SPRATVO® REMS
(Risk Evaluation and Mitigation Strategy)

What is the SPRATVO® 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.

SPRATVO® (esketamine) nasal spray CII is available only through a restricted distribution program called the SPRATVO® REMS because of the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRATVO® administration, and abuse and misuse of SPRATVO®. SPRATVO® is intended for use only in a certified Healthcare Setting.

SPRATVO® 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. SPRATVO® must never be dispensed directly to a patient for home use.

Program Requirements

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

Outpatient Healthcare Setting
Outpatient Healthcare Settings must be certified in the SPRATVO® REMS in order to treat patients with SPRATVO®

Pharmacy
Pharmacies must be certified in the SPRATVO® REMS in order to dispense SPRATVO®

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

SPRATVO® Indication
SPRATVO® 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.
- Depression in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

SPRATVO® is only available through select restricted distribution channels.
If you have any questions about the SPRATVO® 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
   - By 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 the 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.

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
   - By 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

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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 at 1-888-FDA-1088 or online at www.fda.gov/medwatch.

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SPRATIO™ REMS Pharmacy Enrollment - for Outpatient Dispensing Only

Pharmacies must be certified in the SPRATIO™ REMS to be able to receive and dispense SPRATIO™.

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 SPRATIO™ REMS?

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

2. **Step 2:** Review the following materials:
   - SPRATIO™ Prescribing Information
   - SPRATIO™ REMS Program Overview

3. **Step 3:** Complete and submit the SPRATIO™ REMS Pharmacy Enrollment Form to the REMS.
   - Online
   - By Fax

PDFs for Download: Resources for Pharmacies

- SPRATIO™ REMS Pharmacy Enrollment Form
- SPRATIO™ REMS Program Overview
- SPRATIO™ Prescribing Information

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRATIO™ to Janssen at 1-800-JANSSEN (1-800-527-7377) or the FDA at 1-888-FDA-1088 or online at www.fda.gov/medwatch.

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Third-party trademarks used herein are trademarks of their respective owners.

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Reference ID: 4649523
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.
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-JANSSSEN (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

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<th>SPRAVATO® REMS Inpatient Healthcare Setting Enrollment Form</th>
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# Outpatient Healthcare Setting Resources for SPRAVATO® REMS

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# Pharmacy Resources for SPRAVATO® REMS

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<tbody>
<tr>
<td>SPRAVATO® REMS Program Overview</td>
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</table>
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

[Image 0x0 to 1116x916]

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

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

Phone: 1-865-382-6022
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).
Change Password

Your password has expired and must be changed.

* New Password:

* Re-type new Password:

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.**

[CERTIFY INPATIENT HEALTHCARE SETTING]

### 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 OUTPATIENT HEALTHCARE SETTING]

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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.
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

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.SPRAVATOTests.com or complete the paper form and fax to the SPRAVATO® REMS at 1-877-739-0091.

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

Indicates Required Field

Healthcare Setting Information

* DEA License Number (associated with the Healthcare Setting address)
  Name of DEA License Holder (if different from Healthcare Setting Nane)

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

* Healthcare Setting Name

* Healthcare Setting Address 1

City

State

ZIP

* Healthcare Setting Telephone Number

Healthcare Setting Website URL

* Healthcare Setting Type (select all that apply)
  - Hospital Emergency Department
  - Hospital inpatient
  - Mental Health Facility

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 1-855-365-4002.

Healthcare Setting and Pharmacy Authorized Representative Information

* First Name

* Last Name

* Credentials
  - [ ] Physician
  - [ ] Pharmacist
  - [ ] Physician Assistant
  - [ ] Nurse
  - [ ] 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, 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 the SPRAVATO® REMS by completing this form and submitting this form to the SPRAVATO® REMS.
- Have a pharmacist available 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 resolution of sedation and dissociation, and changes in vital signs.
- Establish processes and procedures and task all relevant staff involved in prescribing, dispensing, and administering SPRAVATO® to ensure that the following take 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 every 4 hours.
  - SPRAVATO® is not dispensed for use outside the healthcare setting.
  - If the authorized representative changes, the new authorized representative re-certifies the Inpatient Healthcare Setting into the REMS by completing the Inpatient Healthcare Setting Enrollment Form.
  - Not distribute, transfer, lease, 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 patients’ SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date administered.
  - Comply with any audits carried out by Janssen Pharmaceuticals, Inc., or third-party setting on behalf of Janssen Pharmaceuticals, Inc., to ensure that all processes and procedures are in place and are being followed.

*Authorized Representative Signature
### Inpatient Healthcare Setting Enrollment Form

**Instructions**

1. Review the **SPRAVATO® REMS** 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 1-877-776-0991.

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 submitted. A separate pharmacy enrollment is not required.

**Indicates Required Field**

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<tr>
<th>Healthcare Setting Information</th>
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<td>*DEA License Number (associated with the Healthcare Setting address)</td>
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<tr>
<td>*DEA License Expiration Date (MM/YY/YYYY)</td>
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<tr>
<td>Healthcare Setting Name</td>
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<tr>
<td>Healthcare Setting Address 1</td>
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<tr>
<td>City</td>
</tr>
<tr>
<td>State</td>
</tr>
<tr>
<td>Healthcare Setting Telephone Number</td>
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<tr>
<td>Healthcare Setting Setting Type (check all that apply)</td>
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<tr>
<td>Other Healthcare Setting Type</td>
</tr>
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</table>

Your healthcare setting information will be shared with your patient's 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® REMS**. If you do not want your information listed, please call **SPRAVATO® REMS** at 1-888-362-4022.

<table>
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<tbody>
<tr>
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<td><strong>Last Name</strong></td>
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<td>Credentials</td>
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<td>Telephone number</td>
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<th>Healthcare Setting and Pharmacy Alternate Contact</th>
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<td><strong>First Name</strong></td>
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<td><strong>Last Name</strong></td>
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<td>Telephone number</td>
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<td>Email address</td>
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**Healthcare Setting and Pharmacy Authorized Representative Agreement**

I/We hereby authorize the pharmacist designated by my Healthcare Setting to oversee implementation and coordinate the activities of the **SPRAVATO® REMS**. By signing this form, I/We agree on behalf of myself and my Healthcare Setting, to comply with all REMS requirements.

- Review the **SPRAVATO® REMS** Prescribing Information and REMS Program Overview.
- Email the **SPRAVATO® REMS** FAXs by completing this form and submitting this form to the **SPRAVATO® REMS**.
- Have a prescription ready during **SPRAVATO®** administration and monitoring.
- Have a healthcare provider available to monitor each patient for at least 2 hours following administration of **SPRAVATO®** for medication-related adverse events, and changes in vital signs.
- Establish processes and procedures in place, at the pharmacist, staff involved in monitoring, dispensing, and administering **SPRAVATO®**, to ensure the following take place in my healthcare setting:
  - A healthcare provider oversee the patient prior to receiving **SPRAVATO®** and the need for monitoring due to risks of medication-related adverse events and changes in vital signs, and the need to have arrangements to safely transport the healthcare setting and properly handle any potential hazards associated with the **SPRAVATO®**. The patient's pharmacist is required to receive the drug from the pharmacy and is responsible for verifying the patient's identity and ensuring that the drug is properly handled.
  - The pharmacist administers **SPRAVATO®** to the patient under the direct supervision of a healthcare provider,
  - The pharmacist may administer every patient on at least 24 hours for resolution of medication-related adverse events and changes in vital signs after every dose.
  - **SPRAVATO®** is not dispensed for use outside the healthcare setting.
  - If the patient cannot be followed for 6 hours after initiation of medication-related adverse events and changes in vital signs, the pharmacist may administer the drug at the patient's healthcare setting.
- Complete the appropriate documentation requirements for the **SPRAVATO®** REMS by completing the Inpatient Healthcare Setting Enrollment Form.
- Ensure all staff involved in monitoring, dispensing, and administering **SPRAVATO®** are informed of the risks associated with the drug and the need for proper handling and disposal.
- All pharmacists and pharmacy technicians involved in handling and administration of **SPRAVATO®** are trained in the proper handling and administration of the drug, and are familiar with the proper methods of handling and disposal.

**Authorized Representative Signature:**

| CANCEL |  | CONTINUE |
SPRAVATO® REMS Inpatient Healthcare Setting Certification

Pending

Inpatient Healthcare Setting

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

Introduction:
1. Review the SPRAVATO REMS Program Information on the SPRAVATO REMS Program Overview.
2. Complete this form either at www.SPRAVATO.com or complete the paper form and fax it to the SPRAVATO REMS at 1-877-770-4991.

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

Outpatient Healthcare Setting Information
- DEA License Number (associated with the Healthcare setting address)
- DEA License Renewal Date (MM/DD/YYYY)
- Healthcare Setting Name
- Healthcare Setting Address 1
- City
- State
- Zip
- Healthcare Setting Telephone Number
- Healthcare Setting Website URL
- Other Healthcare Setting Type (if applicable)

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

ADD ANOTHER IN-PATIENT HEALTHCARE SETTING

Healthcare Setting Authorized Representative Information
- First Name
- Last Name
- Credentials
- Telephone Number
- Email Address

Healthcare Setting Alternate Contact
- First Name
- Last Name
- Telephone Number
- Email Address

Healthcare Setting Authorized Representative Agreement
I am the Authorized Representative designated by the healthcare setting to oversee implementation and coordinate the activities of the SPRAVATO REMS. By signing this form, I agree, on behalf of myself and any healthcare setting to comply with all REMS Requirements.

1. Review the SPRAVATO REMS Program Information and REMS Program Overview.
2. Fax all SPRAVATO REMS by completing this form and submitting the form to the SPRAVATO REMS.
3. Have prescription rights during SPRAVATO REMS authorization and renewing.
4. Have healthcare practitioner authority to review each patient account. I agree to follow directions of patients on the SPRAVATO REMS for dispensation and distribution, and changes in status.
5. Entertain processes and procedures and any related staff involved in a year-by-year, dispensing, and administering SPRAVATO REMS to ensure that the following takes place in my healthcare setting.
6. Role any patient entering SPRAVATO, a healthcare provider, or consultant can perform the role of the healthcare professional, including, administration of medication and changes in status.
7. All patients are entered into the SPRAVATO REMS by complying and submitting the Patient Enrollment Form with the pharmacist.
8. Only the patient who receives the SPRAVATO REMS from the pharmacist is exempt.

The participant’s SPRAVATO ensures the patient’s evaluation of each healthcare setting.
A healthcare provider makes random patient visits at least 2 times per 1 year. All patients and their representative shall be trained in the SPRAVATO REMS of any exchanges lasting more than 1 day. For any exchange lasting longer than 1 day, the healthcare setting is to agree with the respective healthcare professional.

If the healthcare setting does not agree with the exchange in the SPRAVATO REMS, the healthcare setting is to agree with the respective healthcare professional.

*Authorized Representative Signature*
**SPLTAVO® REMS Outpatient Healthcare Setting Enrollment Form**

In the event of an isolated incident, patients should contact their healthcare provider for more information. Patients with questions about the SPLTAVO® REMS program should contact the REMS Program at 1-877-779-9991.

### Healthcare Setting Information
- **Name of DSA License Holder (if different from Healthcare Setting Name):**
- **Date of License Expiration:**
- **Healthcare Setting Name:**
- **Address Line 1:**
- **City:**
- **State:**
- **ZIP:**
- **Phone:**
- **Fax:**
- **Email:**

### Healthcare Setting Authorized Representative Information
- **First Name:**
- **Last Name:**
- **Title:**
- **Email:**
- **Telephone:**

### Healthcare Setting Enrollment Agreement
I, the Authorized Representative, agree to the healthcare setting enrollee to the SPLTAVO® REMS Program. This agreement will be updated to reflect changes or updates to the SPLTAVO® REMS Program, including any changes or updates to the healthcare setting enrollee. This agreement will be updated to reflect changes or updates to the SPLTAVO® REMS Program, including any changes or updates to the healthcare setting enrollee. This agreement will be updated to reflect changes or updates to the SPLTAVO® REMS Program, including any changes or updates to the healthcare setting enrollee. This agreement will be updated to reflect changes or updates to the SPLTAVO® REMS Program, including any changes or updates to the healthcare setting enrollee. This agreement will be updated to reflect changes or updates to the SPLTAVO® REMS Program, including any changes or updates to the healthcare setting enrollee. This agreement will be updated to reflect changes or updates to the SPLTAVO® REMS Program, including any changes or updates to the healthcare setting enrollee.
SPRATIVO REMS
Outpatient Healthcare Setting Enrollment Form

Instructions

Read the SPRATIVO REMS Providing Information and the SPRATIVO REMS Program Document. 
1. Complete this form online at www.SPRATIVOOnline.com, or complete the paper form and fax it to the SPRATIVO REMS at 1-877-776-4061.

This form is intended for the Department of Health and Human Services Emergency Response Departments with hospitals that are certified through the Department of Health. Default Response Field

Healthcare Setting information

- **LA License Number (associated with the healthcare setting address)**
- **Name of LA License Holder (different from healthcare setting owner)**
- **LA License Expiration Date**
- **Healthcare Setting Name**
- **Healthcare Setting Address Line 1**
- **Healthcare Setting Address Line 2**
- **Healthcare Setting Address Line 3**
- **Healthcare Setting Address Line 4**
- **Healthcare Setting Address 5**
- **Healthcare Setting Zip Code**
- **Healthcare Setting Telephone Number**

For each additional healthcare setting where SPRATIVO will be delivered, dispensed, and administered within your healthcare system, please include your Healthcare System Authorized Representative as many times as necessary.

Healthcare Setting Authorized Representative Information

- **First Name**
- **Middle Initial**
- **Last Name**
- **Telephone Number**
- **Email Address**

Healthcare Setting Alternate Contact

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

This form may be submitted online at www.SPRATIVOOnline.com or faxed to the SPRATIVO REMS Program Document at 1-877-776-4061.

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRATIVO in person at 1-800-LAIHANA (2-800-524-3743) or the FDA at 1-888-FDA-1088 or online at www.fda.gov/medwatch.

Reference ID: 4649523
SPRAVATO® REMS Outpatient Healthcare Setting Certification

Complete

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

[Outpatient Healthcare Setting #1 Name]
Please check your email for additional requirements.

Pending

- 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.

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.
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
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

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
Change Password

Your password has expired and must be changed.

* New Password:

* Re-type new Password:

CANCEL NEXT
Update Profile

*Security Caption:

*Security Question

-- Please Select --

-- Please Select --

-- Please Select --

Answer

Answer

Answer

CANCEL

NEXT
Review Materials

If you have not 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)
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.SPRAVATOnxms.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

* DEA License Number (On file with distributor account)

* DEA Expiration Date (MM/DD/YYYY)

* Name of Pharmacy

* Pharmacy Address 1

* City

* State

* ZIP

* Pharmacy Telephone Number

* Company 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

Shipping Address - Same as 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

* Fax

* Email Address

Pharmacy Alternate Contact

First Name

Last 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 checking 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® as follows:
  - 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 any of 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:

CANCEL  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.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)

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

Name of Pharmacy

Address

City

State

ZIP

*Pharmacy Telephone Number

*Pharmacy Type (select all that apply)
  - Community/Local
  - 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

Shipping Address - Same as above

Pharmacy Authorized Representative Information

*First Name

*Telephone Number

*Last Name

*Fax

*Title

*Email Address

Pharmacy Alternate Contact

First Name

Telephone Number

Last Name

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.
- Keep the authorized representative updated on the status of the pharmacy to verify the Pharmacy Enrollment Form.
- Maintain records documenting staff's compliance 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 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:

CANCEL CONTINUE
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
SPRAVATO® REMS Pharmacy Certification

Pending

Pharmacy

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.

CONTINUE

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

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

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.
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
  
Prescriber Information

* First Name

* Last Name

* Telephone Number

Fax Number

* Email Address

* Prescriber DEA License Number

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

* Credentials Other
  
* Specialty
  - Psychiatry
  - Internal Medicine
  - Family Practice
  - Other

* Specialty 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
Account Submitted Successfully

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

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

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

Phone: 1-866-382-6022
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).
Change Password

Your password has expired and must be changed.

* New Password:

* Re-type new Password:

[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.

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

### Patient Information Table

<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 St.</td>
<td>Philadelphia</td>
<td>PA</td>
<td>19042</td>
<td>1/1/2000</td>
<td>Enrolled</td>
<td>Submit Form</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>
### Patient Information

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Date of Birth (MM/DD/YYYY)</th>
<th>Gender</th>
<th>Marital Status</th>
<th>Cell Phone</th>
<th>Email Address</th>
</tr>
</thead>
</table>

### Concomitant Medications

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Dosage</th>
<th>Route</th>
<th>Frequency</th>
</tr>
</thead>
</table>

### Healthcare Provider Conducting Patient Monitoring

<table>
<thead>
<tr>
<th>Provider Name</th>
<th>Contact Information</th>
</tr>
</thead>
</table>

### Healthcare Setting Information

<table>
<thead>
<tr>
<th>Address Line 1</th>
<th>Address Line 2</th>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
</tr>
</thead>
</table>

### Patient Treatment Warnings Information (Administration and Monitoring)

- **Treatment Date (MM/DD/YYYY)**: [Enter Date]
- **Start Adherence**: [Enter Start Date]
- **End Adherence**: [Enter End Date]
- **Note**: [Enter Note]

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

- **Reason for Monitoring**: [Enter Reason]
- **Monitoring Tools**: [Enter Tools Used]

### Red Blood Cell Transfusion

<table>
<thead>
<tr>
<th>Indication</th>
<th>Description</th>
</tr>
</thead>
</table>

### Adverse Events

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Description</th>
<th>Event Description</th>
</tr>
</thead>
</table>

### Additional Information

- **Note**: [Enter Additional Notes]

---

*The information on this form is confidential and is intended for use by healthcare providers and patients.*

**Disclaimer:**

- This form is for use with Spravato® REMS. The patient must be monitored for at least 2 hours following the last dose of Spravato®. The patient must be monitored until the patient is no longer under the influence of the medication. The patient must be monitored for at least 2 hours after each dose of Spravato®.

**Contraindications:**

- **Hypersensitivity**
- **Known or suspected hypersensitivity to Spravato® or its components**

**Warnings:**

- **Cardiac arrhythmia**
- **Hypertension**
- **Seizure**

**Precautions:**

- **Hypersensitivity reactions**
- **Immunization**

**Drug Interactions:**

- **Spravato® and other CNS depressants**
- **Spravato® and other spravato®

**Adverse Events:**

- **Cardiac arrhythmia**
- **Hypertension**
- **Seizure**

**Monitoring:**

- **Physiological monitoring**
- **Blood pressure monitoring**

**Emergency Information:**

- **Contact Information:** [Enter Contact Information]

---

**Notes:**

- [Enter Notes]

---

**Revised:** 6/2021

**Spravato® REMS (Medication Guide) at www.spravato.com**
Patient Monitoring Form

Thank you for submitting a Patient Monitoring Form for Patient ID 999999.
SPRAVATO® REMS
Patient Monitoring Form - Outpatient Use Only

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*: [________]  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*: [________]  Healthcare Setting Address 2*: [________]  City*: [________]  State*: [________]  ZIP*: [________]

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

Dose Administered* □ 56 mg □ 94 mg □ Other: [________]  Treatment Duration* [________]  Time of days (from 1st device administration to completion of monitoring)
Patient must be observed for at least 2 hours

REMS Evaluation Question* [________]  Did the patient experience 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 sign are 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
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

Dissociation*: □ Yes □ No
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

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): [________]

Phone: 1-855-382-6022  www.SPRAVATOrems.com  Fax: 1-877-778-0091
SPRAVATO® REMS
Patient Enrollment Form - Outpatient Use Only

Instructions
This form is intended only for use by outpatient medical officers 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 1-877-770-0931.

Indicator required field

Healthcare Setting Information
- Healthcare Setting DEA License Number (associated with the Healthcare Setting address): 32395
- Healthcare Setting Name:
- Address 1: 3800 N. Lake Shore Dr.
- City/Municipality: Chicago
- Phone: 312-555-1232
- Fax: 355-555-1232
- Zip: 60611

Prescriber Information
- First Name: John
- Last Name: Doe
- Credentials: MD, PhD
- Specialty: Psychiatry
- Phone: 312-555-1232
- Email: johndoe@md.com
- Other:

Referred Healthcare Provider - If different from Prescriber
- Referring Healthcare Provider - Same as Prescriber

Relevant Clinical Information
- Have the patient previously been treated with ketamine or esketamine for major depressive disorder, treatment-resistant depression, pain syndromes, or any other condition? Yes No
- List all pre-existing medical and psychiatric conditions:
- List concomitant medications (e.g., antidepressive antidepressive, sedative hypnotics, psychiatric agents, psychoactive antiepileptics, MHCs):

Patient Information
- First Name: John
- Last Name: Doe
- Sex: Male Female
- Address 1:
- Address 2:
- City:
- State:
- Zip:

Patient Agreement
By signing this form, I understand and acknowledge that:
- Before my treatment begins, I will:
  - Good in the SPRAVATO® REMS by completing the Patient Enrollment Form with my healthcare provider. Electronic information will be submitted to the SPRAVATO® REMS.
  - Report any safety risks and the results of monitoring, to achieve the treatment objectives and minimize, and any changes in vital signs.
  - During treatment, and after treatment, I will:
    - Use the SPRAVATO® REMS to report any adverse events and the results of monitoring, to achieve the treatment objectives and minimize, and any changes in vital signs.
    - If I discontinue the healthcare provider will be immediately notified.
  - I understand and acknowledge that:
    - Use of SPRAVATO® is not recommended for the treatment of substance use disorders (SUDs), including opioid use disorders (OUDs), unless the healthcare provider determines that I can safely stop my treatment.

Patient Acknowledgement
If patient, currently to your office to complete patient signature during online enrollment.
Yes No

Prescriber Confirmation
In order to sign this form electronically, please re-enter your signature and password.
Signature: Password:
### 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>

**Instructions**

This form is intended only for use by outpatient medical professionals.

1. Complete this form online at www.SPRAVATOrem.com.
SPRAVATO® REMS Patient Enrollment Form - Outpatient Use Only

Instructions
This form is intended only for use by outpatient medical offices or clinics, excluding emergency departments.
1. Complete this form online at www.SPRAVATO.com, or complete the paper form and fax to the SPRAVATO REMS at 1-877-778-0866.

*Indicator required N/A

Healthcare Setting Information
[Section]
Healthcare Setting Name:
Address 1: 123 Main Street
City: Town
Phone: 555-1234

Prescriber Information
First Name: Last Name:
Credentials: [Section]
Specialty: Psychiatric
License Number:
Phone: 555-567-8901

Other Clinical Information
*Has the patient previously been treated with esketamine or remangan for major depressive disorders, treatment-resistant depression, pain syndromes, or any other condition? Yes No
*List all pre-existing conditions treated with esketamine or remangan
*List all pre-existing medical and psychiatric conditions
*List concomitant medications (e.g., antidepressant medications, sedative hypnotics, psychostimulants, nonsteroidal anti-inflammatory drugs [NSAIDs])

Patient Information
First Name: Last Name:
Date of Birth: [MM/DD/YYYY]
Email: [Email]
Phone Number: [Phone Number]
Address 1: 123 Main Street

Patient Agreement
By signing this form, I understand and acknowledge that:
Before my treatment begins (14d):
- I understand the SPRAVATO REMS by completing this Patient Enrollment Form with my healthcare provider. Enrollment information will be submitted to the SPRAVATO REMS.
- I receive an overview of the potential side effects and monitoring to ensure the safety and effectiveness of the medication,
- I understand the healthcare provider will provide all information and care.
During treatment, and after administration (4w):
- I understand the healthcare provider will provide all information and care.
- I understand the healthcare provider will provide all information and care.
- I understand the healthcare provider will provide all information and care.

Patient Acknowledgement
To sign this form electronically, please re-enter your signature and password.

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

[Signature]
[Password]

[Button] CANCEL SUBMIT

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

Privacy Policy - Terms of Use

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to a person at 1-800-PAH3033 (1-800-724-3033) or the FDA at 1-888-FDA-1088 or online at www.fda.gov/medwatch.
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.

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

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

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

☐ I have read and agree to the terms and conditions

[Start Signing]
Adopt a Signature

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

Signature

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

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

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

You will be given the opportunity to:

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

Username: abc@abc.com

Note - Please check your email for the password.

Password*
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.

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

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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

<table>
<thead>
<tr>
<th>Patient Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name: Mary</td>
</tr>
<tr>
<td>Last Name: Smith</td>
</tr>
<tr>
<td>Phone Number: 555-555-1212</td>
</tr>
<tr>
<td>Address: 100 Main St</td>
</tr>
<tr>
<td>City: Philadelphia</td>
</tr>
<tr>
<td>State: PA</td>
</tr>
<tr>
<td>Zip: 99999</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>By signing this form, I understand and acknowledge that:</td>
</tr>
<tr>
<td>Before my treatment begins, I will:</td>
</tr>
<tr>
<td>• Enroll in the SPRAVATO® REMS by completing this Patient Enrollment Form with my healthcare provider. Enrollment information will be submitted to the SPRAVATO® REMS.</td>
</tr>
<tr>
<td>• Receive counseling on safety risks and the need for monitoring to obtain for evaluation of sedation and dissociation, and for any changes in vital signs.</td>
</tr>
<tr>
<td>During treatment and after administration I will:</td>
</tr>
<tr>
<td>• Use the SPRAVATO® nasal spray myself under the direct observation of a healthcare provider.</td>
</tr>
<tr>
<td>• Be observed at the healthcare setting where I receive REMS for at least 2 hours after each treatment until the healthcare provider determines I am ready to leave the healthcare setting.</td>
</tr>
<tr>
<td>Understood: Sedation and dissociation can be the treatment with SPRAVATO® and I must stay after each treatment.</td>
</tr>
<tr>
<td>• Until these effects resolve I will:</td>
</tr>
<tr>
<td>• Stay and/or disconnected from my own thoughts, feelings, and concerns that involve me.</td>
</tr>
<tr>
<td>• Make arrangements to safely get home.</td>
</tr>
<tr>
<td>• I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO®.</td>
</tr>
<tr>
<td>• 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®.</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me or my prescriber via phone, e-mail, fax, or email to support administration of the REMS.</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
</tbody>
</table>

Patient Name (please print): Mary Smith

Patient Signature: [Signature]

Date: [Date]
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>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Pharmacy</td>
<td>100 Main St</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></td>
<td>PA</td>
<td>12345</td>
<td>555-555-3434</td>
</tr>
</tbody>
</table>
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

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

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](#)
SPRAVATO® REMS
Patient Monitoring Form - Outpatient Use Only

Instructions
This form is intended only for use by outpatient medical officers or clinics, excluding emergency departments.
1. Complete all required fields on this form on a single treatment session for all outpatients enrolled in this SPRAVATO® REMS.
2. Submit completed patient monitoring forms within 2 days online at www.SPRAVATO.com or by fax (1-877-770-8099).

*Indicates Required Field

Patient Information
First Name: John
Birthday: 1/1/2000
Mobile Phone: 555-555-5555
Last Name: Doe
Sex: Male
Unit Name: John Doe

Concomitant Medications
Is the patient currently taking any of the following medications 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
First Name: Jane
Last Name: Doe
Telephone: 555-555-5555
Email: jdoe@what.com

Healthcare Setting Information
Healthcare Setting Name: ABC Healthcare
Healthcare Setting Address 1: 123 Main St
City: New York
State: NY
ZIP: 10001

Patient Treatment Session Information (Administration and Monitoring)
Treatment Date: 01/01/2023
Dose Administered: 200 mg
• Intranasal
• Oral
• Other

Treatment Duration (total time in minutes from 1st dose to administration to completion of monitoring)

Patient must be monitored for at least 2 hours

REMS Evaluation Question
If there was not a 2-hour minimum monitoring requirement, would this patient have been ready to be discharged to the regular monitoring (bedside from start of administration)?

Monitoring of Vital Signs
• What signs were in acceptable range prior to administration?
  ☐ Yes
  ☐ No

• What signs were in acceptable range prior to treatment session completion?
  ☐ Yes
  ☐ No

Monitoring of Blood Pressure
• Prior to administration (string):
  45 minutes post-administration (string):
  Prior to treatment completion (string):

Did the patient experience Sedation and/or Dissociation
• Sedation
  ☐ Yes
  ☐ No

• Disorientation
  ☐ Yes
  ☐ No

Serious Adverse Events
A serious adverse event (SAE) for this SPRAVATO® REMS is defined as any event that results in:
• Hospitalization
• Disability or permanent disability
• Death
• Life-threatening
• Important medical event
• all or any one of the above, or any progression for patient or any required intervention to prevent use of the device

If yes to any event, that may be required for the patient or may require intervention to prevent use of the device

All non-serious adverse events or product quality complaints that are not defined above, should be reported to:
• Janseen at 1-800-JANSESE (1-800-526-7736) or the FDA at 1-888-FDA-1088 or at www.fda.gov/remswatch.

*Did the patient experience a serious adverse event?
☐ Yes
☐ No

Submit
Cancel
SPRATOR® REMS Patient Monitoring Form - Outpatient Use Only

Instructions:
This form is intended only for use by the pharmacist on behalf of a healthcare provider, in accordance with the U.S. Food and Drug Administration’s (FDA) REMS Program, in a hospital setting. The provider must document the patient’s use of SPRATOR® in the patient’s medical record.

Patient Information
- Date
- Patient Name
- Phone Number
- Email Address

Concurrent Medications
- Are you taking any of the following medications that may cause sedation or blood pressure changes?
  - Benzodiazepines
  - Other

Healthcare Facility Conducting Patient Monitoring
- Hospital
-Clinic
- Institution

Healthcare Setting Information
- Healthcare Setting Name
- Address

Patient Treatment Session Information (Administration and Monitoring)
- Treatment Date
- Prescription Device
- Initial Dose
- Total Dose
- % of Total

Patient must be monitored for at least 2 hours:
- RMU Evaluation Question
- If there was no 2-hour Plasma Monitoring period, when would the patient have done the best take a long-term treatment

- Monitoring of Vital Signs
- Heart rate
- Blood pressure
- Respiratory rate

- Monitoring of Blood Pressure
- Prior to treatment
- Post-treatment

Did the patient experience Sudden Loss under Elucidation?
- Yes
- No

Serious Adverse Events
- Any adverse event labeled as life-threatening (SRAEs) or that results in:
  - Hospitalization
  - Disability
  - Death

- All Serious Adverse Events (SAEs) and other adverse events that are potentially life-threatening should be reported to the FDA at www.FDA.gov/medwatch.

- Have you experienced a serious adverse event?
- Yes
- No

- Event Description
- Time

CAPS
- Yes
- No

[Signature]
[Name]
[Title]
Patient Monitoring Form

Thank you for submitting a Patient Monitoring Form for Patient ID 999999.
SPRAVATO® REMS
Patient Monitoring Form - Outpatient Use Only

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* | 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*: | Healthcare Setting Address 2*: |
| City*: | State*: | ZIP*: |

### Patient Treatment Session Information (Administration and Monitoring)
| Treatment Date* |
| Dose Administered* □ 56 mg □ 34 mg □ Other: ______ |
| Lot Number*: |
| Treatment Duration* | Patient must be monitored for at least 2 hours |
| REMS Evaluation Question* |
| Monitoring of Vital Signs* |
| Monitoring of Blood Pressure* |
| Did the patient experience Sedation and/or Dissociation |

### 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* |
| Resolution of symptoms within 2 hours* □ Yes □ No |
| Specify total time to resolution*: ______ minutes |
| Resolution of symptoms within 2 hours* |
| Medication(s) given for sedation* □ Yes □ No |
| Medication(s) given for dissociation* □ Yes □ No |

Phone: 1-855-382-6022
Fax: 1-877-778-0091
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></td>
</tr>
<tr>
<td>3/23/2018</td>
<td>10mg</td>
<td>XYZ Location</td>
<td></td>
</tr>
</tbody>
</table>

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1098 or online at www.fda.gov/medwatch.
Certified Pharmacy Listing

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- Search/Filter the list by entering information in the textbox below any column header.
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<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>555-555-1232</td>
</tr>
<tr>
<td>XYZ Pharmacy</td>
<td>999 Broadway</td>
<td>Philadelphia</td>
<td>PA</td>
<td></td>
<td>12345</td>
<td>555-555-3434</td>
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Fax: 1-877-778-0091
www.SPRAVATOnms.com

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