SPRAVATO® REMS Program Overview
(Risk Evaluation and Mitigation Strategy)

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

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

Spravato® (esketamine) CIII nasal spray

Reference ID:

Reference ID: 4649523

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

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

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

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

Spravato® (esketamine) CIII nasal spray

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How does the SPRAVATO® REMS work?

	Before Prescribing/ Dispensing SPRAVATO®	Before Starting SPRAVATO® for each Patient	During SPRAVATO® Treatment
INPATIENT HEALTHCARE SETTING	Inpatient Healthcare Setting Certification *[covers hospital inpatient, inpatient pharmacy, and emergency departments]*	**Counsel** the patient on the risks and need for monitoring for resolution of sedation and dissociation, and changes in vital signs.	**Supervise** patient administration of SPRAVATO®. **Monitor** each patient for at least 2 hours following administration of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs. **Report** all suspected adverse events to the SPRAVATO® REMS.
OUTPATIENT HEALTHCARE SETTING	Outpatient Healthcare Setting Certification *[covers outpatient medical offices and clinics]*	**Counsel** the patient on the risks and need for monitoring for resolution of sedation and dissociation, and changes in vital signs. **Enroll** the patient using the ***Patient Enrollment Form***.	**Supervise** patient administration of SPRAVATO®. **Monitor** each patient for at least 2 hours following administration of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs. **Submit** the ***Patient Monitoring Form***
PHARMACY	Pharmacy Certification *[covers community, retail, and specialty pharmacies]*	**Verify** that the healthcare setting is certified through the processes and procedures established as a requirement of the SPRAVATO® REMS.	
PATIENT		**Receive counseling** from a healthcare provider on the need for monitoring for resolution of sedation and dissociation, and changes in vital signs. Outpatient Enrollment	**Administer SPRAVATO®** under the direct supervision of a healthcare provider. **Be observed** for at least 2 hours after each treatment of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs at the healthcare setting.

What are the Requirements of the SPRAVATO® REMS?

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

INPATIENT HEALTHCARE SETTING REQUIREMENTS

Become Certified*:

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

Before treating a patient:

1. **Establish** processes and procedures and train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO®
2. Have a healthcare provider **counsel** the patient prior to receiving SPRAVATO® on the need for monitoring due to risks of sedation and dissociation, changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.

*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**.

At All Times:

1. **Ensure** relevant staff are trained and follow all established processes and procedures to comply with SPRAVATO® REMS requirements†
2. **Have a prescriber onsite** during SPRAVATO® administration and monitoring
3. **Have a healthcare provider monitor** every patient for at least 2 hours for resolution of sedation and dissociation and changes in vital signs after every dose
4. **Ensure** SPRAVATO® is not dispensed for use outside the Healthcare Setting
5. **Maintain** records documenting staff completion of training
6. **Maintain** records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date administered
7. **Comply** with audits carried out by Janssen Pharmaceuticals, Inc. or third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed

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

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OUTPATIENT HEALTHCARE SETTING REQUIREMENTS

Become Certified:

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

Before treating a patient:

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

At All Times:

1. **Ensure** relevant staff are trained and follow all established processes and procedures to comply with all SPRAVATO® REMS requirements*
2. Have a **prescriber onsite** during SPRAVATO® administration and monitoring
3. Have the patient **administer** SPRAVATO® under the direct supervision of a healthcare provider
4. Have a **healthcare provider(s) onsite** to monitor each patient for at least 2 hours following administration of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs after every dose
5. **Document** and **submit** a ***Patient Monitoring Form*** for every patient within 7 days following administration of every dose of SPRAVATO®
6. **Notify** the SPRAVATO® REMS in advance if patient treatment will be transferred from one REMS-certified Healthcare Setting to another REMS-certified Healthcare Setting
7. **Ensure** SPRAVATO® is not dispensed for use outside the Healthcare Setting
8. **Maintain** records documenting staff completion of training
9. **Maintain** records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date administered
10. **Comply** with audits carried out by Janssen Pharmaceuticals, Inc. or third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed

*To review all SPRAVATO® REMS Outpatient Healthcare Setting requirements see the ***Outpatient Healthcare Setting Enrollment Form***

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PHARMACY REQUIREMENTS - FOR OUTPATIENT DISPENSING ONLY

Become Certified:

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

Before Dispensing:

1. **Establish** processes and procedures and train all relevant staff involved in dispensing SPRAVATO® to comply with all SPRAVATO® REMS requirements
2. **Verify** the healthcare setting is certified before dispensing SPRAVATO®

At All Times:

1. **Ensure** relevant staff are trained and follow all established processes and procedures to comply with all SPRAVATO® REMS requirements*
2. **Ensure** SPRAVATO® is never dispensed directly to a patient for home use
3 **Ensure** SPRAVATO® is only dispensed to a certified healthcare setting
4. **Maintain** records documenting staff's completion of training
5. **Maintain** records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date dispensed
6. **Comply** with audits carried out by Janssen Pharmaceuticals, Inc. or third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed

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

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PATIENT REQUIREMENTS

Before Treatment:

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

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

During Treatment:

1. **Administer** SPRAVATO® nasal spray under the direct observation of a healthcare provider
2. **Be observed** at the healthcare setting where SPRAVATO® is received for at least 2 hours after each treatment until the healthcare provider determines the patient is ready to leave the healthcare setting

At All Times*:

1. **Make arrangements** to safely get home after receiving SPRAVATO®, if leaving the healthcare setting
2. **Do not** drive or use heavy machinery for the rest of the day after receiving SPRAVATO®
3. **Contact the healthcare provider** or inform the healthcare provider at the next visit if a side effect or reaction from SPRAVATO® occurs

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

SPRAVATO® REMS Resources

INPATIENT HEALTHCARE SETTING	OUTPATIENT HEALTHCARE SETTING	PHARMACY
• *Inpatient Healthcare Setting Enrollment Form* • *REMS Program Overview* • *Prescribing Information*	• *Outpatient Healthcare Setting Enrollment Form* • *Patient Enrollment Form* • *Patient Monitoring Form* • *REMS Program Overview* • *Prescribing Information*	• *Pharmacy Enrollment Form* • *REMS Program Overview* • *Prescribing Information*

Contact the SPRAVATO® REMS

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

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

Please see the Prescribing Information for more information.

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