

## SPRAVATO™ REMS Fact Sheet

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

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. The FDA has determined that a REMS is necessary to ensure that the benefits of SPRAVATO™ outweigh the potential risks.

**The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™ by:**

- Ensuring that SPRAVATO™ is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
- Ensuring pharmacies and healthcare settings that dispense SPRAVATO™ are certified
- Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
- Enrollment of all patients in the REMs (registry) to further characterize the risks and support safe use

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

### What are the SPRAVATO™ REMS requirements?

SPRAVATO™ is available only through a limited distribution program that is part of the SPRAVATO™ REMS. All healthcare settings and pharmacies are required to enroll in the SPRAVATO™ REMS via a designated authorized representative before they can purchase product from a distributor, dispense, or supervise administration of SPRAVATO™. All patients must also be enrolled in the SPRAVATO™ REMS before they can receive SPRAVATO™.

### How can healthcare settings and/or pharmacies obtain SPRAVATO™ for patients?

To order, dispense, prescribe, and/or supervise administration of SPRAVATO™, the healthcare setting and/or pharmacy must be certified in the SPRAVATO™ REMS.

To become certified, the healthcare setting or pharmacy must:

1. Designate an “authorized representative” to complete the **SPRAVATO™ REMS Healthcare Setting Enrollment Form** and/or **SPRAVATO™ REMS Pharmacy Enrollment Form** and submit it to the SPRAVATO™ REMS.
2. Healthcare settings and pharmacies must establish appropriate policies and procedures, and train relevant staff involved in the prescribing, dispensing and administering, and handling of SPRAVATO™ to ensure that product is delivered/dispensed directly to a healthcare provider at the site of care and not dispensed directly to a patient to take home.
3. Healthcare settings must further establish policies and procedures and train relevant staff on the following steps to comply with REMS requirements:
  - a. Counsel and enroll patients in the SPRAVATO™ REMS

- b. Ensure that administration of SPRAVATO™ is under the direct observation by a healthcare provider
- c. Ensure that patients are monitored by a healthcare provider for at least 2 hours post-administration
- d. Report relevant information back to the SPRAVATO™ REMS using the *Patient Monitoring Form*

**Once certified as a healthcare setting and/or pharmacy, SPRAVATO™ may be obtained:**

For a healthcare setting and/or pharmacy: By ordering SPRAVATO™ directly through a distributor/wholesaler

Once your healthcare setting and/or pharmacy is certified, you may obtain a list of distributors/wholesalers to purchase product by contacting the SPRAVATO™ REMS at 1-855-382-6022.

For a healthcare setting: Through a certified pharmacy

Once your healthcare setting is certified, you may obtain a list of REMS certified pharmacies by contacting the SPRAVATO™ REMS at 1-855-382-6022.

**Where can I find more information about the SPRAVATO™ REMS?**

- Visit [www.SPRAVATOREMS.com](http://www.SPRAVATOREMS.com) to access the following materials:
  - SPRAVATO™ REMS Healthcare Setting Enrollment Form
  - SPRAVATO™ REMS Pharmacy Enrollment Form
  - SPRAVATO™ REMS Patient Enrollment Form
  - SPRAVATO™ REMS Patient Monitoring Form
  - SPRAVATO™ REMS Letter for Healthcare Providers
  - SPRAVATO™ Prescribing Information
  - SPRAVATO™ Medication Guide
  - SPRAVATO™ Instructions for Use
- For additional information or questions about the SPRAVATO™ REMS, call 1-855-382-6022.
- Call Janssen Medical Information at 1-800-JANSSEN (1-800-526-7736) for any clinical or medical questions related to SPRAVATO™.

**How should SPRAVATO™ be stored and handled?**

- Once SPRAVATO™ is delivered for a named-patient or is obtained for a healthcare setting's bulk supply, it should be kept in a secure place per State and Federal Drug Enforcement Agency (DEA) laws and regulations for controlled substances.
- Product dispensed for a specific named-patient must be administered within 14 days after receipt by the healthcare setting per DEA requirements. Unused named-patient products must be appropriately disposed of as per State and Federal regulations and may not be returned to the general inventory of the healthcare setting or pharmacy.
- Janssen offers a SPRAVATO™ disposal program, if your healthcare setting is not equipped to do so. Contact 1-800-JANSSEN for more information.

**Reporting Adverse Events and Product Quality Complaints**

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