Spravato® (esketamine) CIII
28 mg nasal spray

Dosing and Administration Guide

- Treatment-Resistant Depression (TRD) in Adults
- Depressive Symptoms in Adults with MDD with Acute Suicidal Ideation or Behavior (MDSI)

Indications:

SPRAVATO® (esketamine) CIII Nasal Spray is 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.

Limitations of Use:

- The effectiveness of SPRAVATO® in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of SPRAVATO® does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of SPRAVATO®.
- SPRAVATO® is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO® as an anesthetic agent have not been established.

MDD=major depressive disorder.

Important Safety Information

WARNING: SEDATION; DISSOCIATION; RESPIRATORY DEPRESSION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS

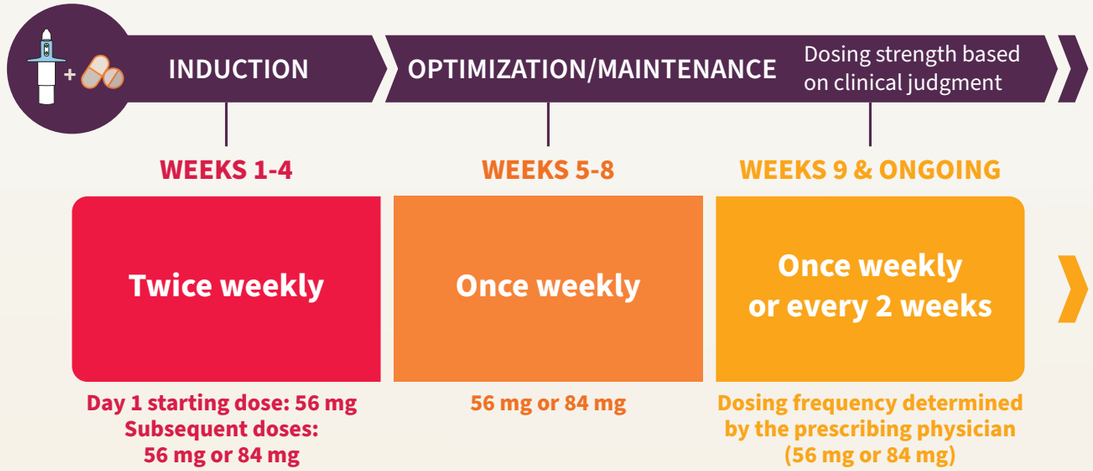
See full prescribing information for complete boxed warning

- **Risk for sedation, dissociation, and respiratory depression after administration. Monitor patients for at least two hours after administration (5.1, 5.2, 5.3).**
- **Potential for abuse and misuse. Consider the risks and benefits of using SPRAVATO® prior to use in patients at higher risk of abuse. Monitor for signs and symptoms of abuse and misuse (5.4).**
- **SPRAVATO® is only available through a restricted program called the SPRAVATO® REMS (5.5).**
- **Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. SPRAVATO® is not approved for use in pediatric patients (5.6).**

Please see Important Safety Information on pages 7 through 9. Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

Induction and maintenance dosing for adult patients with TRD

TRD dosing frequency and strengths are flexible.[1]



= 56 mg

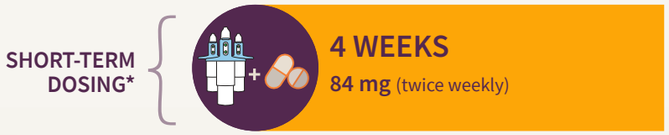
= 84 mg

- SPRAVATO® must be taken with an oral AD
- SPRAVATO® is self-administered only under the supervision of a healthcare provider
- The starting dose of SPRAVATO® for TRD is **56 mg (2 devices)**
- Evidence of therapeutic benefit should be evaluated at the end of the Induction phase to determine need for continued treatment
- Dosing frequency should be individualized to the lowest frequency required to maintain remission/response
- Dosing frequency for continued treatment to be determined by the prescribing physician

Short-term dosing for adult patients with MDSI

8 doses over 4 weeks is the recommended dose for adults with MDSI.[1]

DEPRESSIVE SYMPTOMS IN ADULTS WITH MDSI[1]



*After 4 weeks of treatment with SPRAVATO®, evidence of therapeutic benefit should be evaluated to determine need for continued treatment. Treatment beyond 4 weeks has not been systematically evaluated.

- SPRAVATO® must be taken with an oral AD
- SPRAVATO® is self-administered, only under the supervision of a healthcare provider
- The dose of SPRAVATO® for depressive symptoms in adults with MDSI is **84 mg† (3 devices)**[1] throughout treatment

†Dosing may be reduced to 56 mg twice per week based on tolerability.

IMPORTANT REMINDERS FOR BOTH INDICATIONS

- SPRAVATO® must be taken with an oral AD.[1]
- SPRAVATO® is self-administered, only under the supervision of a healthcare provider.
- Careful consideration is advised prior to treatment of individuals with a history of substance use disorder, including alcohol. Monitoring for signs of abuse and dependence is recommended.

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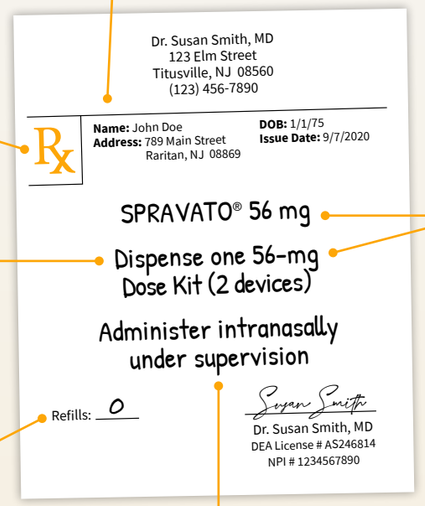
How to prescribe SPRAVATO®

An example prescription for a single 56-mg dose as written for TRD is shown below.

Indicate the REMS-certified treatment center location where SPRAVATO® should be delivered by the REMS-certified pharmacy. This ensures SPRAVATO® is only administered to patients in a medically supervised setting with appropriate monitoring.

For SPRAVATO® prescription protocol, please consult your pharmacy.



Indicate the quantity prescribed in number of devices and dose amount.

Indicate SPRAVATO® dose.

- **Standard TRD dosing**
  - 56-mg prescription (2 devices per treatment)
- **Standard MDSI dosing**
  - 84-mg prescription (3 devices per treatment)

Laws governing refills of prescriptions for controlled substances vary by state.

Each nasal spray device of SPRAVATO® has 2 green dots on it – 1 dot for each nostril. Each dot represents 14 mg of esketamine (the device contains 28 mg of esketamine total). Wait 5 minutes between devices to allow the medication to be fully absorbed.

REMS=Risk Evaluation and Mitigation Strategy.

SPRAVATO® Dose Kits

SPRAVATO® is available in Dose Kits of either 56 mg (2 devices) or 84 mg (3 devices).

56 mg =

Total volume to be delivered (per device):
0.2 mL, equivalent to 28 mg of esketamine

Package dimensions:
4.6 in x 2.5 in x 2.9 in

For more details:

Click here

84 mg =

Total volume to be delivered (per device):
0.2 mL, equivalent to 28 mg of esketamine

Package dimensions:
4.6 in x 2.5 in x 4.1 in

For more details:

Click here

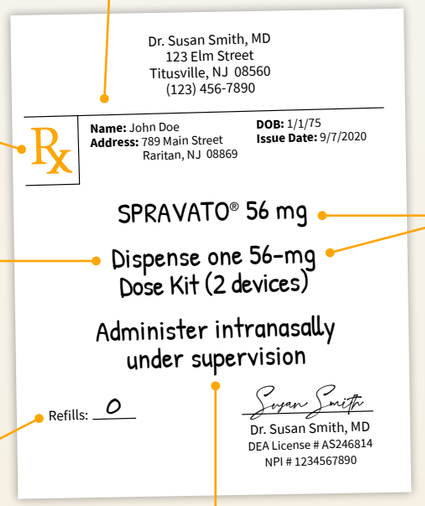
Spravato® (esketamine) CIII
28 mg nasal spray

How to prescribe SPRAVATO®

An example prescription for a single 56-mg dose as written for TRD is shown below.

Indicate the REMS-certified treatment center location where SPRAVATO® should be delivered by the REMS-certified pharmacy. This ensures SPRAVATO® is only administered to patients in a medically supervised setting with appropriate monitoring.

For SPRAVATO® prescription protocol, please consult your pharmacy.



Indicate the quantity prescribed in number of devices and dose amount.

Indicate SPRAVATO® dose.

- **Standard TRD dosing**
  - 56-mg prescription (2 devices per treatment)
- **Standard MDSI dosing**
  - 84-mg prescription (3 devices per treatment)

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REMS=Risk Evaluation and Mitigation Strategy.

SPRAVATO® Dose Kits

SPRAVATO® is available in Dose Kits of either 56 mg (2 devices) or 84 mg (3 devices).

56-mg Dose Kit

NDC #	50458-028-02
How supplied	Two nasal spray devices each containing 28 mg of esketamine
Package Dimensions	4.6 in x 2.5 in x 2.9 in
Package weight	0.18 lbs
Case quantity	18 x 56-mg dose kits
Case dimensions	4.74 in x 15.3 in x 8.1 in
Case weight	4 lbs

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How to prescribe SPRAVATO®

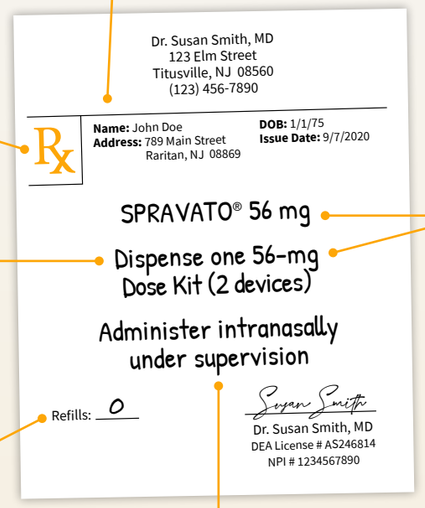
An example prescription for a single 56-mg dose as written for TRD is shown below.

Indicate the REMS-certified treatment center location where SPRAVATO® should be delivered by the REMS-certified pharmacy. This ensures SPRAVATO® is only administered to patients in a medically supervised setting with appropriate monitoring.

For SPRAVATO® prescription protocol, please consult your pharmacy.

Indicate the quantity prescribed in number of devices and dose amount.

Laws governing refills of prescriptions for controlled substances vary by state.



Indicate SPRAVATO® dose.

- **Standard TRD dosing**
  - 56-mg prescription (2 devices per treatment)
- **Standard MDSI dosing**
  - 84-mg prescription (3 devices per treatment)

Each nasal spray device of SPRAVATO® has 2 green dots on it – 1 dot for each nostril. Each dot represents 14 mg of esketamine (the device contains 28 mg of esketamine total). Wait 5 minutes between devices to allow the medication to be fully absorbed.

REMS=Risk Evaluation and Mitigation Strategy.

SPRAVATO® Dose Kits

SPRAVATO® is available in Dose Kits of either 56 mg (2 devices) or 84 mg (3 devices).

84-mg Dose Kit

NDC #	50458-028-03
How supplied	Three nasal spray devices, each containing 28 mg of esketamine
Package dimensions	4.6 in x 2.5 in x 4.1 in
Package weight	0.22 lbs
Case quantity	12 x 84-mg Dose Kits
Case dimensions	4.75 in x 15.3 in x 9.1 in
Case weight	3.6 lbs

NDC=National Drug Code.

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How to prepare for patient self-administration of SPRAVATO®

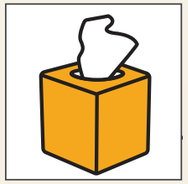
This device is intended for administration by the patient, under the supervision of a healthcare provider.

Read the SPRAVATO® Instructions for Use in full before training and supervising patient.

Storage

- Once SPRAVATO® is delivered for a named-patient or is obtained for a healthcare setting's bulk supply, it must be kept in a secure place per state and federal regulations
- Store at 20° to 25°C (68° to 77°F); excursions permitted from 15° to 30°C (59° to 86°F)
- Product dispensed for a specific, named-patient must be administered within 14 days after receipt by the healthcare setting

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 provider:

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

Healthcare provider:

- **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

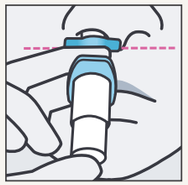
Instruct the patient to:

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

Instruct the patient to:

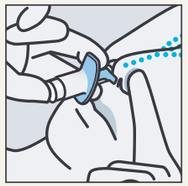
- Recline head at about **45 degrees** during administration to keep medication inside the nose

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**

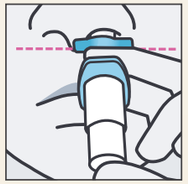


Instruct the patient to:

- 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

Continued on next page

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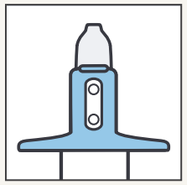
How to prepare for patient self-administration of SPRAVATO® (continued)

STEP 5 - Confirm delivery and rest



Healthcare provider:

- 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

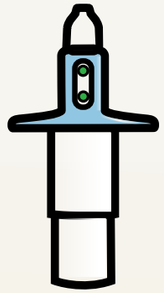
⚠ **Do not** blow nose.

This device is intended for administration by the patient, under the supervision of a healthcare provider.

Read the SPRAVATO® Instructions for Use in full before training and supervising patient.

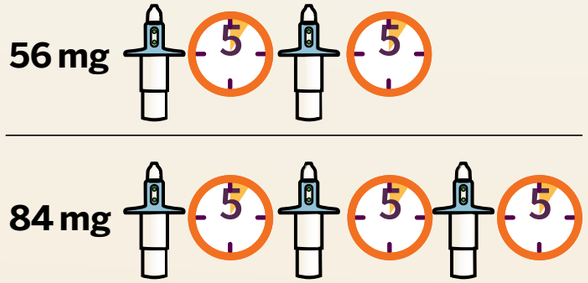
Scan QR code to review the dosing and administration instruction video:

Next device



Healthcare provider: Repeat steps 2-5 for the next device

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



It is important to properly dispose of devices

Used devices:

- Once the SPRAVATO® device has been used by the patient, it should be disposed of as medical waste according to local, state, and federal regulations for controlled substances

Unused devices:

- If the patient hasn't been treated with SPRAVATO® within 14 days of receipt of the patient-labeled product dispensed from a pharmacy, then the product must be disposed of

Partially used devices:

- If the patient received 1 spray and then either the patient or the healthcare provider decided not to continue with treatment, then the partially used product must be disposed of

Turn to the SPRAVATO® Disposal Program to dispose of unused or partially used devices if your healthcare setting is not equipped to do so. Simply call the **SPRAVATO® Disposal Program at 888-912-7348.**

Expired product:

- If the product is past the expiration date printed on the box and blister pack, then coordinate with the pharmacy that sent you the expired product to exchange it for new product

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SPRAVATO® REMS

A Risk Evaluation and Mitigation Strategy (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, dissociation and respiratory depression 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.

What are the REMS requirements?

1. **Healthcare setting certification**

   All healthcare settings must be certified in the REMS in order to receive, dispense, and/or treat patients with SPRAVATO®.

2. **Pharmacy certification**

   All pharmacies must be certified in the REMS in order to receive and dispense SPRAVATO®.

3. **Patient enrollment**

   Patients in an **outpatient** setting must be enrolled in the REMS with their prescriber in order to receive SPRAVATO® treatment.

Healthcare settings type*

All REMS-certified Inpatient and Outpatient Healthcare Settings must have a healthcare provider counsel patients on the safety risk of SPRAVATO® and monitor patients post-dose.

Inpatient healthcare settings

- Covers inpatient units, inpatient pharmacy, and emergency departments
- Before prescribing SPRAVATO® treatment, complete and submit the ***inpatient healthcare setting enrollment form***
- Before starting SPRAVATO® treatment, inpatient settings are not required to enroll the patient in the SPRAVATO® REMS
- During SPRAVATO® treatment, inpatient settings are not required to submit the ***patient monitoring form***. Report all suspected adverse events to the SPRAVATO® REMS

Outpatient healthcare settings

- Covers outpatient medical offices and clinics
- Before prescribing SPRAVATO® treatment, complete and submit the ***outpatient healthcare setting enrollment form***
- Before starting SPRAVATO® treatment, enroll the patient by completing and submitting the ***patient enrollment form*** to the SPRAVATO® REMS
- During SPRAVATO® treatment, submit the ***patient monitoring form*** and report all suspected adverse events to the SPRAVATO® REMS

REMS

*To get started, find more information on how to certify as a healthcare setting and/or pharmacy, and view all REMS requirements and attestations by type of REMS stakeholder, **visit www.SPRAVATOrems.com or call 1-855-382-6022 (Monday – Friday, 8 AM to 8 PM ET)**.

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Important Safety Information (continued)

CONTRAINDICATIONS

SPRAVATO® is contraindicated in patients with:

- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation.
- History of intracerebral hemorrhage.
- Hypersensitivity to esketamine, ketamine, or any of the excipients.

WARNINGS AND PRECAUTIONS

Sedation: SPRAVATO® may cause sedation or loss of consciousness. In some cases, patients may display diminished or less apparent breathing. In clinical trials, 48% to 61% of SPRAVATO®-treated patients developed sedation and 0.3% to 0.4% of SPRAVATO®-treated patients experienced loss of consciousness.

Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Closely monitor for sedation with concomitant use of SPRAVATO® with CNS depressants (e.g., benzodiazepines, opioids, alcohol).

Dissociation: The most common psychological effects of SPRAVATO® were dissociative or perceptual changes (including distortion of time, space and illusions), derealization and depersonalization (61% to 84% of SPRAVATO®-treated patients developed dissociative or perceptual changes). Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering SPRAVATO®; treatment should be initiated only if the benefit outweighs the risk.

Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Respiratory Depression: In postmarketing experience, respiratory depression was observed with the use of SPRAVATO®. In addition, there were rare reports of respiratory arrest.

Because of the risks of respiratory depression, patients must be monitored for changes in respiratory status by a healthcare provider for at least 2 hours (including pulse oximetry) at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Abuse and Misuse: SPRAVATO® contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient's risk for abuse or misuse prior to prescribing and monitor all patients for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Individuals with a history of drug abuse or dependence are at greater risk; therefore, use careful consideration prior to treatment of individuals with a history of substance use disorder and monitor for signs of abuse or dependence.

SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS): SPRAVATO® is available only through a restricted program called the SPRAVATO® REMS because of the risks of serious adverse outcomes from sedation, dissociation, respiratory depression, and abuse and misuse.

Important requirements of the SPRAVATO® REMS include the following:

- Healthcare settings must be certified in the program and ensure that SPRAVATO® is:
  - Only dispensed and administered in healthcare settings.
  - Patients treated in outpatient settings (e.g., medical offices and clinics) must be enrolled in the program.
  - Administered by patients under the direct observation of a healthcare provider and that patients are monitored by a healthcare provider for at least 2 hours after administration of SPRAVATO®.
- Pharmacies must be certified in the REMS and must only dispense SPRAVATO® to healthcare settings that are certified in the program.

Further information, including a list of certified pharmacies, is available at www.SPRAVATOrems.com or 1-855-382-6022.

Please see additional Important Safety Information continued on next page.

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Important Safety Information (continued)

Suicidal Thoughts and Behaviors in Adolescents and Young Adults: In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included adult and pediatric patients, the incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater than in placebo-treated patients. SPRAVATO® is not approved in pediatric (<18 years of age) patients.

There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied.

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing SPRAVATO® and/or the concomitant oral antidepressant, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

Increase in Blood Pressure: SPRAVATO® causes increases in systolic and/or diastolic blood pressure (BP) at all recommended doses. Increases in BP peak approximately 40 minutes after SPRAVATO® administration and last approximately 4 hours.

Approximately 8% to 19% of SPRAVATO®-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours after administration at least once during the first 4 weeks of treatment. A substantial increase in blood pressure could occur after any dose administered even if smaller blood pressure effects were observed with previous administrations. SPRAVATO® is contraindicated in patients for whom an increase in BP or intracranial pressure poses a serious risk (e.g., aneurysmal vascular disease, arteriovenous malformation, history of intracerebral hemorrhage). Before prescribing SPRAVATO®, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO® outweigh its risk.

Assess BP prior to administration of SPRAVATO®. In patients whose BP is elevated prior to SPRAVATO® administration (as a general guide: >140/90 mmHg), a decision to delay SPRAVATO® therapy should take into account the balance of benefit and risk in individual patients.

BP should be monitored for at least 2 hours after SPRAVATO® administration. Measure blood pressure around 40 minutes post-dose and subsequently as clinically warranted until values decline. If BP remains high, promptly seek assistance from practitioners experienced in BP management. Refer patients experiencing symptoms of a hypertensive crisis (e.g., chest pain, shortness of breath) or hypertensive encephalopathy (e.g., sudden severe headache, visual disturbances, seizures, diminished consciousness, or focal neurological deficits) immediately for emergency care.

Closely monitor blood pressure with concomitant use of SPRAVATO® with psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil) or monoamine oxidase inhibitors (MAOIs).

In patients with a history of hypertensive encephalopathy, more intensive monitoring, including more frequent blood pressure and symptom assessment, is warranted because these patients are at increased risk for developing encephalopathy with even small increases in blood pressure.

Cognitive Impairment

Short-Term Cognitive Impairment: In a study in healthy volunteers, a single dose of SPRAVATO® caused cognitive performance decline 40 minutes post-dose. Compared to placebo-treated subjects, SPRAVATO®-treated subjects required a greater effort to complete the cognitive tests at 40 minutes post-dose. Cognitive performance and mental effort were comparable between SPRAVATO® and placebo at 2 hours post-dose. Sleepiness was comparable after 4 hours post-dose.

Long-Term Cognitive Impairment: Long-term cognitive and memory impairment have been reported with repeated ketamine misuse or abuse. No adverse effects of SPRAVATO® nasal spray on cognitive functioning were observed in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO® have not been evaluated beyond one year.

Impaired Ability to Drive and Operate Machinery: Before SPRAVATO® administration, 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 following a restful sleep. Patients will need to arrange transportation home following treatment with SPRAVATO®.

Ulcerative or Interstitial Cystitis: Cases of ulcerative or interstitial cystitis have been reported in individuals with long-term off-label use or misuse/abuse of ketamine. In clinical studies with SPRAVATO® nasal spray, there was a higher rate of lower urinary tract symptoms (pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) in SPRAVATO®-treated patients than in placebo-treated patients. No cases of esketamine-related interstitial cystitis were observed in any of the studies, which involved treatment for up to a year.

Monitor for urinary tract and bladder symptoms during the course of treatment with SPRAVATO® and refer to an appropriate healthcare provider as clinically warranted.

Please see Important Safety Information continued on next page.

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Important Safety Information (continued)

PREGNANCY, EMBRYO-FETAL TOXICITY, AND LACTATION

SPRAVATO® is not recommended during pregnancy. SPRAVATO® may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to SPRAVATO® *in utero*. Advise women of reproductive potential to consider pregnancy planning and prevention.

There are risks to the mother associated with untreated depression in pregnancy. If a woman becomes pregnant while being treated with SPRAVATO®, treatment with SPRAVATO® should be discontinued and the patient should be counseled about the potential risk to the fetus.

Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including SPRAVATO®, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/.

SPRAVATO® is present in human milk. Because of the potential for neurotoxicity, advise patients that breastfeeding is not recommended during treatment with SPRAVATO®.

SELECT USE IN SPECIFIC POPULATIONS

Geriatric Use: No overall differences in the safety profile were observed between patients 65 years of age and older and patients younger than 65 years of age. At the end of a 4-week, randomized, double-blind study, there was no statistically significant difference between groups on the primary efficacy endpoint.

Hepatic Impairment: SPRAVATO®-treated patients with moderate hepatic impairment may need to be monitored for adverse reactions for a longer period of time.

SPRAVATO® has not been studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended.

ADVERSE REACTIONS

The most common adverse reactions with SPRAVATO® plus oral antidepressant (incidence ≥5% and at least twice that of placebo nasal spray plus oral antidepressant) were:

TRD: dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk.

Treatment of depressive symptoms in adults with MDD with acute suicidal ideation or behavior: dissociation, dizziness, sedation, blood pressure increased, hypoesthesia, vomiting, euphoric mood, and vertigo.

Please see Indications and Important Safety Information on pages 7 through 9. Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

cp-170362v5

Spravato® (esketamine) CIII
28 mg nasal spray

Once a decision has been made to prescribe SPRAVATO®

Spravato withMe can help navigate access and affordability processes efficiently so you can focus on your patients

Learn how to minimize delays in the access process with the help of SPRAVATO withMe Case Managers. They will provide you with educational support to help your patients navigate the process and get them started on treatment quickly.

- Benefits investigations for medical and pharmacy coverage
- A progress tracker that provides visibility to your patients' access status
- Confirmation on which pharmacies accept your patients' insurance
- Real-time notifications via a custom portal view with updates on your individual patients and accounts
- Prior authorization and appeals support
- Coding and reimbursement support
- Patient affordability support

SPRAVATO withMe Care Navigators — dedicated support for your patients at every step of their treatment journey. Your adult patients prescribed SPRAVATO®, regardless of their insurance, will have access to SPRAVATO withMe Care Navigators, mental health professionals* who can offer supplemental one-to-one support.

*Care Navigators do not provide medical advice.

SPRAVATO withMe is limited to education for patients about SPRAVATO®, its administration, and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, or provide case management services.

Information about your patients' insurance coverage, cost support options, and treatment support is given by service providers for SPRAVATO withMe. The information you get does not require you or your patient to use any Janssen product. Because the information we give you comes from outside sources, SPRAVATO withMe cannot promise the information will be complete. SPRAVATO withMe cost support is not for patients in the Johnson & Johnson Patient Assistance Foundation.

Please see Indications and Important Safety Information on pages 7 through 9. Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

Reference:

1. SPRAVATO® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.

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