2 hours for resolution of restlessness and dissociation and changes in vital signs after administration.
  - SPRAVATO® is not dispensed for use outside the healthcare setting.
  - If the authorized representative changes, have the new authorized representative re-certify the Inpatient Healthcare setting for the REMS, by completing the Inpatient Healthcare Setting Enrollment Form.
  - Not distribute, transport, hire, 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 of all payments or SPRAVATO® and dispensing information including the patient name, dose, number of doses, and date administered.

I certify that all such records and procedures are in place and are being followed. I agree to comply with any audits carried out by Janssen Pharmaceuticals, Inc., or any 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:

[Signature]

[Date]

[Location]

[City, State, Zip]

CANCEL  CONTINUE

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 to the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
SPRAVATO® REMS
Inpatient Healthcare Setting Enrollment Form

Instructions
1. Review the SPRAVATO® Prescribing Information and the SPRAVATO® REMS Program Overview.
2. Complete this form online at www.SPRAVATO.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-779-5091.

As an Inpatient Healthcare Setting (with Inpatient units, emergency department, etc.), your Inpatient Pharmacy, operating under the same Drug Enforcement Administration (DEA) license and physical location, will be considered certified once this form is completed/submitted. A separate pharmacy enrollment is not required.

Indicates Required Field

Healthcare Setting Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA License Number (associated with the Healthcare Setting address)</td>
<td>1234567890</td>
</tr>
<tr>
<td>DEA License Expiration Date</td>
<td>01/01/2025</td>
</tr>
<tr>
<td>Healthcare Setting Name</td>
<td>123 Main Street, Suite 100</td>
</tr>
<tr>
<td>Healthcare Setting Address 1</td>
<td>123 Main Street, Suite 100</td>
</tr>
<tr>
<td>City</td>
<td>123 Main Street, Suite 100</td>
</tr>
<tr>
<td>State</td>
<td>123 Main Street, Suite 100</td>
</tr>
<tr>
<td>Hospital Setting Telephone Number</td>
<td>123-456-7890</td>
</tr>
<tr>
<td>Hospital Setting Type (select all that apply)</td>
<td>[checkboxes] Hospital, Emergency Department, Inpatient</td>
</tr>
<tr>
<td>Other Healthcare Setting Type</td>
<td></td>
</tr>
</tbody>
</table>

Healthcare Setting and Pharmacy Authorized Representative Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>John</td>
</tr>
<tr>
<td>Last Name</td>
<td>Doe</td>
</tr>
<tr>
<td>Credentials</td>
<td>Physician</td>
</tr>
<tr>
<td>Other Credentials</td>
<td>Other</td>
</tr>
<tr>
<td>Telephone Number</td>
<td>123-456-7890</td>
</tr>
<tr>
<td>Email Address</td>
<td><a href="mailto:johndoe@hospital.com">johndoe@hospital.com</a></td>
</tr>
</tbody>
</table>

Healthcare Setting and Pharmacy Alternate Contact

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>Jane</td>
</tr>
<tr>
<td>Last Name</td>
<td>Smith</td>
</tr>
<tr>
<td>Telephone Number</td>
<td>123-456-7890</td>
</tr>
<tr>
<td>Email Address</td>
<td><a href="mailto:janessmith@hospital.com">janessmith@hospital.com</a></td>
</tr>
</tbody>
</table>

Healthcare Setting and Pharmacy Authorized Representative Agreement

I/We, the Authorized Representative, designated by my/our Healthcare Setting to oversee implementation and coordinate the activities of the SPRAVATO® REMS, by signing this form, I/We assume responsibility for, and shall comply with all REMS requirements.

- Review the SPRAVATO® Prescribing Information and REMS Program Overview.
- Email to the SPRAVATO® FURM by completing this form and emailing it to the SPRAVATO® REMS.
- Have a protocol on file regarding SPRAVATO® administration and monitoring.
- Have a healthcare provider capable of monitoring each patient for at least 2 hours following administration of SPRAVATO® for evaluation of sedation and dissociation and changes in vital signs.
- Submit adverse experiences and procedures including all adverse events occurring post-prior to discontinuing, dispensing, and administering SPRAVATO® to ensure that the following take place at the Healthcare Setting:
- Healthcare provider reviews the patient prior to receiving SPRAVATO® and is the need for monitoring due to risk of sedation and dissociation changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.
- The patient receives SPRAVATO® under the direct supervision of a healthcare provider.
- The healthcare provider monitors each patient for at least 3 hours for resolution of sedation and dissociation and changes in vital signs every 2 hours.
- SPRAVATO® is not dispensed for use outside the healthcare setting.
- The patient receives their first dose.
- If the patient experiences adverse events, the healthcare practitioner contacts the patient to receive their second dose.
- SPRAVATO® is not dispensable for use outside the healthcare setting.
- Healthcare providers shall report suspected adverse effects or product quality complaints associated with SPRAVATO® to pharmacy at 1-800-PABSEEN (1-800-722-7366) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

Authorized Representative Signature: 

[Signature]

[Submit Button] CANCEL
[Submit Button] CONTINUE
SPRAVATO® REMS Inpatient Healthcare Setting Certification

Pending

The enrollment of the following Inpatient Healthcare Setting(s) in the SPRAVATO® REMS is pending.

[Inpatient Healthcare Setting #1 Name]

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

ADD ANOTHER INPATIENT HEALTHCARE SETTING  CERTIFY OUTPATIENT HEALTHCARE SETTING

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 Inpatient Healthcare Setting Certification

✔ Complete

Inpatient Healthcare Setting

The Inpatient Healthcare Setting is now certified in the SPRAVATO® REMS.

[Inpatient Healthcare Setting #1 Name]

Please check your email for additional requirements.

ADD ANOTHER INPATIENT HEALTHCARE SETTING  CERTIFY OUTPATIENT HEALTHCARE SETTING

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.
Review Materials

If you have not yet reviewed the materials below, please review now by clicking on each link. Each document will open in a new window.

**SPRAVATO® REMS Materials**

- **SPRAVATO® Prescribing Information**
- **SPRAVATO® REMS Program Overview**

NEXT
SPRAVATO® REMS
Outpatient Healthcare Setting Enrollment Form

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

This form is intended only for Outpatient Medical Offices and Clinics. Emergency departments within hospitals are certified through the Inpatient Healthcare Setting enrollment.

*Indicates Required Field

Healthcare Setting Information

*DEA License Number (associated with the Healthcare Setting address)

CONTINUE

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
Outpatient Healthcare Setting Enrollment Form

Instructions
1. Review the SPRAVATO® Prescribing Information and the SPRAVATO® REMS Program Overview.
2. Complete this form online at www.SPRAVATOf orm.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-777-0989.

This form is intended only for outpatient medical offices and clinics. Emergency departments within hospitals are certified through the inpatient Healthcare Setting enrollment.

**Indicated Required Field**

**Healthcare Setting Information**
- **DEA License Number (associated with the Healthcare Setting address):**
- **Name of DEA License Holder:**
  - Different from Healthcare Setting Name:
- **DEA License Expiration Date (MM/DD/YYYY):**
- **Healthcare Setting Name:**
- **Healthcare Setting Address 1:**
- **City:**
- **State:**
- **ZIP:**
- **Healthcare Setting Telephone Number:**
- **Healthcare Setting Email Address:**
- **Healthcare Setting Type (check all that apply):**
  - Inpatient-Resident Facility
  - Outpatient Clinic
  - Independent Practice
  - Group Practice

**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.**

**Healthcare Setting Authorized Representative Information**
- **First Name:**
- **Last Name:**
- **Credentials:**
  - Physician
  - Physician Assistant
  - Nurse
  - Pharmacist
  - Other
- **Telephone Number:**
- **Address:**
- **Email Address:**
- **Address Line 2:**

**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,agna, on behalf of myself and my Healthcare Setting, to comply with all REMS Requirements:

**Healthcare Setting Authorized Representative Signature:**

CANCEL CONTINUE
**SPRATOM REMS Outpatient Healthcare Setting Enrollment Form**

**Instructions:**
1. Review the **SPRATOM** Prescribing Information on the **SPRATOM** REMS Program Overview.
2. Complete this form either at www.SPRATOM.com or complete the paper form and fax it to the **SPRATOM REMS** at 1-877-770-4931.

This form is intended only for Outpatient Medical Offices and Clinics. Emergency departments within hospitals are certified through the inpatient healthcare setting enrollment.

**Healthcare Setting Information**

<table>
<thead>
<tr>
<th>DEA License Number (Associated with the Healthcare Setting address)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
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<table>
<thead>
<tr>
<th>DEA License Expiration Date (MM/DD/YYYY)</th>
<th></th>
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<tbody>
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<table>
<thead>
<tr>
<th>Healthcare Setting Name</th>
<th></th>
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<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Address Line 1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>City</th>
<th>Zip code</th>
<th></th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
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</table>

**Healthcare Setting Telephone Number**

<table>
<thead>
<tr>
<th>309-696-1200</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Healthcare Setting Website (URL)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

**Other Healthcare Setting Type**

<table>
<thead>
<tr>
<th>Type</th>
<th>Website</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*If your healthcare setting is an independent general practice, group practice, or outpatient clinic, how does your practice intend to acquire **SPRATOM** for patients? (select all that apply):
* By sending a written request for **SPRATOM** (or designated substitute) to a REMS-licensed pharmacy, have that pharmacy deliver a patient name product to your practice, and follow all required steps and federal OIG laws and regulations.
* By acquiring **SPRATOM** (or designated substitute) as bulk supply directly from **SPRATOM** REMS-qualified distributor, and follow all required steps and federal OIG laws and regulations.

For each additional healthcare setting where **SPRATOM** will be delivered, dispensed, and administered within your healthcare system which the same Authorized Representative will be irresponsible, click below.

**AUTHORIZE ADDITIONAL OUTPATIENT HEALTHCARE SETTING**

Your healthcare setting information will be shared with your patient’s prescriber and distributor of your product, to allow your healthcare setting to purchase product.

Your healthcare setting information (name, location, and phone number) will be billed as a location field, as a certified healthcare setting, available to healthcare professionals and patients seeking treatment with **SPRATOM** if you disclose this information (required, please call **SPRATOM REMS** at 1-800-802-8022).

**Healthcare Setting Authorized Representative Information**

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Credentials</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Telephone Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1-800-802-8022</td>
<td></td>
</tr>
</tbody>
</table>

**Healthcare Setting Alternate Contact**

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Telephone Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1-800-802-8022</td>
<td></td>
</tr>
</tbody>
</table>

**Healthcare Setting Authorized Representative Agreement**

I, the Authorized Representative designated by my healthcare setting to oversee implementation and coordinate the activities of the **SPRATOM** REMS, by signing this form, I agree, on behalf of myself and my healthcare setting, to comply with all REMS Requirements.

I will:

- Review the **SPRATOM** Prescribing Information and REMS Program Overview.
- Submit the **SPRATOM REMS** by completing this form and submitting this form to the **SPRATOM REMS**.
- Have a prescription on file in the **SPRATOM** distribution and monitoring.
- Have the healthcare provider properly interpret the patient’s chart, including obtaining a statement from the **SPRATOM REMS** for review of the patient’s diagnosis and treatment of the illness.
- Establish processes and procedures in a variety of suitable drugs involved in a sufficient, dosing, dispensing, and administering **SPRATOM REMS** to ensure that the following takes place in my Healthcare Setting:
- Review the patient’s status in the **SPRATOM REMS** for each patient before prescribing **SPRATOM REMS**. The patient’s status will be distributed to the pharmacy distribution center.
- Monitor the patient’s status periodically and discontinue treatment in the event of any adverse reactions. The patient’s history is confirmed at the time of **SPRATOM REMS** dispensing. Each **SPRATOM REMS** is labeled with the name of the healthcare setting.
- If authorized and required, the healthcare provider can verify the patient’s status in the **SPRATOM REMS** by completing the following process:
- Healthcare providers should report suspected adverse events or product quality complaints associated with **SPRATOM** to Pearson at 1-888-JANSSON (1-888-526-7796) or the FDA at 1-888-ROA-1088 or online at www.fda.gov/medwatch.

CANCEL

**Authorized Representative Signature:**
**Healthcare Setting Information**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID# License number (associated with the Healthcare Setting address)</td>
<td></td>
</tr>
<tr>
<td>Name of DSA license holder (Different from Healthcare Setting Name)</td>
<td></td>
</tr>
<tr>
<td>*SA License Expiration date (Start/End Date)</td>
<td></td>
</tr>
<tr>
<td>Healthcare Setting Name</td>
<td></td>
</tr>
<tr>
<td>Healthcare Setting Address 1</td>
<td></td>
</tr>
<tr>
<td>Address Line 2</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Zip Code</td>
<td></td>
</tr>
<tr>
<td>Independent Practice Site</td>
<td></td>
</tr>
<tr>
<td>Group Practice</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

**Healthcare Setting Telephone Number**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Setting Type (select all that apply)</td>
<td></td>
</tr>
<tr>
<td>Home Health Facility</td>
<td></td>
</tr>
<tr>
<td>Independent Practice Site</td>
<td></td>
</tr>
<tr>
<td>Group Practice</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

**Healthcare Setting Website URL**

[Click to add healthcare setting website information.]

[Click to add additional healthcare setting information if necessary.]
SPRAVATO® REMS Outpatient Healthcare Setting Certification

Complete

- Outpatient Healthcare Setting
  - The Outpatient Healthcare Setting is now certified in the SPRAVATO® REMS.
  - [Outpatient Healthcare Setting #1 Name]
    Please check your email for additional requirements.

Pending

- Outpatient Healthcare Setting
  - The certification of the following Outpatient Healthcare Setting(s) in the SPRAVATO® REMS is pending.
  - [Outpatient Healthcare Setting #2 Name]
    If you have any questions, please contact the SPRAVATO® REMS Coordinating Center at 1-855-382-6022.

ADD ANOTHER OUTPATIENT HEALTHCARE SETTING  CERTIFY INPATIENT HEALTHCARE SETTING
Login
Your username was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 1-855-382-6022.

Forgot Username

OR

Don't have an online account?

Register
To create your online account for the SPRAVATO® REMS, please start by completing the fields below.

* I am a
   - Healthcare Setting
   - Prescriber
   - Pharmacy

Pharmacy Authorized Representative Information

* First Name

* Last Name

* Title

* Telephone Number

* Fax Number

* Email Address

SUBMIT

If you have questions about the SPRAVATO® REMS or need help enrolling, call 1-855-382-6022
Monday – Friday, 8:00 AM – 6:00 PM ET
Account Submitted Successfully

Thank you for submitting your information to create your web account for the SPRAVATO® REMS.

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

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

Login

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

Please enter your password

Password:

CANCEL  NEXT

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

Healthcare providers should report all adverse events and product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN (1-800-526-7736).
Your password has expired and must be changed.

* New Password:

* Re-type new Password:

CANCEL NEXT
Review Materials

If you have not yet reviewed the materials below, please review now by clicking on each link. Each document will open in a new window.

### SPRAVATO® REMS Materials

- SPRAVATO® Prescribing Information
- SPRAVATO® REMS Program Overview

NEXT
SPRAVATO® REMS Pharmacy Enrollment Form

Instructions

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

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

* Indicates Required Field

Pharmacy Information

* DEA License Number (On file with distributor account)

CONTINUE
# SPRAVATO® REMS
Pharmacy Enrollment Form

**Instructions**
1. Review the SPRAVATO® Prescribing Information and the SPRAVATO® REMS Program Overview.
2. Complete this form online at www.SPRAVATOnmcs.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-775-0091.

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

* Indicates Required Field

## Pharmacy Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA License Number (On file with distributor account)</td>
<td></td>
</tr>
<tr>
<td>DEA Expiration Date (MM/DD/YYYY)</td>
<td></td>
</tr>
<tr>
<td>Name of Pharmacy</td>
<td>ABC Pharmacy</td>
</tr>
<tr>
<td>Pharmacy Address 1</td>
<td>ABC 123</td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>ZIP</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Telephone Number</td>
<td>555-1234</td>
</tr>
<tr>
<td>Pharmacy Type (select all that apply)</td>
<td>CommunityRetail, Specialty, Other</td>
</tr>
</tbody>
</table>

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

## Pharmacy Shipping Address, if different from above

<table>
<thead>
<tr>
<th>Field</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Address (address must match the DEA address associated with your Pharmacy’s DEA License Number)</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>ZIP</td>
<td></td>
</tr>
</tbody>
</table>

## Pharmacy Authorized Representative Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>Last Name</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Telephone Number</td>
<td>EXT</td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
<td></td>
</tr>
</tbody>
</table>

## Pharmacy Alternate Contact

<table>
<thead>
<tr>
<th>Field</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>Last Name</td>
<td></td>
</tr>
<tr>
<td>Telephone Number</td>
<td>EXT</td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
<td></td>
</tr>
</tbody>
</table>

## Pharmacy Authorized Representative Agreement

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

- I will:
  - Review the SPRAVATO® Prescribing Information and REMS Program Overview.
  - Enroll in the SPRAVATO® REMS by completing this Pharmacy Enrollment Form and submitting this form to the SPRAVATO® REMS.
  - Establish processes and procedures and train all relevant staff involved in dispensing SPRAVATO® on the following:
    - SPRAVATO® can only be dispensed to a certified healthcare setting.
    - SPRAVATO® must never be dispensed directly to a patient for home use.
    - Before dispensing SPRAVATO®, verify the healthcare setting is certified.
    - No distribute, transfer, buy, or sell SPRAVATO® except to certified dispensers.
  - If the authorized representative changes, have the new authorized representative re-certify the Pharmacy into the REMS by completing the Pharmacy Enrollment Form.
  - Maintain records documenting staff’s completion of training.
  - Maintain records that all REMS processes and procedures are in place and are being followed.
  - Maintain records of all shipments of SPRAVATO® received and dispensing information including patient name, dose, number of devices, and date dispensed.
  - Confer with audits carried out by Janssen Pharmacoeconomics, Inc., or third-party acting on behalf of Janssen Pharmacoeconomics, Inc., to ensure that all processes and procedures are in place and are being followed.

*Authorized Representative Signature:* [signature]

---

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: 4649523
SPRAVATO® REMS
Pharmacy Enrollment Form

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

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

* Indicates Required Field

Pharmacy Information

**DEA License Number (On file with distributor account)**

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

*Name of Pharmacy*

*Pharmacy Address 1* 123 Main Street

*City*

*State*

*ZIP*

*Pharmacy Telephone Number* 555-555-1212

*Pharmacy Type (select all that apply)

- Community
- 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 from above

Shipping Address - Same as above

Pharmacy Authorized Representative Information

*First Name*

*Telephone Number*

*Fax*

*Email Address*

Pharmacy Alternate Contact

*First Name*

*Telephone Number*

*Fax*

*Email Address*

Pharmacy Authorized Representative Agreement

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

I will:
- Review the SPRAVATO® Prescribing Information and REMS Program Overview.
- Enroll in the SPRAVATO® REMS by completing this Pharmacy Enrollment Form and submitting this form to the SPRAVATO® REMS.
- Establish processes and procedures and train all relevant staff involved in dispensing SPRAVATO® on the following:
  - SPRAVATO® can only be dispensed to a certified healthcare setting.
  - SPRAVATO® must never be dispensed directly to a patient for home use.
  - Before dispensing SPRAVATO®, verify the healthcare setting is certified.
  - Do not distribute, transfer, loan, or sell SPRAVATO®, except to certified dispensers.
- If the authorized representative changes, have the new authorized representative re-certify the pharmacy into the REMS by completing the Pharmacy Enrollment Form.
- Maintain records documenting staff’s competence of training.
- Maintain records of all REMS processes and procedures that 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:*
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
The certification of the following Pharmacy in the SPRAVATO® REMS is pending.

[Pharmacy Name]

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

Your username was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 1-855-382-6022.

User Name

Forgot Username

LOGIN

Don't have an online account?

Register

To create your online account for the SPRAVATO® REMS, please start by completing the fields below.

*I am a

- Healthcare Setting
- Prescriber
- 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: 1-877-778-0091
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.
Don't have an online account?

Register
To create your online account for the SPRAVATO® REMS, please start by completing the fields below.

* I am a
  ○ Healthcare Setting  ○ Prescriber  ○ Pharmacy

Prescriber
Healthcare Setting Information
* Certified Healthcare Setting DEA License Number
  12345

Prescriber Information
* First Name

* Last Name

* Telephone Number

Fax Number

* Email Address

* Prescriber DEA License Number

* Credentials
  ○ Physician  ○ Physician Assistant  ○ Nurse  ○ Pharmacist  ○ 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

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
Account Submitted Successfully

Thank you for submitting your information to create your web account for the SPRAVATO® REMS.

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

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

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Fax: 1-877-778-0091
www.SPRAVATOrems.com

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Login
Your username was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 1-855-382-6022.

User Name

Forgot Username

OR

Don't have an online account?

Register
To create your online account for the SPRAVATO® REMS, please start by completing the fields below.

* I am a
  - Healthcare Setting
  - Prescriber
  - 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: 1-877-778-0091
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 was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 855-382-6022.

User Name

Forgot Username

LOGIN

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

Password:

CANCEL  NEXT

I am a

○ Healthcare Setting  ○ Prescriber  ○ Pharmacy

Healthcare providers should report all adverse events and product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN (1-800-526-7736).
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 --

* Answer

CANCEL NEXT
### 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.
- Click on Patient REMS ID to view treatment history.

### Patient Monitoring Form

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**

<table>
<thead>
<tr>
<th>Patient REMS ID</th>
<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>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>11111</td>
<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>Enrolled</td>
<td></td>
</tr>
<tr>
<td>22222</td>
<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>
</tr>
</tbody>
</table>
# SPRAVATO® REMS Patient Monitoring Form - Outpatient Use Only

## Instructions
This form is intended only for use by outpatient medical offices or clinics, excluding nursing departments.

1. Complete at least once on the form to notify the prescriber of the patient monitoring plan for the SPRAVATO® REMS Program. The patient monitoring plan is outside the SPRAVATO® REMS Program. Submit completed patient monitoring forms online, ZAPP, or at www.SPRAVATO.com or by fax (215) 677-7936.

2. Indicate number of patients that may cause sedation or blood pressure changes.

3. Additional patient monitoring forms should be submitted to the prescriber when appropriate.

---

### Patient Information
- **First Name**: [Field]
- **Last Name**: [Field]
- **Date of Birth**: [Field]
- **Gender**: [Male/Female]
- **Address**: [Field]
- **City/State/Zip**: [Field]
- **Telephone**: [Field]
- **E-mail**: [Field]
- **Lien Name**: [Field]

### Concomitant Medications
- Is the patient currently taking any of the following medications that may cause sedation or blood pressure changes?
- Yes
- No

### Healthcare Providers Conducting Patient Monitoring
- **First Name**: [Field]
- **Last Name**: [Field]
- **Address**
- **City/State/Zip**
- **Telephone**: [Field]
- **Fax**: [Field]
- **E-mail**: [Field]

### Healthcare Testing Information
- **Healthcare testing location 1**: [Field]
- **Healthcare testing location 2**: [Field]
- **Test Date**: [Field]
- **Test Value**: [Field]

### Patient Treatment Overview (Administration and Monitoring)
- **Treatment Date (MM/DD/YYYY)**
- **Drug Administration**: [Yes/No]
- **Lot Number**: [Field]
- **Treatment Duration (total time in minutes)**

### Patient must be monitored for at least 2 hours

- **Reason for treatment oversight**: [Field]

### Did the patient experience a serious adverse event? (Add event to summary table)

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Occurred</th>
<th>Event Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serious adverse event</strong>: [Yes/No]</td>
<td>[Field]</td>
<td>[Field]</td>
</tr>
</tbody>
</table>

- **Event resolved**: [Yes/No]

- **Serious adverse event**: [Yes/No]

- **Event described**: [Yes/No]

- **Event resolution**: [Yes/No]

---

**ADD SERIOUS ADVERSE EVENT**

- **Patient's name**: [Field]
- **Date of event (MM/DD/YYYY)**
- **Event description**: [Field]
- **Event type**: [Field]
- **Patient's condition**: [Field]
- **Patient's response**: [Field]
- **Event resolved**: [Yes/No]

---

**ADD ADVERSE EVENT**

- **Patient's name**: [Field]
- **Date of event (MM/DD/YYYY)**
- **Event description**: [Field]
- **Event type**: [Field]
- **Patient's condition**: [Field]
- **Patient's response**: [Field]
- **Event resolved**: [Yes/No]

---

**ADD MEDICATION REGISTRATION**

- **Patient's name**: [Field]
- **Date of event (MM/DD/YYYY)**
- **Event description**: [Field]
- **Event type**: [Field]
- **Patient's condition**: [Field]
- **Patient's response**: [Field]
- **Event resolved**: [Yes/No]
Patient Monitoring Form

Thank you for submitting a Patient Monitoring Form for Patient ID 999999.
INSTRUCTIONS:
This form is intended only for use by outpatient medical offices or clinics, excluding emergency departments.
1. Complete all required fields on this form after every treatment session for all outpatients enrolled in the SPRAVATO® REMS.
2. Submit completed patient monitoring forms within 7 days, online at www.SPRAVATOrems.com or by fax (1-877-778-0091).

* Indicates Required Field

Patient Information (PRINT)
First Name: ___________________________  Last Name: ___________________________
Middle Initial: M  Last Name: ___________________________
Birthdate (MM/DD/YYYY): ___________________________
Sex: □ Male  □ Female  □ Other

Concomitant Medication
Is the patient currently taking any of the following medication(s) that may cause sedation or blood pressure changes?
• Benzodiazepines* □ Yes  □ No
• Non-benzodiazepine sedative hypnotics* □ Yes  □ No
• Psychostimulants* □ Yes  □ No
• Monoamine oxidase inhibitors (MAOIs)* □ Yes  □ No

Healthcare Provider Conducting Patient Monitoring (PRINT)
First Name: ___________________________  Last Name: ___________________________
Telephone: ___________________________  Email: ___________________________

Healthcare Setting Information (PRINT)
Healthcare Setting Name: ___________________________
Healthcare Setting Address 1: ___________________________
City: ___________________________  State: ___________________________  ZIP: ___________________________

Healthcare Setting Address 2: ___________________________

Patient Treatment Session Information (Administration and Monitoring)
Treatment Date*: ___________________________
Date (MM/DD/YYYY):
Lot Number*: ___________________________

Dose Administered*: □ 56 mg  □ 34 mg  □ Other: ___________________________  Lot Number*: ___________________________

Treatment Duration*: _________ minutes (from 1st device administration to completion of monitoring)
Patient must be monitored for at least 2 hours

REMS Evaluation Question*: Was not administered 2-hour minimum monitoring requirement, when would this patient have been ready to leave if no longer require monitoring? _________ minutes from start of administration

Monitoring of Vital Signs*: Vital signs were in acceptable range prior to:
• administration? □ Yes  □ No
• treatment session completion? □ Yes  □ No

Monitoring of Blood Pressure*: Prior to administration _________ / _________ mmHg
40 mins post-administration _________ / _________ mmHg
Prior to treatment session completion _________ / _________ mmHg

Did the patient experience Sedation and/or Dissociation
Sedation*: □ Yes  □ No
Dissociation*: □ Yes  □ No

Onset of symptoms from start of administration*: 1-29 mins □ 30-59 mins □ 60-89 mins □ 90-120 mins □ >120 mins
Onset of symptoms from start of administration*: 1-29 mins □ 30-59 mins □ 60-89 mins □ 90-120 mins □ >120 mins

Resolution of symptoms within 2 hours*: □ Yes  □ No
Specify total time to resolution*: _________ minutes
Resolution of symptoms within 2 hours*: □ Yes  □ No
Specify total time to resolution*: _________ minutes

Medication(s) given for sedation*: □ Yes  □ No
• If YES, name and dose of medication(s): ___________________________

Medication(s) given for dissociation*: □ Yes  □ No
• If YES, name and dose of medication(s): ___________________________
Change Healthcare Setting

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

<table>
<thead>
<tr>
<th>DEA License Number</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>

CANCEL  CONTINUE
SPRAVATO® REMS
Patient Enrollment Form - Outpatient Use Only

Instructions
This form is intended only for use by outpatient remifentanil offices or clinics, excluding emergency departments.
1. Complete this form on-line at www.SPRAVATO.com, or complete the paper form and fax to the SPRAVATO REMS at 1-877-778-0861.

Healthcare Setting Information
Healthcare Setting Information (Box your information with the Healthcare Setting address, if available)

Healthcare Setting Name:
Address 1: 123 Main St
City: Sunnyville
Phone: 555-1234
Fax: 555-4567

Address 2:
State: CA
Zip: 12345

Prescriber Information
First Name:
Last Name:

Credentials:
[ ] Doctor [ ] Nurse [ ] Pharmacist [ ] Other

NPI:
[ ] http://npi.xds.com [ ] NPI assigned by State

Full Name of Prescriber:

Phone: 555-1234
Fax: 555-4567

Fax: 555-4567

Prescribing Clinical Information
Has the patient previously been treated with ketamine or remifentanil for major depression disorder, treatment-resistant depression, panic syndromes, or any other condition?
[ ] Yes [ ] No

List of all existing conditions treated with ketamine or remifentanil:

List of all existing medical and psychiatric conditions:

List of concurrent medications (e.g., antidepressant medications, sodium channel blockers, cardiovascular medication, anticonvulsants, antipsychotics, etc.)

Patient Information
First Name:
Last Name:

Birthdate (MM/DD/YYYY):

Email:

Address 1:

City:

Address 2:

State:

Zip:

Date of Birth:

Phone Number:

Patient Agreement
By signing this form, I understand and acknowledge that:

Before my treatment begins (1.6.2) I have completed the SPRAVATO REMS by reviewing the instructions in the Patient Enrollment Form with my healthcare provider.

[ ] I have reviewed and understood the information in the Patient Enrollment Form and will follow the instructions provided by my healthcare provider.

[ ] I have read and understood the information in the Patient Enrollment Form and will follow the instructions provided by my healthcare provider.

Date of Birth:

Patient Acknowledgement
In order to sign this form electronically, please have your provider's name and signature pre-approved.

Provider Name: 
Provider Signature: 

Prescriber Confirmation
In order to sign this form electronically, please have your provider's name and signature pre-approved.

Provider Name: 
Provider Signature: 

Submit
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

Preview Document Start Signing

Reference ID: 4649523
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**

[continue button]
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
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 Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:

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

During treatment and after administration I will:

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

I understand:

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

Patient Name (please print):

Mary Smith

Patient Signature:

[Signature]

[Date]
**Patient Profile**

**REMS ID:** 111111  
Robert Smith  
123 Main Street  
Philadelphia, PA 19042  
rsmith@abc.com

**Date of Birth:** 1/1/2000  
**REMS Status:** Enrolled  
**Most Recent Status Date:** 5/23/2018

---

### Patient Monitoring Forms

<table>
<thead>
<tr>
<th>Treatment Date: 5/23/2018</th>
<th>Treatment Dosage: 10mg</th>
<th>HCS Location: ABC Location</th>
<th>Print/Download</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Date: 3/23/2018</td>
<td>Treatment Dosage: 10mg</td>
<td>HCS Location: XYZ Location</td>
<td>Print/Download</td>
</tr>
</tbody>
</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.
Certified Pharmacy Listing

Below is a listing of pharmacies that are REMS-certified and can purchase SPRAVATO®.

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>Pharmacy Name</th>
<th>Address 1</th>
<th>Address 2</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>Pharmacy Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Pharmacy</td>
<td>100 Main Street</td>
<td>Suite 41</td>
<td>Spicewood</td>
<td>TX</td>
<td>12345</td>
<td>555-555-1212</td>
</tr>
<tr>
<td>XYZ Pharmacy</td>
<td>999 Broadway</td>
<td>Philadelphia</td>
<td>PA</td>
<td>PA</td>
<td>12345</td>
<td>555-555-3434</td>
</tr>
</tbody>
</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.
Login

Please enter your password

Password: [Field]

CANCEL  NEXT

Forgot Username

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

Healthcare providers should report all adverse events and product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN (1-800-526-7736).
Change Password

Your password has expired and must be changed.

*New Password:

*Re-type new Password:

CANCEL NEXT

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
**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.
- Click on Patient REMS ID to view treatment history.

<table>
<thead>
<tr>
<th>Patient REMS ID</th>
<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>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>111111</td>
<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>Enrolled</td>
<td></td>
</tr>
<tr>
<td>222222</td>
<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>
</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](submit-button.png)
SPRATRO™ REMS
Patient Monitoring Form - Outpatient Use Only

Instructions:

This form is intended only for use by healthcare providers or patients, excluding insurance dispensaries.

- Use handwritten notes for any changes or corrections to this form.
- Submit completed forms electronically to your PMSI or, in case of adverse events, to 1-877-700-3350.

Concurrent Medications

Is the patient currently taking any of the following medications that may cause cytochrome P450 inhibition/desensitization?

- Enzyme Inducers
  - Yes
  - No
- Enzyme Inducers with a P450 inhibitor
  - Yes
  - No
- CYP3A4 inhibitors
  - Yes
  - No
- CYP2B6 inhibitors
  - Yes
  - No
- CYP2C9 inhibitors
  - Yes
  - No
- CYP2D6 inhibitors
  - Yes
  - No
- CYP2C19 inhibitors
  - Yes
  - No
- CYP2C19 activators
  - Yes
  - No

Healthcare Provider Conducting Patient Monitoring

- Name of Provider
- Address
- Telephone
- Email

Healthcare Setting Information

- Healthcare Setting Name
- Healthcare Setting Address 1
- Healthcare Setting Address 2
- City
- State
- Zip

Patient Treatment Session Information (Administration and Monitoring)

- Treatment Date
- Treatment Time
- Treatment Route
- Dosage Form
- % at Number:
  - Yes
  - No
- Treatment duration (time in minutes) for IV device administration to completion of monitoring

Patient must be monitored for at least 2 hours

AVM Evaluation Question

If there was 2 or more instances of monitoring, when would the patient have been likely to become truly more responsive to the treatment and/or prior to administration?

Monitoring of Vital Signs

- Pulse
  - Current
  - Prior
- Blood Pressure
  - Current
  - Prior

Did the patient experience Seizure under Dosage Information?

- None
- Yes

Seizure Activity

- Yes
- No
- Unknown

Date of First Seizure

- 1st Seizure
- 2nd Seizure
- 3rd Seizure
- 4th Seizure
- > 4th Seizure

Event Narrative

- Please provide narrative of events for the SPRATRO REMS database.
- Include all medical and non-medical events.
- Include medications, dosages, and administration.
- Include all hospitalizations, admissions, and clinic visits.
- Include all adverse events.
- Include all deaths.
- Include all deaths and cite cause.
- Include all patient contact information.

- Date of Event
- Description
- Event Narrative
- Event Resolution

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRATRO to the FDA at 1-888-FDA-1088 or at www.fda.gov/medwatch.
Patient Monitoring Form

Thank you for submitting a Patient Monitoring Form for Patient ID 999999.

[PRINT/DOWNLOAD] [MY PATIENTS]

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/smedwatch.
### INSTRUCTIONS:
This form is intended only for use by outpatient medical offices or clinics, **excluding emergency departments**. 
1. Complete all required fields on this form after **every** treatment session for **all** outpatients enrolled in the SPRAVATO® REMS. 
2. Submit completed patient monitoring forms within **7 days**, online at [www.SPRAVATOrems.com](http://www.SPRAVATOrems.com) or by fax (1-877-778-0091).

* Indicates Required Field

### Patient Information (PRINT)
- **First Name**: 
- **Middle Name**: 
- **Last Name**: 
- **Date of Birth* (MM/DD/YYYY)**: 
- **Sex**: □ Male  □ Female  □ Other

### Concomitant Medication
Is the patient currently taking any of the following medication(s) that may cause sedation or blood pressure changes? 
- □ Benzodiazepines* 
- □ Non-benzodiazepine sedative hypnotics* 
- □ Psychostimulants* 
- □Monoamine oxidase inhibitors (MAOIs)*

### Healthcare Provider Conducting Patient Monitoring (PRINT)
- **First Name**: 
- **Last Name**: 
- **Telephone**: 
- **Email**: 

### Healthcare Setting Information (PRINT)
- **Healthcare Setting Name**: 
- **Healthcare Setting Address 1**: 
- **City**: 
- **State**: 
- **ZIP**: 

### Patient Treatment Session Information (Administration and Monitoring)
- **Treatment Date**
- **Date (MM/DD/YYYY)**: 
- **Dose Administered**
  - □ 56 mg  □ 64 mg  □ Other: _________ 
  - **Lot Number**: 
- **Treatment Duration**
  - Time: ________ minutes (from 1st device administration to completion of monitoring) 
  - **Patient must be monitored for at least 2 hours**
- **REMS Evaluation Question**
  - **Was not ready to leave at last monitoring**
  - **2-hour minimum monitoring requirement,** when would this patient have been ready to leave no longer require monitoring? ________ minutes from start of administration

### Monitoring of Vital Signs*
- **Vital signs in acceptable range prior to:**
  - □ administration? □ Yes □ No
  - □ treatment session completion? □ Yes □ No

### Monitoring of Blood Pressure*
- **Prior to administration** ________ / ________ mmHg 
- **40 min post-administration** ________ / ________ mmHg 
- **Prior to treatment session completion** ________ / ________ mmHg

### Did the patient experience Sedation and/or Dissociation
<table>
<thead>
<tr>
<th>Sedation</th>
<th>Dissociation</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes</td>
<td>□ Yes</td>
</tr>
<tr>
<td>□ No</td>
<td>□ No</td>
</tr>
</tbody>
</table>

- **Onset of symptoms from start of administration**
  - □ 1-29 mins  □ 30-59 mins  □ 60-89 mins  □ 90-120 mins  □ >120 mins 

- **Resolution of symptoms within 2 hours?**
  - □ Yes  | □ Yes |
  - □ No   | □ No |

- **Specify total time to resolution**: ________ minutes

- **Medication(s) given for sedation?**
  - □ If YES, name and dose of medication(s): ________

- **Medication(s) given for dissociation?**
  - □ If YES, name and dose of medication(s): ________

---

Phone: 1-855-382-6022  
Fax: 1-877-778-0091  
© Janssen Pharmaceuticals, Inc. 2020 <MM/YY>  
www.SPRAVATOrems.com
Patient Profile

REMS ID: 111111
Robert Smith
123 Main Street
Philadelphia, PA 19042
rsmith@abc.com

Date of Birth: 1/1/2000
REMS Status: Enrolled
Most Recent Status Date: 5/23/2018

Patient Monitoring Forms

<table>
<thead>
<tr>
<th>Treatment Date</th>
<th>Treatment Dosage</th>
<th>HCS Location</th>
<th>Print/Download</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/23/2018</td>
<td>10mg</td>
<td>ABC Location</td>
<td>Print/Download</td>
</tr>
<tr>
<td>3/23/2018</td>
<td>10mg</td>
<td>XYZ Location</td>
<td>Print/Download</td>
</tr>
</tbody>
</table>

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Certified Pharmacy Listing

Below is a listing of pharmacies that are REMS-certified and can purchase SPRAVATO®.

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Address 1</th>
<th>Address 2</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>Pharmacy Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Pharmacy</td>
<td>100 Main Street</td>
<td>Suite 41</td>
<td>Spicewood</td>
<td>TX</td>
<td>12345</td>
<td>555-555-1212</td>
</tr>
<tr>
<td>XY2 Pharmacy</td>
<td>999 Broadway</td>
<td></td>
<td>Philadelphia</td>
<td>PA</td>
<td>12345</td>
<td>555-555-3434</td>
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