ELEMENTAL
CENTER

PATIENT SPRAVATO WELCOME PACKET

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DOWNERS GROVE, IL 60515

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spravato@elementalcenter.com.

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 in adults.

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Informed Consent

Spravato nasal treatment for Depression

I, _____ hereby give my consent to the following procedure.

Spravato nasal treatment for Depression

I understand the risks include but are not limited to: Dissociation, Dizziness, Nausea, Sedation, Vertigo, Headache, Dysgeusia, Hypoesthesia, Anxiety, Lethargy, Blood pressure increased, Vomiting, Insomnia, and Diarrhea. I also understand that the potential side effects form Spravato nasal treatment may include: Nasal discomfort, Throat irritation, feeling drunk, Dry mouth, Hyperhidrosis, Euphoric mood, Dysarthria, Tremor, Oropharyngeal pain, Mental impairment, Constipation, Pollakiuria, Feeling abnormal, and Tachycardia.

Furthermore, by signing below I am confirming that I have received and reviewed the pre-treatment instructions, post treatment instructions and that I can fully comply.

I understand that I may not drive nor operate machinery for at least 12 hours after my nasal treatment is completed. And that I will only be discharged to the care of a responsible adult. I understand that good results are expected but not guaranteed. My depression may not improve with Spravato treatment even if I follow the complete treatment protocol.

I understand that to achieve the desired results that a series of nasal treatments are needed, and it is my full intent to complete the course of treatment. By signing this document, I am given consent for such a series.

I understand that Spravato nasal treatment is not a substitute for continued behavioral medicine treatment. My psychiatrist or family doctor will determine if any oral medications or other treatments may be stopped if my depression improves.

Patient Name: Print: _____ Date/time: _____

Patient Signature or Guardian: _____ Date/time: _____

Physician: _____ Date/time: _____I have carefully explained the nature of Spravato nasal treatment to _____. I hereby certify that to the best od my knowledge, the individual signing this consent form understands the nature, conditions, risks and potential benefits involved in participating in Spravato nasal treatment. A medical problem or language or education barrier has not precluded a clear understanding of the subject's involvement in Spravato nasal treatment.

Witness: _____ Date/time: _____

Date: _____

Patient Name: _____ Date of Birth: _____

Please initial Each Statement:

_____I have been explained thoroughly about the use of Spravato for Major Depression and I had the opportunity to ask all the relevant questions I felt necessary.

_____I voluntarily request Dr Adeoye and his team at Elemental Center Ltd to administer Spravato for the treatment of my condition.

_____I understand that I can revoke this consent at any time including during treatment.

_____I understand that the duration of the treatment will be approximately two hours and I understand that it will be necessary for me to stay in the office for a while after the treatment ends, typically a few more hours.

_____Potential side effects from Spravato treatment include Dissociation, Dizziness, Nausea, Sedation, Vertigo, Headache, Dysgeusia, Hypoesthesia, Anxiety, Lethargy, Blood pressure increased, Vomiting, Insomnia, and Diarrhea.

____Use of Spravato for the treatment of Major Depression is Food and Drug Administration approved

_____I understand that Spravato nasal spray is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression in adults.

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 SPRAVATOTM administration. SPRAVATOTM must never be dispensed directly to a patient for home use.

SPRAVATO™ is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO™ as an anesthetic agent have not been established.

Patients Signature: _____ Date: _____

Witness Signature: _____ Name: _____ Date: _____

SPRAVATO™ REMS
Patient Enrollment Form

SPRAVATO™ is available only through the SPRAVATO™ REMS, a restricted distribution program. Only healthcare settings, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive SPRAVATO™. Your healthcare provider will help you complete this form and provide you with a copy.

Prescribers and patients: Please complete this form online at www.SPRAVATOrems.com or, once completed, fax it to the REMS at 1-877-778-0091

** Indicates Required Field*

Healthcare Setting Information

Healthcare Setting Name*:		
Healthcare Setting DEA#*(on file with distributor account):		
Address 1*:	Address 2:	
City*:	State*:	ZIP*:
Phone*:	Fax*:	

Prescribing Physician

First Name*:	Last Name*:	
Credentials*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other Specialty:* ☐ Psychiatry ☐ Internal Medicine ☐ Family Practice ☐ Other(specify)_____		Prescriber DEA#*:
Phone*:	Fax*:	Email*:
Signature*:		Date*:

Referring Physician – if different than Prescribing Physician

First Name:	Last Name:
Phone:	

Relevant Clinical Information

Has the patient previously been treated with ketamine for treatment-resistant depression, pain syndromes or any other condition?*	☐ Yes ☐ No
If YES, list all pre-existing conditions treated with ketamine:	
List all pre-existing medical and psychiatric conditions:	
List concomitant medications (e.g., adjunctive depression medications, sedative hypnotics, psychostimulants, monoamine oxidase inhibitors (MAOIs))	

Spravato™ (esketamine) CIII nasal spray

janssen PHARMACEUTICAL COMPANIES of Johnson & Johnson

This section is to be completed by the Patient

Patient Information

First Name*:	MI:	Last Name*:	Birthdate*: (MM/DD/YYYY):	Sex*: ☐ M ☐ F ☐ Other
Email*: (Email is required for online enrollment only)			Phone Number*:	
Address 1*:			Address 2:	
City*:		State*:	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 provided to the REMS.
- Agree to receive counseling on the risks and the need for monitoring for resolution of sedation and dissociation, and for any changes in my vital signs.

During treatment 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 leave the healthcare setting and 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™, I am required to be enrolled in the REMS, and my information will be stored in a database of all patients who receive SPRAVATO™ in the United States.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me 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:	
Patient Signature*:	**Date*:**

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

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Spravato Treatment Worksheet:

Identifying information

Name: _____ Date: _____

Age: _____ Weight: _____ Height: _____

Diagnosis: _____

Indication for Spravato treatment: _____

Pertinent medical/surgical history: _____

_____

Allergies: _____

Current medications: _____

_____

Medical clearance by: _____ Date/time: _____

Psychiatry assessment by: _____ Date/time: _____

Spravato dose/route recommended: _____

Last intake of solids (hours): _____ Last intake of clear liquids (hours): _____

Location where the treatment will be provided: _____

Patient Monitor:_____

Medical provider administering Spravato treatment: _____

Medical provider ordering Spravato treatment: _____

Medical provider present during treatment or given Spravato treatment: _____

Patient signed medication consent form: Yes_____ No _____

Time/Date	HR	BP	RR	O Sat	Pain	Level of consciousness	Comments/Medications ordered/side effects

SPRAVATO™ REMS
Patient Monitoring Form

INSTRUCTIONS

- Complete this form after every treatment session to record the administration and monitoring for all patients enrolled in the SPRAVATO™ REMS starting from the first dose
- Submit completed forms promptly by fax (1-877-778-0091) or online at www.SPRAVATOrems.com

** Indicates Required Field*

Patient Information (PRINT)

First Name*:	Middle Initial:	Last Name*:	Birthdate* (MM/DD/YYYY):

Concomitant Medication

Is the patient currently taking any of the following concomitant 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 Setting and Healthcare Provider Information (PRINT)

First Name*:	Last Name*:	
Phone*:	Email*:	
Healthcare Setting Name*:		
Healthcare Setting Address 1*:	Healthcare Setting Address 2:	
City*:	State*:	ZIP*:

Treatment Session Information

Date _____MM/ _____DD/_____YYYY

Dose _____28 mg _____56 mg _____84 mg

Time at start of administration: _____:_____ AM / PM	**Patient must be monitored for at least 2 hours**	Time of discharge: _____:_____ AM/PM

☐ I confirmed vital signs (BP, HR, RR) were in an acceptable range **prior to SPRAVATO™ administration.**

☐ I confirmed vital signs were in an acceptable range **prior to patient discharge.**

BP prior to administration	BP 40 minutes post administration	BP prior to discharge
_____mmHg	_____mmHg	_____mmHg

Was the patient clinically ready for discharge **prior to the required 2 hours**? ☐ Yes ☐ No

If Yes, when was the patient ready for discharge? _____minutes from start of administration

If No, use the below sections to describe as appropriate

Sedation and Dissociation

Did the patient experience sedation or dissociation?

Sedation ☐ Yes ☐ No	If yes, indicate onset of symptoms from start of administration ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins Did symptom resolve within 2 hours of administration? ☐ Yes ☐ No If greater than 2 hours, specify total time since administration _____
Dissociation ☐ Yes ☐ No	If yes, indicate onset of symptoms from start of administration ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins Did symptom resolve within 2 hours of administration? ☐ Yes ☐ No If greater than 2 hours, specify total time since administration _____

Serious Adverse Events

Did the patient experience a serious adverse event during this treatment session or since the last treatment session? A serious adverse event is one which is any undesirable experience associated with the use of SPRAVATO™ that resulted in patient hospitalization, a disability or permanent damage, death, required medical intervention, or was life threatening.

Serious Adverse Event	Occurrence	Date of Event MM/DD/YYYY	The event resulted in: (check all that apply)	Did the event resolve?
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical Intervention ☐ Life threatening ☐ Death	☐ Yes ☐ No ☐ Unknown
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical Intervention ☐ Life threatening ☐ Death	☐ Yes ☐ No ☐ Unknown
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical Intervention ☐ Life threatening ☐ Death	☐ Yes ☐ No ☐ Unknown

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

Reporting of other events

For any other adverse event not captured above, 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.

FREQUENTLY ASKED QUESTIONS ABOUT SPRAVATO (SPRAVATO FAQs)

IS SPRAVATO SAFE?

SPRAVATO is a very safe depression medication *in the hands of properly trained healthcare professionals.*

Its use as a treatment for depression, including treatment resistant depression, and other mental health conditions. The appropriate dosage determined by your physician, below those necessary to induce general anesthesia. SPRAVATO is also frequently used to treat patients with treatment resistant depression

IS SPRAVATO A RECREATIONAL DRUG?

SPRAVATO is esketamine, however Ketamine has been abused as a recreational drug. Street drug use is in doses vastly higher than the sub-anesthetic doses used for the treatment of depression and other mental health conditions. As mentioned above, SPRAVATO is used legally and safely and is a very safe medication in experienced hands. Incidentally, many of the drugs used in anesthesia practice have the potential for abuse, so SPRAVATO is not unique in this respect. The key is administering the right dose to the right patient in the right setting.

IS INTRANASAL SPRAVATO THE ONLY WAY TO DELIVER SPRAVATO FOR TREATMENT RESISTANT DEPRESSION?

SPRAVATO is only administered intranasal. Unfortunately, the effectiveness and predictability of response and the overwhelming majority of scientific studies of SPRAVATO for depression and mental health conditions have been performed using intranasal SPRAVATO. In short, intranasal SPRAVATO is the gold standard route for SPRAVATO administration.

CAN SPRAVATO HELP ME?

Research over the last 5-10 years has shown that Intranasal administration of SPRAVATO in sub-anesthetic doses remarkably benefits 70% of people suffering from severe depression. While the benefits can truly be remarkable, they often occur in ways that differ from some patients' expectations. That is, the changes produced by SPRAVATO can be subtle, and while they occur quickly, they do not always manifest themselves *immediately.* This phenomenon stands in contrast to some patients' expectations of a benevolent "thunderbolt" response from SPRAVATO treatment. With this in mind, we will work closely with you to identify and evaluate the benefits of SPRAVATO as a depression medication.

WHAT DOES THE RESEARCH SHOW ABOUT SPRAVATO BENEFITS?

Please review spravato tab of our website to learn about the clinical research and read other newsworthy articles related to SPRAVATO for depression and other mental health disorders.

WHAT SHOULD I EXPECT DURING MY FIRST INITIAL SPRAVATO VISIT?

After we have received your medical and psychiatric history and completed acknowledgement of ongoing care by a mental health professional or primary care doctor, we will schedule an initial consultation. At the initial consultation, we will discuss all your options regarding treatment for depression and assess if you are a good candidate for SPRAVATO Intranasal administrations, you are welcome to receive your first SPRAVATO treatment once all insurance benefits and authorizations have been completed. You would also need to be enrolled in the Spravato REMS program.

The logistics are as follows: we will apply monitors to enable us to record your heart rate and rhythm, blood pressure, and oxygen level continuously throughout the treatment, then we begin the intranasal administration while you are seated with your head at 45-degree incline. Afterwards, we will monitor you for approximately 120 minutes (2hours) before you are released with a friend or relative who can drive you safely home.

During the treatment, occasionally people experience nausea, mild non-threatening hallucinations, or dizziness. If you experience nausea, we are equipped to treat it with an anti-nausea medication.

You will be awake during the treatment and able to interact with those around you. It is best to relax quietly or listen to relaxing music during the session.

The effects of SPRAVATO wear off quickly, although we ask that you refrain from driving until the day after the treatment.

Please do not eat solid foods, milk, pulp-filled juices or soup for 4-hours prior to your appointment. You may have clear liquids such as water, Gatorade, apple juice, black coffee or tea up to two hours prior to your appointment.

HOW MANY INTRANASAL ADMINISTRATIONS DO I NEED?

The standard SPRAVATO protocol for depression that has resulted from scientific trials and clinical experience around the U.S. is about 2 times per week for the first 4 weeks, and the weekly for 2-4weeks and then maintenance. It has been shown that serial Intranasal administrations are more effective than single Intranasal administrations, and many patients who respond to SPRAVATO treatment require maintenance Intranasal administrations on an ongoing basis following the initial series. The frequency of these maintenance Intranasal administrations varies greatly from person to person. *It is important to note that SPRAVATO Intranasal administrations should not be viewed as a cure for depression, but rather a depression treatment that is a piece of a multi-modal approach that may include ongoing mental health therapy or other depression medication.*

CAN I CONTINUE TO TAKE MY REGULAR MEDICATIONS?

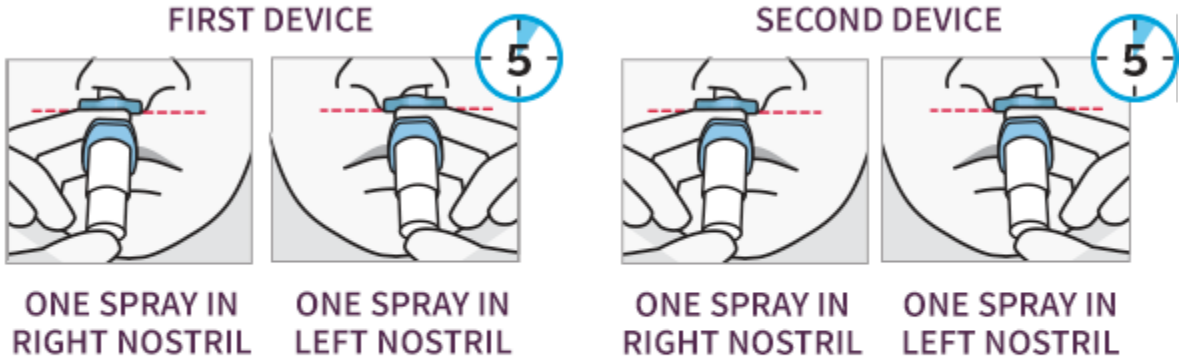
Yes, you should not stop your antidepressant medications in order to receive SPRAVATO. It is essential that we review your current medication list prior to beginning SPRAVATO treatments.

IS SPRAVATO ADDICTING?

SPRAVATO is not physically addicting but it could be psychologically addicting in those using it recreationally at much higher doses and in far greater frequencies than we will use. **There is potential for abuse and misuse. Consider the risks and benefits of using SPRAVATO™ prior to use in patients at higher risk of abuse. All patients will be monitor for signs and symptoms of abuse and misuse.**

OTHER SPRAVATO FAQs

1. **Is there a difference between Spravato Nasal Spray and Ketamine Infusions?** SPRAVATO™ (esketamine) is the s-enantiomer of racemic ketamine. There are no head-to-head studies comparing esketamine and ketamine infusion. SPRAVATO™ (esketamine) is delivered in a nasal spray form and ketamine is delivered intravenously.
2. **Are there Samples of Spravato?** There are no samples of SPRAVATO™ available—in accordance with federal guidelines, which prohibit the distribution of samples of class III medications.
3. **How much dose Spravato Cost?** The cost of SPRAVATO™ to your patients is dependent on their insurance plan. Janssen CarePath offers access and affordability options for your patients, depending on their plan.
4. **Can Spravato be taken with other medications for depression?** SPRAVATO™ should be administered in conjunction with an oral antidepressant (AD). The new open-label oral AD initiated during Study 1 (short-term) was an SSRI in 32% of patients and an SNRI in 68% of patients.
5. **What if a patient misses a dose of Spravato?** If a patient misses treatment session, and depression symptoms worsen, consider returning your patient to their previous dosing schedule (ie, every 2 weeks to once weekly, once or twice per week), per clinical judgment.
6. **Can my patients pick up Spravato and self-administer at home? No**, under the REMS, SPRAVATO™ must be administered in a certified healthcare setting. Due to the possibility of delayed or prolonged sedation or dissociation in some cases, patients should be monitored by a healthcare professional for at least 2 hours following each treatment session, or until the clinician determines the patient is safe to leave.
7. **How soon can my patients drive after taking Spravato?** Caution patients that SPRAVATO™ may impair their ability to drive or operate machinery. Instruct patients not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep.



Wait 5 minutes after each device to allow medication to absorb.

Instructions for Use
SPRAVATO™
(SPRAH VAH' TOE)
(esketamine)

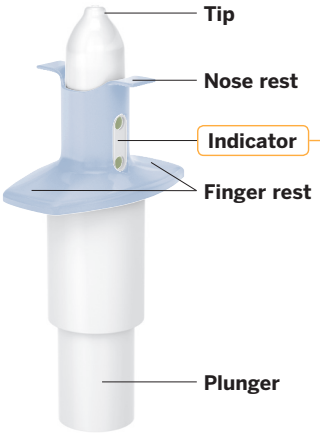
Important

This device is intended for administration by the patient, **under supervision of a healthcare professional**. Read this Instructions for Use in full before training and supervising patient.

Need help?

For additional assistance or to share your feedback call 800-JANSSEN (800-526-7736).

Nasal Spray Device

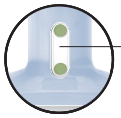


Each device delivers two sprays containing a total of 28 mg of esketamine.

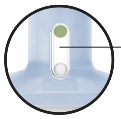
Indicator

One device contains 2 sprays. (1 spray for each nostril)

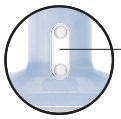
2 green dots (0 mg delivered)



1 green dot



No green dots
Two sprays (28 mg) delivered



Step 1 Get ready

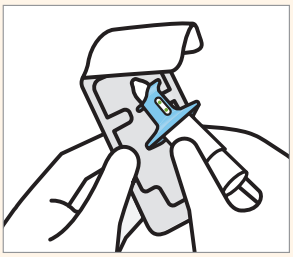
Before first device only:

Instruct patient to blow nose **before first device only**.

Confirm required number of devices.

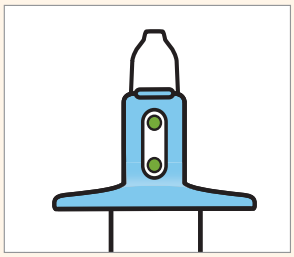
56 mg = 2 devices
84 mg = 3 devices

Step 2 Prepare device



Healthcare professional:

- Check expiration date ('EXP'). If expired, get a new device.
- Peel blister and remove device.



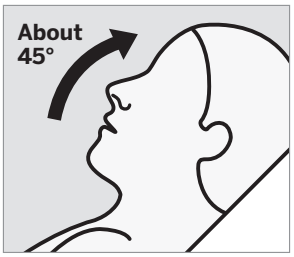
Healthcare professional:

- **Do not prime device.** This will result in a loss of medication.
- Check that indicator shows **2 green dots**. If not, dispose of device and get a new one.
- Hand device to patient.

Step 3 Prepare patient

Instruct the patient to:

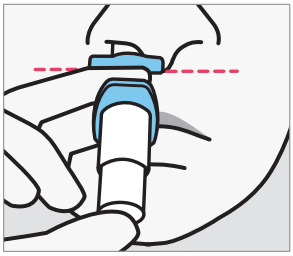
- Hold device as shown with the thumb gently supporting the plunger.
- **Do not** press the plunger.



Instruct the patient to:

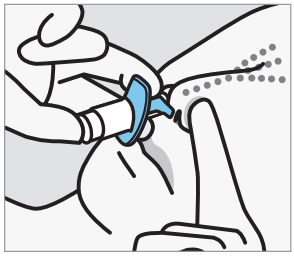
- Recline head at about **45 degrees** during administration to keep medication inside the nose.

Step 4 Patient sprays once into each nostril



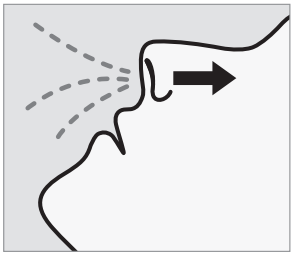
Instruct the patient to:

- Insert tip straight into the **first nostril**.
- Nose rest should touch the **skin between the nostrils**.



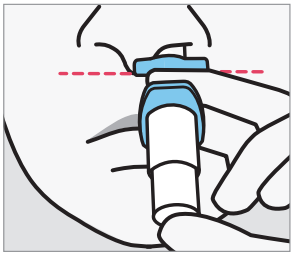
Instruct the patient to:

- Close opposite nostril.
- **Breathe in through nose** while pushing plunger all the way up until it stops.



Instruct the patient to:

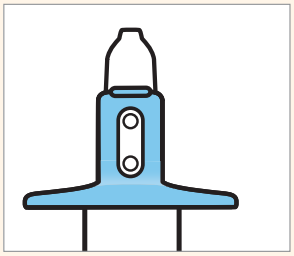
- **Sniff gently** after spraying to keep medication inside nose.



Instruct the patient to:

- Switch hands to insert tip into the **second nostril**.
- Repeat Step 4 to deliver second spray.

Step 5 Confirm delivery and rest



Healthcare professional:

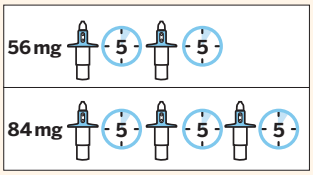
- Take device from patient.
- **Check that indicator shows no green dots**. If you see a green dot, have patient spray again into the second nostril.
- Check indicator again to confirm device is empty.

Instruct the patient to:

- Rest in a comfortable position (preferably, semi-reclined) for **5 minutes after each device.**
- If liquid drips out, dab nose with a tissue.

⚠ **Do not** blow nose.

Next device



Healthcare professional:

- **Repeat Steps 2-5** for the next device.

IMPORTANT: Ensure that patient **waits 5 minutes after each device** to allow medication to absorb.

Disposal

Dispose of used device(s) per facility procedure for a Schedule III drug product and per applicable federal, state, and local regulations.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Renaissance Lakewood LLC
Lakewood, NJ 08701

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Revised: March 2019

cp-81317v1

janssen

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 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.