

When oral ADs have your patients going in circles,

SPRAVATO® may help them on the path to being themselves again.

SPRAVATO® is the only FDA-approved treatment used as monotherapy or in conjunction with an oral antidepressant for adults with treatment-resistant depression (MDD with inadequate response to at least 2 oral antidepressants of adequate dose and duration)¹

After inadequate response to at least 2 oral ADs for MDD, the same treatment modality may not be enough

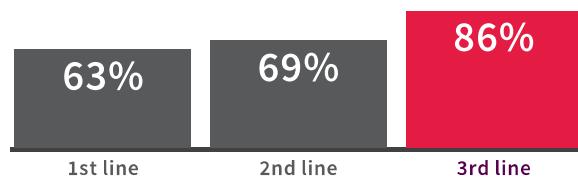
- Oral ADs don't work for everyone
- Patients cycling through current oral medications may wait 4-6 weeks for potential relief²

ADs=antidepressants; MDD=major depressive disorder;
STAR*D=Sequenced Treatment Alternatives to Relieve Depression.

*Remission was defined as a score of ≤ 5 on the Quick Inventory of Depressive Symptomatology—Self-report (QIDS-SR₁₆).³

Based on the STAR*D trial:

When patients try their third line of treatment, 86% do not achieve remission^{3*}



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).

Indications:

SPRAVATO® (esketamine) CIII Nasal Spray is indicated for the treatment of:

- Treatment-resistant depression (TRD) in adults as monotherapy or in conjunction with an oral antidepressant.
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant.

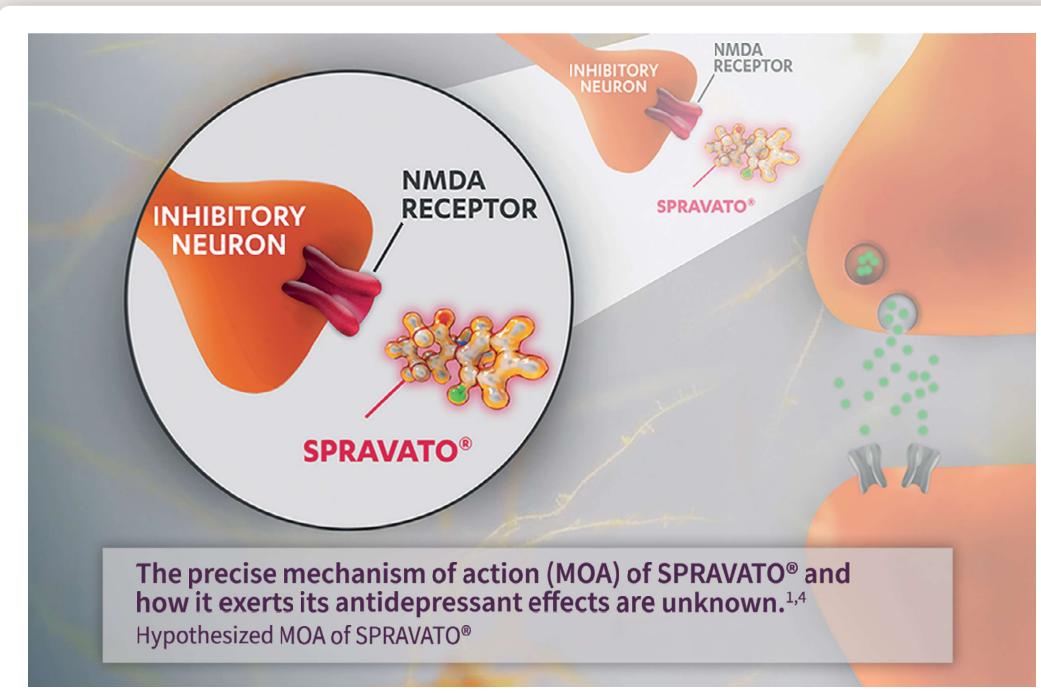
Limitations of Use:

- 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.

Please see additional Important Safety Information throughout this brochure, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

SPRAVATO® is different because it acts on the glutamate pathway⁴

SPRAVATO® targets glutamate, the most abundant excitatory neurotransmitter in the brain⁵



MDD=major depressive disorder; NMDA=N-methyl-D-aspartate.

SPRAVATO® is a non-competitive NMDA receptor antagonist, leading to increased glutamate release in the synapse.^{1,4}

SPRAVATO® is the ONLY agent with glutamatergic activity indicated to treat adults with MDD with inadequate response to at least 2 oral antidepressants.^{1,4,6}

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](http://SPRAVATOREMS.com) or 1-855-382-6022.

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.

Please see additional Important Safety Information throughout this brochure, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

Join the community of SPRAVATO® treaters!

Key considerations to get started as a treater:

1

Evaluate your space and identify your staff

Many practices already have what they need to get started.



[Learn more >](#)

2

Verify patient insurance to determine how to acquire SPRAVATO®

SPRAVATO® treatment is in-office and includes both drug administration and patient monitoring.



[Learn more >](#)

3

Review access and support resources

Resources and specialists are available to support your practice and patients.



[Learn more >](#)

SPRAVATO® practices need to complete a one-time enrollment in a REMS program that supports the safe and appropriate use of SPRAVATO®

REMS=Risk Evaluation and Mitigation Strategy.

Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

Suicidal Thoughts and Behaviors in Adolescents and Young Adults: (continued)

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 3% 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. In 1-year and 3-year, long-term, open-label clinical trials in adults, the effect of SPRAVATO® on cognitive functioning remained stable over time as evaluated by the Cogstate computerized battery and Hopkins Verbal Learning Test-Revised.

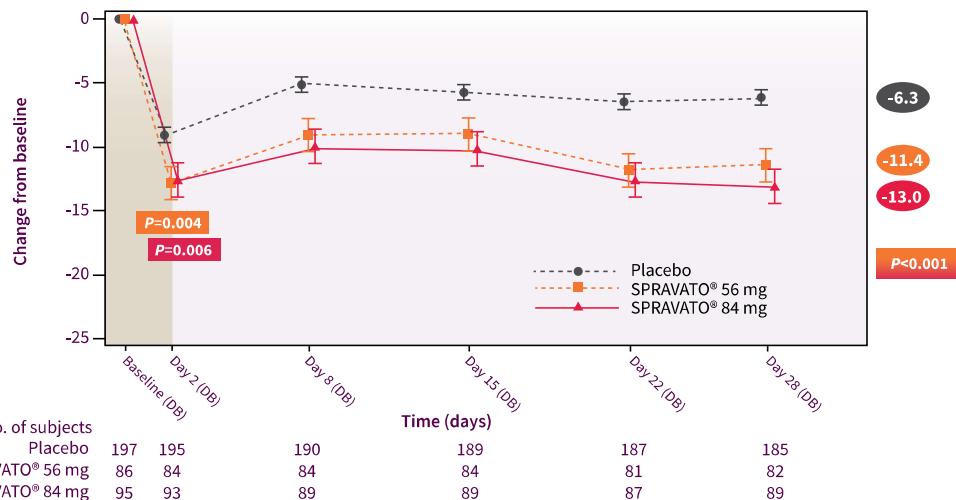
Impaired Ability to Drive and Operate Machinery: Before SPRAVATO® administration, instruct patients not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination, such as driving a motor vehicle or operating machinery, until the next day following a restful sleep. Patients will need to arrange transportation home following treatment with SPRAVATO®.

Please see additional Important Safety Information throughout this brochure, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

Reduction in the burden of depressive symptoms in as early as 1 day^{1,7}

SPRAVATO® demonstrated rapid and superior improvement in depressive symptoms at 4 weeks (primary endpoint) and at 24 hours (key secondary endpoint) vs placebo^{1,7}

Least-Squares Mean Change from Baseline in MADRS Total Score Over Time in Patients with TRD in Study 3 (Full Analysis Set)⁸



DB=double blind; LS=least squares; MADRS=Montgomery-Åsberg Depression Rating Scale; TRD=treatment-resistant depression.

Demographics and baseline characteristics

Patients had a mean age of 45.4 years; 61.1% female; 86.8% white; 6.6% Black⁸

Double-blind, placebo-controlled, multicenter, phase 4 study^{1,7}
Adult patients with TRD were randomized to receive SPRAVATO® 56 mg (n=86), SPRAVATO® 84 mg (n=95), or placebo (n=197)

Primary endpoint

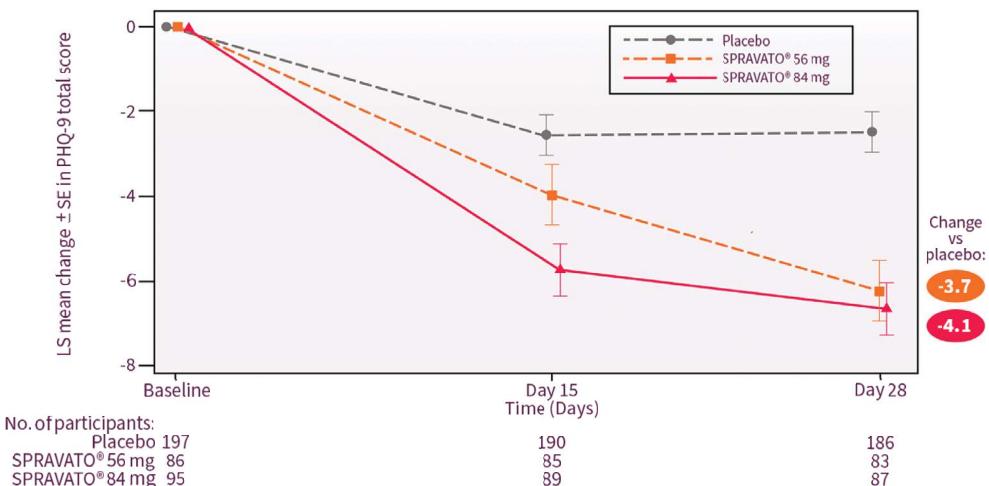
- Mean MADRS total score decreased from baseline to Day 28, showing statistically significant improvement with individual doses of SPRAVATO® vs placebo (2-sided $P<0.001$). The LS mean difference between SPRAVATO® and placebo was -5.1 (95% CI, -7.9 to -2.3) for 56 mg and -6.8 (95% CI, -9.5 to -4.1) for 84 mg⁸

Key Secondary endpoint

- Significantly greater improvement was noted in the SPRAVATO® 56-mg group (2-sided $P=0.004$) and SPRAVATO® 84-mg group (2-sided $P=0.006$) vs placebo. On day 2, the LS mean difference between SPRAVATO® and placebo was -3.8 (95% CI, -6.3 to -1.2) for 56 mg and -3.4 (95% CI, -5.9 to -1.0) for 84 mg⁸

Other Secondary Endpoint (PHQ-9)

Least-Squares Mean Change from Baseline in PHQ-9 Total Score Over Time in Study 3 (Full Analysis Set)⁹



DB=double blind; LS=least squares; MMRM=mixed model for repeated measures; PHQ-9=Patient Health Questionnaire-9; SE=standard error.

Mean PHQ-9 total score decreased from baseline to Day 28⁷

- MMRM analysis: Difference of LS means (SE) of PHQ-9 scores for SPRAVATO® 56 mg vs placebo was -3.7 (0.80) (95% CI, -5.28 to -2.15), and for SPRAVATO® 84 mg vs placebo was -4.1 (0.77) (95% CI, -5.65 to -2.61)⁷

SPRAVATO® is the only FDA-approved medication for adults with TRD with 5-year safety and efficacy data.

See more details at SpravatoHCP.com or scan the QR code.*



*Data rates may apply.

Please see additional Important Safety Information throughout this brochure, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

SPRAVATO® offers your patients an established safety profile¹⁰

Low incidence of weight gain and sexual dysfunction, and no safety signal identified for tardive dyskinesia^{1*}

- Weight gain and sexual dysfunction were not observed in short-term SPRAVATO® trials at a rate $\geq 2\%$ and greater than placebo¹

Most common adverse reactions (ARs) ¹ (incidence $\geq 5\%$ and at least twice that of placebo nasal spray)	SPRAVATO® 56 mg + 84 mg (N=226)	Placebo (N=250)
Dissociation [†]	63 (28%)	11 (4%)
Nausea	56 (25%)	21 (8%)
Dizziness [†]	50 (22%)	18 (7%)
Headache	43 (19%)	22 (9%)
Anxiety [†]	22 (10%)	8 (3%)
Feeling drunk	16 (7%)	2 (<1%)
Vomiting	15 (7%)	1 (<1%)
Sedation [†]	13 (6%)	4 (2%)
Blood pressure increased [†]	11 (5%)	4 (2%)

¹The following terms were combined:

Dissociation includes: delusional perception; depersonalization/derealization disorder; derealization; diplopia; dissociation; dysesthesia; feeling cold; feeling hot; feeling of body temperature change; hallucination; hallucination, auditory; hallucination, visual; hyperacusis; illusion; ocular discomfort; oral dysesthesia; paresthesia; paresthesia oral; pharyngeal paresthesia; photophobia; time perception altered; tinnitus; vision blurred; visual impairment. **Dizziness** includes: dizziness; dizziness exertional; dizziness postural; procedural dizziness. **Sedation** includes: altered state of consciousness; hypersomnia; sedation; somnolence. **Vertigo** includes: vertigo; vertigo positional. **Hypoesthesia** includes: hypoesthesia; hypoesthesia oral, hypoesthesia teeth, pharyngeal hypoesthesia. **Anxiety** includes: agitation; anticipatory anxiety; anxiety; fear; feeling jittery; irritability; nervousness; panic attack; tension. **Lethargy** includes: fatigue; lethargy. **Blood pressure increased** includes: blood pressure diastolic increased; blood pressure increased; blood pressure systolic increased; hypertension.

Of the treatment-emergent adverse events (TEAEs) that occurred on the day of dosing in the monotherapy study, the majority (~90%) resolved on the same day¹¹

- The majority of dissociation (99.6%), blood pressure increased (100%), and sedation (93.5%) TEAEs occurred and resolved on the same day¹¹

2.7% of patients taking SPRAVATO® in the monotherapy study discontinued treatment due to adverse events vs 1% of patients who received placebo nasal spray¹¹

*No new safety signals have emerged as of June 2025.

Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

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/research/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

TRD: The most commonly observed adverse reactions in patients treated with SPRAVATO® plus oral antidepressant (incidence $\geq 5\%$ and at least twice that of placebo nasal spray plus oral antidepressant) were 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: The most commonly observed adverse reactions in patients treated with SPRAVATO® plus oral antidepressant (incidence $\geq 5\%$ and at least twice that of placebo nasal spray plus oral antidepressant) were dissociation, dizziness, sedation, blood pressure increased, hypoesthesia, vomiting, euphoric mood, and vertigo.

The most common adverse reactions with SPRAVATO® TRD monotherapy ($\geq 5\%$ and at least twice that of placebo nasal spray) were dissociation, nausea, dizziness, headache, anxiety, vomiting, feeling drunk, blood pressure increased, and sedation.

Please see pocketed full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

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Please see additional Important Safety Information throughout this brochure, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

Once a decision has been made to prescribe SPRAVATO®.

SPRAVATO® has broad coverage.

Access across many local and regional plans



9 in 10
commercially insured
patients are covered^{12*}

SPRAVATO® is also covered under Medicare and Medicaid[†]

Spravato with Me

Discover a suite of access, affordability, and treatment support resources for your patients.

Program does not cover the cost of treatment observation.
Non-Transferable. Patient must submit a valid prescription.

Spravato with Me



Medical Claims
Payer ID: 56155
GROUP: 00003636
Member: 0000000000

Pharmacy Claims
BIN: 610020
GROUP: 99994002
Member: 000000000000

Physicians: For medical claims, patient may direct payment to you or elect to receive a mailed rebate check. Call 855-872-1776 to understand payment selection made by patient.

Please read the full Prescribing Information, including Boxed WARNINGS and Medication Guide for SPRAVATO®, and discuss any questions you have with your doctor.

PROGRAM REQUIREMENTS APPLY.



Explore SPRAVATO withMe

See more details at
SpravatoHCP.com
or scan the QR code.[‡]



[‡]Data rates may apply.

*TRD data only. Managed Markets Insights and Technology, LLC™, a trademark of MMIT, as of September 2024. Collected as of September 2024 and may change. This percentage may not represent 100% of formulary lives due to data limitations.

[†]Coverage relevant to your patients may vary by payer and may change over time. Contact the plan for the most current policies.

For adults with MDD who have had inadequate response to at least 2 oral antidepressants

SPRAVATO® can deliver rapid relief, established safety, and durability over time—alone or in combination with an oral antidepressant^{1,7,13,14}



RAPID RELIEF:

24-hour and 28-day data¹



ESTABLISHED SAFETY PROFILE^{1,7}



DURABILITY OVER TIME:

Demonstrated through MADRS
scores and remission data^{1,13,14}



MORE FREEDOM:

Flexibility in treatment approach,
dosing, and post-induction
frequency¹



MADRS=Montgomery-Åsberg Depression Rating Scale;
MDD=major depressive disorder.

View Real Patient Videos

See the stories at
Spravato.com
or scan the QR code.*



^{*}Data rates may apply.

References:

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2. Gelenberg AJ, Freeman MP, Markowitz JC, et al. *Practice Guideline for the Treatment of Patients with Major Depressive Disorder*. 3rd ed. American Psychiatric Association; 2010. Accessed August 13, 2025. https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd-1410197717630.pdf
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7. Janik A, Qiu X, Lane R, et al. Efficacy and safety of esketamine nasal spray as monotherapy in adults with treatment-resistant depression: a randomized, double-blind, placebo-controlled study. Poster presented at: American College of Neuropsychopharmacology (ACNP) Annual Congress; December 8-11, 2024; Phoenix, AZ.
8. Janik A, Qiu X, Lane R, et al. Efficacy and safety of esketamine nasal spray as monotherapy in adults with treatment-resistant depression: a randomized, double-blind, placebo-controlled study. Poster presented at: European College of Neuropsychopharmacology (ECNP) Annual Congress; September 21-24, 2024; Milan, Italy.
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12. Data on file. SD-217397. Janssen Pharmaceuticals, Inc.
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14. Zaki N, Fu DJ, Daly E, et al. Long-term safety of esketamine nasal spray in adults with treatment-resistant depression: a subgroup analysis of the ongoing SUSTAIN-3 study. Safety poster presented at: Neuroscience Education Institute (NEI) Congress; November 4-7, 2021; Colorado Springs, CO.

