



SPRAVATO[®] REMS (Risk Evaluation and Mitigation Strategy)

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 CIII 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[®].

[Inpatient Healthcare Setting Certification](#)



Outpatient Healthcare Setting

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

[Outpatient Healthcare Setting Certification](#)



Pharmacy

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

[Pharmacy Certification](#)



Patient

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

[Patient Enrollment](#)

SPRAVATO[®] Indication

SPRAVATO[®] is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment 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



For SPRAVATO[®] REMS Program information contact:

Phone: 1-855-382-6022

Fax: 1-877-778-0091

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

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

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Inpatient Healthcare Settings

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 1-855-382-6022.

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](#)



Outpatient Healthcare Settings

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.

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?



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



Step 2: Review the following materials:

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



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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For SPRAVATO® REMS Program information contact:

Phone: 1-855-382-6022

Fax: 1-877-778-0091

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Pharmacies

SPRAVATO[®] REMS Pharmacy Enrollment - for Outpatient Dispensing Only

Pharmacies must be certified in the SPRAVATO[®] REMS to be able to receive and dispense SPRAVATO[®].

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 SPRAVATO[®] REMS?

1

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

2

Step 2: Review the following materials:

- [SPRAVATO[®] Prescribing Information](#)
- [SPRAVATO[®] REMS Program Overview](#)

3

Step 3: Complete and submit the *SPRAVATO[®] REMS Pharmacy Enrollment Form* to the REMS.

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

PDFs for Download: Resources for Pharmacies

[SPRAVATO[®] REMS Pharmacy Enrollment Form](#)

[SPRAVATO[®] Prescribing Information](#)

[SPRAVATO[®] REMS Program Overview](#)



For SPRAVATO[®] REMS Program
information contact:

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Fax: 1-877-778-0091

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Patients

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

Because of the risks associated with SPRAVATO®, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS). As part of the REMS, your 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 Us

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

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Resources



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® REMS Patient Enrollment Form

SPRAVATO® Prescribing Information

SPRAVATO® REMS Patient Monitoring Form



Pharmacy Resources for SPRAVATO® REMS

SPRAVATO® REMS Pharmacy Enrollment Form

SPRAVATO® Prescribing Information

SPRAVATO® REMS Program Overview



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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.

[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

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

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

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* 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,
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* 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

SUBMIT

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Account Submitted Successfully

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

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

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

[LOGIN](#)

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[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
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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](#)

LOGIN

I am a

Healthcare Setting Prescriber Pharmacy

If you are not a healthcare provider, please start by completing the fields below.

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
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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](#)

LOG IN

If you are not a REMS, please start by completing the fields below.

pharmacy

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,
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Monday – Friday, 8:00 AM – 8:00 PM ET

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Login

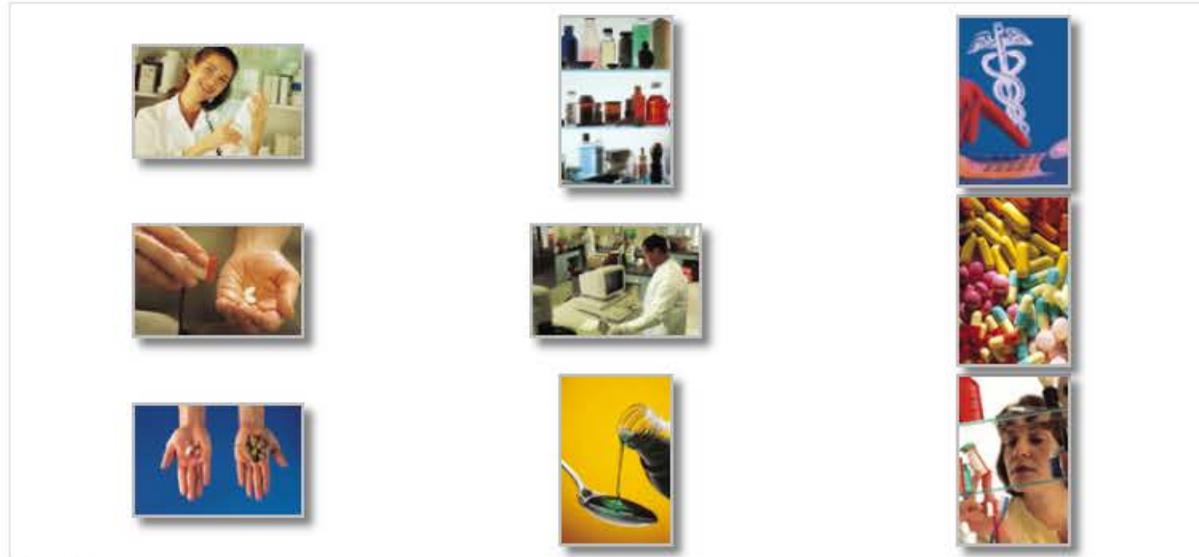
Your username was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 855-382-6022.

User Name

[Forgot Username](#)

LOG IN

Update Profile



* Security Caption:

* Security Question

* Answer

-- Please Select --

▼ Answer

-- Please Select --

▼ Answer

-- Please Select --

▼ Answer

CANCEL

NEXT

* If you are not a REMS, please start by completing the fields below.

pharmacy

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SPRAVATO[®] to Janssen

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

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.SPRAVATorems.com, or complete the paper form and fax to the SPRAVATO[®] REMS at 1-877-778-0091

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*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 Name)

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

*Healthcare Setting Name

*Healthcare Setting Address 1

Address Line 2

*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
 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 1-855-382-6022.**

Healthcare Setting and Pharmacy Authorized Representative Information

*First Name MI *Last Name

*Credentials
 Physician
 Physician Assistant
 Nurse
 Pharmacist
 Other

*Telephone Number EXT *Fax

*Email Address

Healthcare Setting and Pharmacy Alternate Contact

First Name Last Name

Telephone Number EXT Fax

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 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 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 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.

*Authorized Representative Signature:

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)

Name of DEA License Holder (if different from Healthcare Setting Name)

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

*Healthcare Setting Name

*Healthcare Setting Address 1

Address Line 2

*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
 Other

*Other Healthcare Setting Type

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 Setting and Pharmacy Authorized Representative Information

*First Name MI *Last Name

*Credentials
 Physician
 Physician Assistant
 Nurse
 Pharmacist
 Other

Credentials Other

*Telephone Number EXT *Fax

*Email Address

Healthcare Setting and Pharmacy Alternate Contact

First Name Last Name

Telephone Number EXT Fax

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 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 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 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.

* Authorized Representative Signature:

SPRAVATO[®] REMS Inpatient Healthcare Setting Certification

-  Registration
- ...
-  Review Materials
- ...
-  Online Enrollment

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](#)

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](#)

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

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.

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

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)

Name of DEA License Holder (if different from Healthcare Setting Name)

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

*Healthcare Setting Name

*Healthcare Setting Address 1

Address Line 2

*City

*State

*ZIP

*Healthcare Setting Telephone Number

Healthcare Setting Website URL

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

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

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 Setting Authorized Representative Information

*First Name MI *Last Name

*Credentials
 Physician Physician Assistant Nurse Pharmacist Other

*Telephone Number EXT *Fax

*Email Address

Healthcare Setting Alternate Contact

First Name Last Name

Telephone Number EXT Fax

Email Address

Healthcare Setting Authorized Representative Agreement

I am the Authorized Representative designated by my Healthcare Setting to oversee implementation and coordinate the activities of the SPRAVATO[®] REMS. By signing this form, I agree, on behalf of myself and my Healthcare Setting, to comply with 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.
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 - 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.
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SPRAVATO[®] REMS Outpatient Healthcare Setting Enrollment Form



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*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 Name)

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

*Healthcare Setting Name

*Healthcare Setting Address 1

Address Line 2

*City

*State

*ZIP

*Healthcare Setting Telephone Number

Healthcare Setting Website URL

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

*Other Healthcare Setting Type

*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.

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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 Setting Authorized Representative Information

*First Name MI *Last Name

*Credentials
 Physician Physician Assistant Nurse Pharmacist Other

Credentials Other

*Telephone Number EXT *Fax

*Email Address

Healthcare Setting Alternate Contact

First Name Last Name

Telephone Number EXT Fax

Email Address

Healthcare Setting Authorized Representative Agreement

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- Enroll in the SPRAVATO[®] REMS by completing this form *and* submitting this form to the SPRAVATO[®] REMS.
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- 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.
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 - 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.

*Authorized Representative Signature:

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)
12345 CONTINUE

Name of DEA License Holder (if different from Healthcare Setting Name)

*DEA License Expiration Date (MM/DD/YYYY)
99/99/9999 

*Healthcare Setting Name
ABC HealthCare

*Healthcare Setting Address 1
123 Main Street

Address Line 2

*City
Blue Bell

*State
PA

*ZIP
99999

Healthcare Setting Website URL

*Healthcare Setting Telephone Number
555 555-1212

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

*Other Healthcare Setting Type

*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.

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

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 OUTPATIENT HEALTHCARE SETTING

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

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Healthcare Setting Authorized Representative Information

*First Name MI *Last Name

*Credentials
 Physician Physician Assistant Nurse Pharmacist Other

Credentials Other

*Telephone Number EXT *Fax

*Email Address

Healthcare Setting Alternate Contact

First Name Last Name

Telephone Number EXT Fax

Email Address

Healthcare Setting Authorized Representative Agreement

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

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* Authorized Representative Signature:

CANCEL CONTINUE

SPRAVATO® REMS Outpatient Healthcare Setting Enrollment Form



Instructions

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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

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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)

Name of DEA License Holder (if different from Healthcare Setting Name)

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

*Healthcare Setting Name

*Healthcare Setting Address 1

*City

*Healthcare Setting Telephone Number

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

*Other Healthcare Setting Type

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Name of DEA License Holder (if different from Healthcare Setting Name)

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

*Healthcare Setting Name

*Healthcare Setting Address 1

*City

*Healthcare Setting Telephone Number

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 Mental Health Facility Outpatient Clinic Independent Practice Group Practice
 Other

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Healthcare Setting Authorized Representative Information

*First Name MI *Last Name

*Credentials
 Physician Physician Assistant Nurse Pharmacist Other

Credentials Other

*Telephone Number EXT *Fax

*Email Address

Healthcare Setting Alternate Contact

First Name Last Name

Telephone Number EXT Fax

Email Address

Healthcare Setting Authorized Representative Agreement

I am the Authorized Representative designated by my Healthcare Setting to oversee implementation and coordinate the activities of the SPRAVATO® REMS. By signing this form, I agree, on behalf of myself and my Healthcare Setting, to comply with 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:
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 - All patients are enrolled in the SPRAVATO® REMS by completing and submitting the *Patient Enrollment Form* with their prescriber.
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- 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.
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*Authorized Representative Signature:

SPRAVATO[®] REMS Outpatient Healthcare Setting Certification

-  Registration
- ...
-  Review Materials
- ...
-  Online Enrollment

✓ 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](#)

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

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

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

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Login

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[Forgot Username](#)

LOGIN

OR

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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 – 8:00 PM ET

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

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Account Submitted Successfully

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

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

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

[LOGIN](#)

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

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Fax: 1-877-778-0091
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User Name

[Forgot Username](#)

LOGIN

OR

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- Healthcare Setting Prescriber Pharmacy

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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.

User Name

[Forgot Username](#)

LOGIN

I am a

- Healthcare Setting Prescriber Pharmacy

If you are not a healthcare provider, please start by completing the fields below.

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

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

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User Name

[Forgot Username](#)

LOG IN

Change Password



Your password has expired and must be changed.

*New Password:



*Re-type new Password:

CANCEL

NEXT

If you are not a REMS, please start by completing the fields below.

pharmacy

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Login

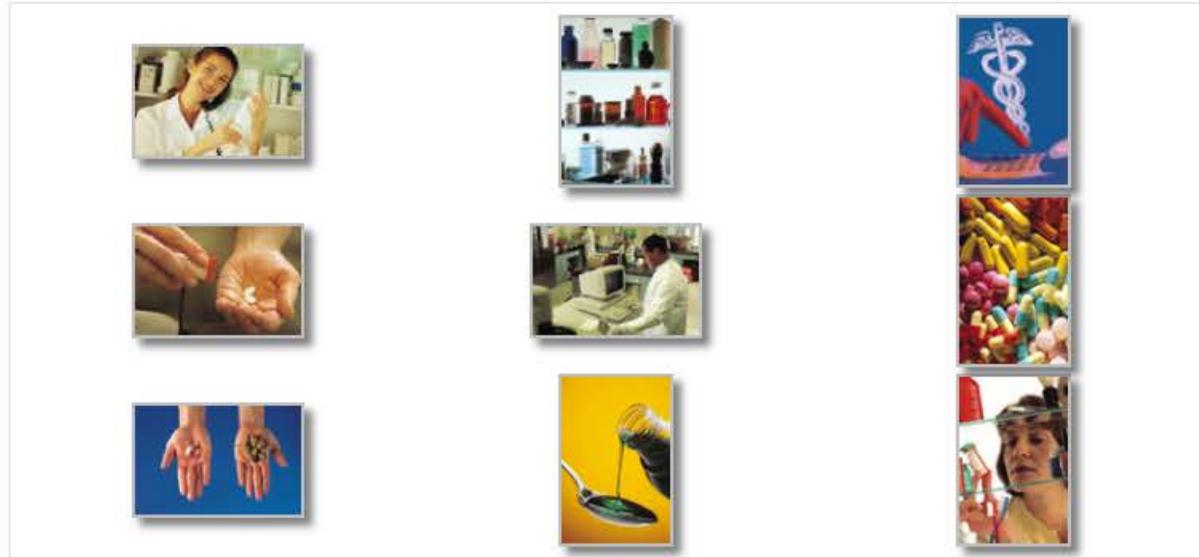
Your username was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 1-855-382-6022.

User Name

[Forgot Username](#)

LOG IN

Update Profile



* Security Caption:

* Security Question

* Answer

-- Please Select --	▼	Answer
-- Please Select --	▼	Answer
-- Please Select --	▼	Answer

CANCEL

NEXT

If you are not a REMS, please start by completing the fields below.

pharmacy

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SPRAVATO[®] to Janssen

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

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* 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

Address Line 2

*City

*State

*ZIP

*Pharmacy Telephone Number

*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

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 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:

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

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Pharmacy Information

*DEA License Number (On file with distributor account)

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

*Name of Pharmacy

*Pharmacy Address 1

Address Line 2

*City

*State

*ZIP

*Pharmacy Telephone Number

*Pharmacy Type (select all that apply)
 Community/Retail 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

*Last Name

*Title

*Telephone Number EXT

*Fax

*Email Address

Pharmacy Alternate Contact

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- 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

SPRAVATO[®] REMS Pharmacy Certification

-  Register
- ...
-  Review Materials
- ...
-  Online Enrollment

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

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](#)

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

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* I am a

Healthcare Setting Prescriber Pharmacy

Prescriber

Healthcare Setting Information

* Certified Healthcare Setting DEA License Number

CONTINUE

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* 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

* Specialty

Psychiatry Internal Medicine Family Practice Other

SUBMIT

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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

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Account Submitted Successfully

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

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

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

[LOGIN](#)

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

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Fax: 1-877-778-0091
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[Forgot Username](#)

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User Name

[Forgot Username](#)

LOGIN

CANCEL

NEXT

If you are not a healthcare provider, please start by completing the fields below.

I am a

- Healthcare Setting Prescriber Pharmacy

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Login

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User Name

[Forgot Username](#)

LOG IN

Change Password



Your password has expired and must be changed.

*New Password:



*Re-type new Password:

CANCEL

NEXT

If you are not a REMS, please start by completing the fields below.

pharmacy

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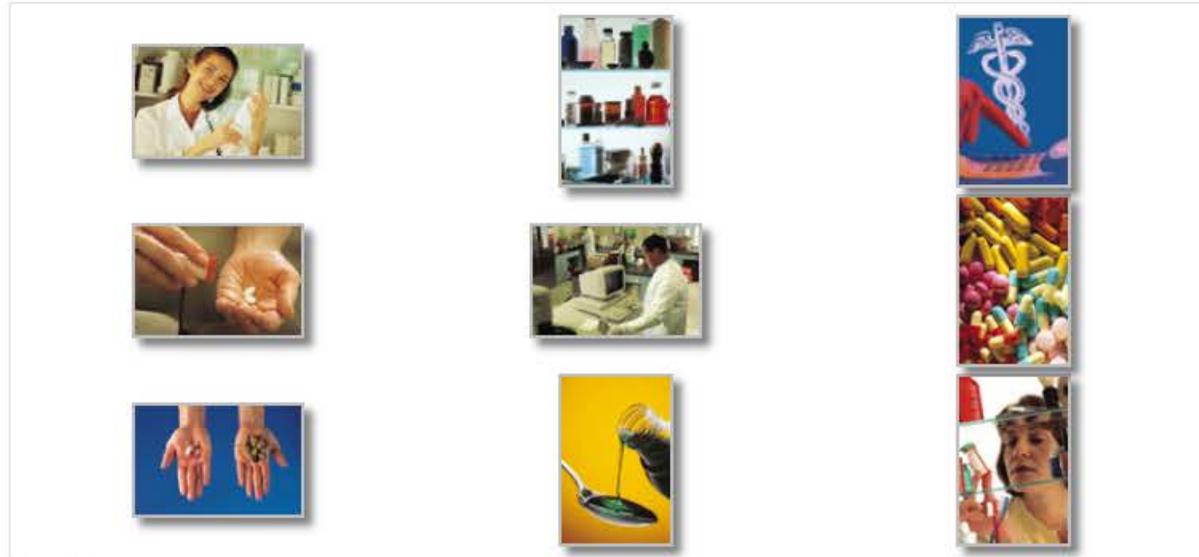
Your username was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 1-855-382-6022.

User Name

[Forgot Username](#)

LOG IN

Update Profile



* Security Caption:

* Security Question

* Answer

-- Please Select --	▼	Answer
-- Please Select --	▼	Answer
-- Please Select --	▼	Answer

CANCEL

NEXT

If you are not a REMS, please start by completing the fields below.

pharmacy

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

SPRAVATO[®] to Janssen

My Patients

Below is a list of your patients.

[Enroll a Patient ▶](#)

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.

[SUBMIT A PATIENT MONITORING FORM](#)



Patient REMS ID	First Name	Last Name	Address	City	State	Zip	Date of Birth	REMS Status	Action
<input type="text"/>	- ▾								
111111	Robert	Smith	123 Main Street	Philadelphia	PA	19042	1/1/2000	Enrolled	Submit a Patient Monitoring Form
22222	Mary	Connors	3 Broadway	Blue Bell	PA	19042	1/1/2000	Pending	

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

First Name: Peggy Middle Initial: Last Name: Sue
 Birthdate (MM/DD/YYYY): 1/1/2000 Sex: Female

Concomitant Medications

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

*First Name: John *Last Name: Smith
 *Telephone: 555-555-1212 *Email: jsmith@abc.com

Healthcare Setting Information

*Healthcare Setting Name: ABC HealthCare
 *Healthcare Setting Address 1: 123 Main Street Healthcare Setting Address 2:
 *City: Blue Bell *State: PA *ZIP: 99999

Patient Treatment Session Information (Administration and Monitoring)

*Treatment Date (MM/DD/YYYY): *Dose Administered: 56 mg 84 mg Other
 *Treatment Duration (total time in minutes from 1st device 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, when would this patient have been ready to leave/ho longer require monitoring (minutes from start of administration)?

Monitoring of Vital Signs

- *Vital signs were in acceptable range prior to administration?
 Yes No
- *Vital signs were in acceptable range prior to treatment session completion?
 Yes No

Monitoring of Blood Pressure

*Prior to administration (mmHg): *40 minutes post-administration (mmHg): *Prior to treatment session completion (mmHg):

Did the patient experience Sedation and/or Dissociation

- *Sedation
 Yes No
- *Dissociation
 Yes No

Serious Adverse Events

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

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**.

- Complete all required fields on this form after **every** treatment session for **all outpatients** enrolled in the SPRAVATO® REMS.
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First Name: Peggy Middle Initial: Last Name: Sue
 Birthdate (MM/DD/YYYY): 1/1/2000 Sex: Female

Concomitant Medications

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

*First Name: John *Last Name: Smith
 *Telephone: 555 555-1212 *Email: jsmith@abc.com

Healthcare Setting Information

*Healthcare Setting Name: ABC HealthCare
 *Healthcare Setting Address 1: 123 Main Street Healthcare Setting Address 2:
 *City: Blue Bell *State: PA *ZIP: 99999

Patient Treatment Session Information (Administration and Monitoring)

*Treatment Date (MM/DD/YYYY): *Dose Administered: 56 mg 84 mg Other
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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

*Vital signs were in acceptable range prior to treatment session completion? Yes No

Monitoring of Blood Pressure

*Prior to administration (mmHg): *40 minutes 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 (mins)

*Medication(s) given for sedation? Yes No

*Name and dose of medication(s)

*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 (mins)

*Medication(s) given for dissociation? Yes No

*Name and dose of medication(s)

Serious Adverse Events

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

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

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

#	Event resulted in the following (check all that apply)	Event Timing	Date of Event (MM/DD/YYYY)	Event Description	Event Resolution
1	<input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Death <input type="checkbox"/> Life-threatening <input type="checkbox"/> Important Medical Event	<input type="checkbox"/> During treatment sessions <input type="checkbox"/> Between treatment sessions	<input type="text"/>	Serious Adverse Event	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown

REMOVE

➕ ADD SERIOUS ADVERSE EVENT

Janssen Pharmaceuticals, Inc., Safety Department may follow up to obtain more information about these events.

CANCEL

SUBMIT

Patient Monitoring Form

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

[PRINT/DOWNLOAD](#)

[MY PATIENTS](#)



SPRAVATO® REMS

Patient Monitoring Form - Outpatient Use Only

For Healthcare Setting Use Place Patient Label or Barcode Here

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*	MI	Last Name*	Birthdate* (MM/DD/YYYY): Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other
Concomitant Medication			
Is the patient currently taking any of the following medication(s) that may cause sedation or blood pressure changes?			
• Benzodiazepines*	<input type="checkbox"/> Yes <input type="checkbox"/> No		
• Non-benzodiazepine sedative hypnotics*	<input type="checkbox"/> Yes <input type="checkbox"/> No		
• Psychostimulants*	<input type="checkbox"/> Yes <input type="checkbox"/> No		
• Monoamine oxidase inhibitors (MAOIs)*	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Healthcare 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): _____		
Dose Administered*	<input type="checkbox"/> 56 mg <input type="checkbox"/> 84 mg <input type="checkbox"/> Other: _____		
Treatment Duration*	Total time _____ minutes (from 1st device 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, 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? <input type="checkbox"/> Yes <input type="checkbox"/> No • treatment session completion? <input type="checkbox"/> Yes <input type="checkbox"/> 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*: <input type="checkbox"/> Yes <input type="checkbox"/> No		Dissociation*: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Onset of symptoms from start of administration* <input type="checkbox"/> 1-29 mins <input type="checkbox"/> 30-59 mins <input type="checkbox"/> 60-89 mins <input type="checkbox"/> 90-120 mins <input type="checkbox"/> >120 mins		Onset of symptoms from start of administration* <input type="checkbox"/> 1-29 mins <input type="checkbox"/> 30-59 mins <input type="checkbox"/> 60-89 mins <input type="checkbox"/> 90-120 mins <input type="checkbox"/> >120 mins	
Resolution of symptoms within 2 hours?* <input type="checkbox"/> Yes <input type="checkbox"/> No Specify total time to resolution*: _____ min		Resolution of symptoms within 2 hours?* <input type="checkbox"/> Yes <input type="checkbox"/> No Specify total time to resolution*: _____ min	
Medication(s) given for sedation?* <input type="checkbox"/> Yes <input type="checkbox"/> No -If YES, name and dose of medication(s): _____		Medication(s) given for dissociation?* <input type="checkbox"/> Yes <input type="checkbox"/> No -If YES, name and dose of medication(s): _____	

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.SPRAVATOREMS.com, or complete the paper form and fax to the SPRAVATO[®] REMS at 1-877-778-0091.

*Indicates required field

Healthcare Setting Information

[Change Healthcare Setting](#)

Healthcare Setting DEA License Number (associated with the Healthcare Setting address): 12345

Healthcare Setting Name:

Address 1: 100 Main Street

City: Malvern

Phone: 555 555-1212

Address 2:

State: PA

Fax: 555 555-3434

ZIP: 19542

Prescriber Information

*First Name

Marc

*Last Name

Jones

*Credentials

Physician Physician Assistant Nurse Pharmacist Other

*Specialty

Psychiatry Internal Medicine Family Practice Other

*Prescriber DEA License Number

12345

*Email

mjones@abc.com

*Phone

555 555-1212

Fax

555 555-3434

Referring Healthcare Provider - if different from Prescriber

Referring Healthcare Provider- Same as Prescriber

First Name

Last Name

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

*List all pre-existing medical and psychiatric conditions

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

Patient Information

*First Name:

MI:

*Last Name:

*Birthdate (MM/DD/YYYY):

*Sex:

Male Female Other

*Email:

*Phone Number:

*Address 1:

Address 2:

*City:

*State:

-- Please Select --

*ZIP:

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 Acknowledgement

*Is patient currently in your office to complete patient signature during online enrollment?:

Yes No

Prescriber Confirmation

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

*Username:

*Password:

CANCEL

CONTINUE TO SIGN

Change Healthcare Setting ✕

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

DEA License Number	HCS Name	City	State
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
11111	Healthcare Facility Name1	Philadelphia	PA
22222	Healthcare Facility Name2	NY	NY

CANCEL

CONTINUE

Instructions

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

1. Complete this form online at www.SPRAVATOrems.com.

**Indicates required field*

Healthcare Setting Information

Change Healthcare Setting ▶

Healthcare Setting DEA License Number (associated with the Healthcare Setting address): 12345

Healthcare Setting Name:

Address 1: 100 Main Street

City: Malvern

Phone: 555 555-1212

Address 2:

State: PA

Fax: 555 555-3434

ZIP: 19542

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

*Indicates required field

Healthcare Setting Information

[Change Healthcare Setting ▾](#)

Healthcare Setting DEA License Number (associated with the Healthcare Setting address): 12345

Healthcare Setting Name:

Address 1: 100 Main Street

City: Malvern

Phone: 555 555-1212

Address 2:

State: PA

Fax: 555 555-3434

ZIP: 19542

Prescriber Information

*First Name

Marc

*Last Name

Jones

*Credentials

Physician Physician Assistant Nurse Pharmacist Other

*Specialty

Psychiatry Internal Medicine Family Practice Other

*Prescriber DEA License Number

12345

*Email

mjones@abc.com

*Phone

555 555-1212

Fax

555 555-3434

Referring Healthcare Provider - if different from Prescriber

Referring Healthcare Provider- Same as Prescriber

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

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])

Patient Information

*First Name:

MI:

*Last Name:

*Birthdate (MM/DD/YYYY):

*Sex:

Male Female Other

*Email:

*Phone Number:

*Address 1:

Address 2:

*City:

*State:

-- Please Select -- ▾

*ZIP:

Patient Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:

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- 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 Acknowledgement

*Is patient currently in your office to complete patient signature during online enrollment?:

Yes No

Prescriber Confirmation

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

*Username:

*Password:

CANCEL

CONTINUE TO SIGN

Welcome

Agree to Terms

Sign

Done



2

3

4

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

Powered by AssureSign

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

Welcome



Agree to Terms



Sign



Done



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

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

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



Please sign with your mobile device with a pen on paper.



Back

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

Welcome

Agree to Terms

Sign

Done



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

1 of 2



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.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			
Healthcare Setting Name*: Professional Testing Facility			
Healthcare Setting DEA License Number* (associated with the Healthcare Setting address): 99999			
Address 1*: 999 Broadway		Address 2:	
City*: Philadelphia	State*: PA	ZIP*: 99999	
Phone*: 555-555-1212	Fax*: 555-555-3434		
Prescriber Information			
First Name*: John		Last Name*: Smith	
Credentials*: <input checked="" type="checkbox"/> Physician <input type="checkbox"/> Physician Assistant <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other _____ Specialty*: <input checked="" type="checkbox"/> Psychiatry <input type="checkbox"/> Internal Medicine <input type="checkbox"/> Family Practice <input type="checkbox"/> Other _____			Prescriber DEA License Number*: 444444
Phone*: 555-5557777	Fax*: 555-555-8888	Email*: jsmith@xyz.com	
Prescriber Signature*: 			Date*:
Referring Healthcare Provider – if different from Prescriber			
First Name:		Last Name:	

SAMPLE FORM

Welcome



Agree to Terms

2

Sign

3

Done

4

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

Welcome



Agree to Terms



Sign

3

Done

4

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

Powered by AssureSign

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



Please sign with your mobile device
with a pen on paper.



Back

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

Welcome

Agree to Terms

Sign

Done



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

1 of 2

Patient Information					
First Name* Mary	MI:	Last Name* Smith	Birthdate* (MM/DD/YYYY): 1/1/2000	Sex: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female <input type="checkbox"/> Other	
Email* (Email is required for online enrollment only) abc@abc.com			Phone Number*: 555-555-1212		
Address 1* 100 Main St			Address 2:		
City* Philadelphia			State* PA		ZIP* 99999

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 receive 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 must:
 - 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): Mary Smith	
Patient 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

Treatment Date: 5/23/2018

Treatment Dosage: 10mg

HCS Location: ABC Location

[Print/Download](#)

Treatment Date: 3/23/2018

Treatment Dosage: 10mg

HCS Location: XYZ Location

[Print/Download](#)

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.

Pharmacy Name	Address 1	Address 2	City	State	Zip	Pharmacy Phone Number
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-- Please Select -- ▾	<input type="text"/>	<input type="text"/>
ABC Pharmacy	100 Main Street	Suite 41	Spicewood	TX	12345	555 555-1212
XYZ Pharmacy	999 Broadway		Philadelphia	PA	12345	555 555-3434

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](#)

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

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

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.

User Name

[Forgot Username](#)

LOGIN

I am a

- Healthcare Setting Prescriber Pharmacy

If you are not a healthcare provider, please start by completing the fields below.

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

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

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Login

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User Name

[Forgot Username](#)

LOG IN

If you are not a REMS, please start by completing the fields below.

pharmacy

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

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

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

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

Login

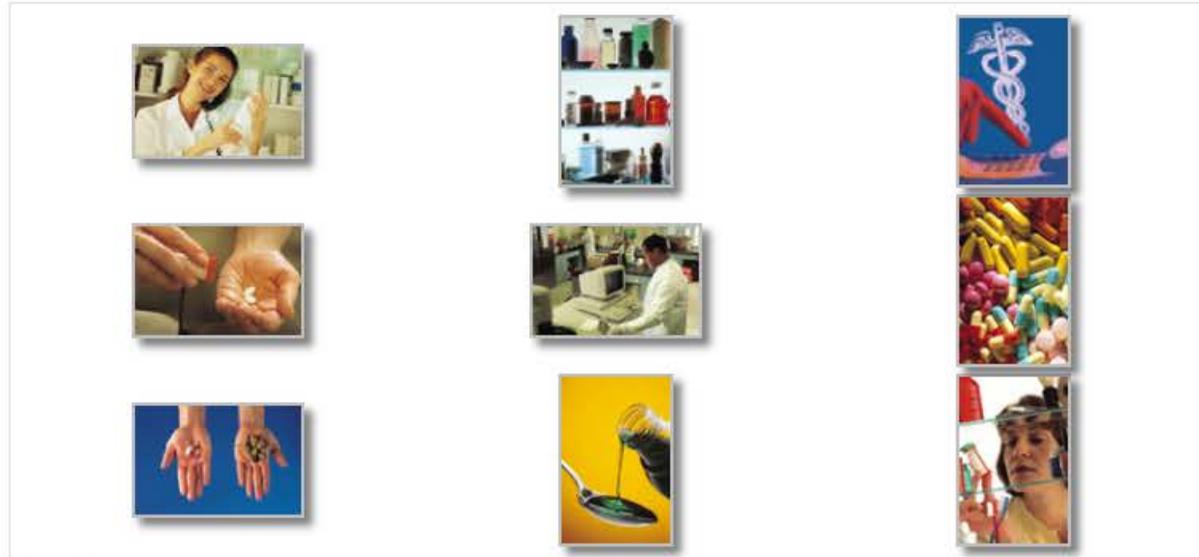
Your username was supplied to you via email when you registered. If you need assistance, please contact the REMS Coordinating Center at 855-382-6022.

User Name

[Forgot Username](#)

LOG IN

Update Profile



* Security Caption:

* Security Question

* Answer

-- Please Select --	▼	Answer
-- Please Select --	▼	Answer
-- Please Select --	▼	Answer

CANCEL

NEXT

* If you are not a REMS, please start by completing the fields below.

pharmacy

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

SPRAVATO[®] to Janssen

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.

[SUBMIT A PATIENT MONITORING FORM](#)



Patient REMS ID	First Name	Last Name	Address	City	State	Zip	Date of Birth	REMS Status	Action
<input type="text"/>									
111111	Robert	Smith	123 Main Street	Philadelphia	PA	19042	1/1/2000	Enrolled	Submit a Patient Monitoring Form
22222	Mary	Connors	3 Broadway	Blue Bell	PA	19042	1/1/2000	Pending	

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

First Name: Peggy Middle Initial: Last Name: Sue
 Birthdate (MM/DD/YYYY): 1/1/2000 Sex: Female

Concomitant Medications

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

*First Name: John *Last Name: Smith
 *Telephone: 555-555-1212 *Email: jsmith@abc.com

Healthcare Setting Information

*Healthcare Setting Name: ABC HealthCare
 *Healthcare Setting Address 1: 123 Main Street Healthcare Setting Address 2:
 *City: Blue Bell *State: PA *ZIP: 99999

Patient Treatment Session Information (Administration and Monitoring)

*Treatment Date (MM/DD/YYYY): *Dose Administered: 56 mg 84 mg Other
 *Treatment Duration (total time in minutes from 1st device 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, 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
- *Vital signs were in acceptable range prior to treatment session completion?
 Yes No

Monitoring of Blood Pressure

*Prior to administration (mmHg): *40 minutes post-administration (mmHg): *Prior to treatment session completion (mmHg):

Did the patient experience Sedation and/or Dissociation

- *Sedation
 Yes No
- *Dissociation
 Yes No

Serious Adverse Events

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

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**.

- Complete all required fields on this form after **every** treatment session for **all** outpatients enrolled in the SPRAVATO® REMS.
- 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

First Name: Peggy Middle Initial: Last Name: Sue
Birthdate (MM/DD/YYYY): 1/1/2000 Sex: Female

Concomitant Medications

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
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- *Psychostimulants
 Yes No
- *Monoamine oxidase inhibitors (MAOIs)
 Yes No

Healthcare Provider Conducting Patient Monitoring

*First Name: John *Last Name: Smith
*Telephone: 555 555-1212 *Email: jsmith@abc.com

Healthcare Setting Information

*Healthcare Setting Name: ABC HealthCare
*Healthcare Setting Address 1: 123 Main Street Healthcare Setting Address 2:
*City: Blue Bell *State: PA *ZIP: 99999

Patient Treatment Session Information (Administration and Monitoring)

*Treatment Date (MM/DD/YYYY): *Dose Administered:
 56 mg 84 mg Other

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

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REMS Evaluation Question

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- *Vital signs were in acceptable range prior to administration?
 Yes No
- *Vital signs were in acceptable range prior to treatment session completion?
 Yes No

Monitoring of Blood Pressure

*Prior to administration (mmHg): *40 minutes 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 (mins):
- *Medication(s) given for sedation?
 Yes No
- *Name and dose of medication(s):
-
- *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 (mins):
- *Medication(s) given for dissociation?
 Yes No
- *Name and dose of medication(s):

Serious Adverse Events

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

Event resulted in the following (check all # that apply)	Event Timing	Date of Event (MM/DD/YYYY)	Event Description	Event Resolution
<input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Death <input type="checkbox"/> Life-threatening <input type="checkbox"/> Important Medical Event	<input type="checkbox"/> During treatment sessions <input type="checkbox"/> Between treatment sessions	<input type="text"/>	Serious Adverse Event	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown

REMOVE

➕ ADD SERIOUS ADVERSE EVENT

Janssen Pharmaceuticals, Inc., Safety Department may follow up to obtain more information about these events.

CANCEL

SUBMIT



MY PATIENTS

CERTIFIED PHARMACIES

Patient Monitoring Form

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

PRINT/DOWNLOAD

MY PATIENTS

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

Phone: 1-855-382-6022

Fax: 1-877-778-0091

www.SPRAVATorems.com

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



SPRAVATO® REMS

Patient Monitoring Form - Outpatient Use Only

For Healthcare Setting Use Place Patient Label or Barcode Here

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*	MI	Last Name*	Birthdate* (MM/DD/YYYY): Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other
Concomitant Medication			
Is the patient currently taking any of the following medication(s) that may cause sedation or blood pressure changes?			
• Benzodiazepines*	<input type="checkbox"/> Yes <input type="checkbox"/> No		
• Non-benzodiazepine sedative hypnotics*	<input type="checkbox"/> Yes <input type="checkbox"/> No		
• Psychostimulants*	<input type="checkbox"/> Yes <input type="checkbox"/> No		
• Monoamine oxidase inhibitors (MAOIs)*	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Healthcare 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): _____		
Dose Administered*	<input type="checkbox"/> 56 mg <input type="checkbox"/> 84 mg <input type="checkbox"/> Other: _____		
Treatment Duration*	Total time _____ minutes (from 1st device 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, 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? <input type="checkbox"/> Yes <input type="checkbox"/> No • treatment session completion? <input type="checkbox"/> Yes <input type="checkbox"/> 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*: <input type="checkbox"/> Yes <input type="checkbox"/> No		Dissociation*: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Onset of symptoms from start of administration* <input type="checkbox"/> 1-29 mins <input type="checkbox"/> 30-59 mins <input type="checkbox"/> 60-89 mins <input type="checkbox"/> 90-120 mins <input type="checkbox"/> >120 mins		Onset of symptoms from start of administration* <input type="checkbox"/> 1-29 mins <input type="checkbox"/> 30-59 mins <input type="checkbox"/> 60-89 mins <input type="checkbox"/> 90-120 mins <input type="checkbox"/> >120 mins	
Resolution of symptoms within 2 hours?* <input type="checkbox"/> Yes <input type="checkbox"/> No Specify total time to resolution*: _____ min		Resolution of symptoms within 2 hours?* <input type="checkbox"/> Yes <input type="checkbox"/> No Specify total time to resolution*: _____ min	
Medication(s) given for sedation?* <input type="checkbox"/> Yes <input type="checkbox"/> No -If YES, name and dose of medication(s): _____		Medication(s) given for dissociation?* <input type="checkbox"/> Yes <input type="checkbox"/> No -If YES, name and dose of medication(s): _____	

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

Treatment Date: 5/23/2018

Treatment Dosage: 10mg

HCS Location: ABC Location

[Print/Download](#)

Treatment Date: 3/23/2018

Treatment Dosage: 10mg

HCS Location: XYZ Location

[Print/Download](#)

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.

Pharmacy Name	Address 1	Address 2	City	State	Zip	Pharmacy Phone Number
				-- Please Select -- ▾		
ABC Pharmacy	100 Main Street	Suite 41	Spicewood	TX	12345	555 555-1212
XYZ Pharmacy	999 Broadway		Philadelphia	PA	12345	555 555-3434

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

/s/

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07/31/2020 06:36:13 PM