

# Rep-Provided SPRAVATO® Resources



Janssen has several SPRAVATO® resources that may be helpful to you when communicating with patients or your referral community. **You may request the following supplementary resources from your SPRAVATO® representative:**

## Customizable Patient Brochure

**Starting SPRAVATO®**

### What to Expect When Starting Treatment

Any is a real patient with treatment-resistant depression and has been compensated for her time by Janssen Pharmaceuticals, Inc.

**What is SPRAVATO® (esketamine) CII nasal spray?**

SPRAVATO® is a prescription medicine, used along with an antidepressant taken by mouth to treat:

- Adults with treatment-resistant depression (TRD)
- Depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions

SPRAVATO® is not for use as a medicine to prevent or relieve pain (anesthetic). It is not known if SPRAVATO® is safe or effective as an anesthetic medicine.

It is not known if SPRAVATO® is safe and effective for use in preventing suicide or in reducing suicidal thoughts or actions. SPRAVATO® is not for use in place of hospitalization if your healthcare provider determines that hospitalization is needed, even if improvement is experienced after the first dose of SPRAVATO®.

It is not known if SPRAVATO® is safe and effective in children.

Please see important safety information throughout this brochure. Please see accompanying full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO® and discuss any questions you may have with your healthcare provider.

A patient brochure that treatment centers may customize with reps by selecting educational modules. Treatment centers can also personalize the brochure with their name, location, and contact information.

**IMPORTANT SAFETY INFORMATION (continued)**

**What is the most important information I should know about SPRAVATO®?**

SPRAVATO® may cause serious side effects, including:

- **Sedation and dissociation.** SPRAVATO® may cause sedation (feeling, dizziness, feeling unsteady, trouble in being alert), dissociation (feeling unreal, loss of touch, feeling, loss of time), or loss of consciousness.
- **High blood pressure.** SPRAVATO® may cause high blood pressure. You may feel your heart racing or your blood pressure may rise. Your healthcare provider will monitor your blood pressure before and after each treatment.
- **Changes in heart rate.** SPRAVATO® may cause changes in heart rate. You may feel your heart racing or your heart rate may rise. Your healthcare provider will monitor your heart rate before and after each treatment.
- **Changes in blood pressure.** SPRAVATO® may cause changes in blood pressure. You may feel your blood pressure rising or your blood pressure may rise. Your healthcare provider will monitor your blood pressure before and after each treatment.
- **Changes in heart rate.** SPRAVATO® may cause changes in heart rate. You may feel your heart racing or your heart rate may rise. Your healthcare provider will monitor your heart rate before and after each treatment.

**Is it time for a different approach to your treatment?**

If you've taken two or more oral antidepressants (ADs) and still experience symptoms of depression, you might have treatment-resistant depression (TRD).

When people have TRD, the same type of treatment might not be the best option.

**In a study of treatments for people who could have TRD:**

- One in five people did not experience a benefit (a reduction of their depressive symptoms) when taking oral ADs alone.
- This chance to see a benefit dropped to 14% once they started treatment with a third oral AD.

**Percentage of people who saw results after treatment:**

- 37% First oral AD
- 31% Second oral AD
- 14% Third oral AD

**SPRAVATO® offers a different approach**

SPRAVATO® is the only oral and nasal treatment option for people who take two or more oral antidepressants and still experience symptoms of TRD.

SPRAVATO® is a medicine that works differently than the medicines you've taken before. It works by blocking a part of the brain that is involved in mood. The effect may be different from other medicines.

**Frequently Asked Questions About SPRAVATO®**

How has SPRAVATO® helped patients with TRD? Scan the QR code below to watch real patients with TRD share their stories.

**Has the effect of treatment with SPRAVATO® been studied over time?**

There was a SPRAVATO® long-term maintenance-of-effect trial. This study was designed for patients in remission to see if the effect of treatment was maintained over time.

- The trial compared patients who stayed on SPRAVATO® and oral antidepressant to placebo and oral antidepressant long term.
- Patients who stayed on SPRAVATO® were less likely to experience a return of depressive symptoms (known as relapse) compared to those who stopped therapy.

## SPRAVATO® Brand Presentation

**If oral ADs have your patients going in circles**

**Help transform their path by adding Spravato (esketamine) CII**

See inside for SPRAVATO® clinical data, including data from a subanalysis of the first head-to-head study of SPRAVATO® versus an oral antidepressant.

**AD=antidepressant**

**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 (1, 1.5, 2, 3, 3.5).
- 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 (1, 4).
- SPRAVATO® is only available through a restricted program called the SPRAVATO® REMS (1, 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 (1, 6).

**Indications:**

SPRAVATO® (esketamine) CII nasal spray, in conjunction with an oral antidepressant, is indicated for the treatment of:

- Treatment-resistant depression (TRD) in adults.
- Depressive symptoms in adults with major depressive disorder (MDD) with 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 their 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.

A presentation for treatment center staff to use with potential referring healthcare providers (HCPs). The presentation includes information on SPRAVATO® efficacy, safety, and dosing; the SPRAVATO® REMS; and SPRAVATO withMe access support.

**Spravato (esketamine) CII**

- A different treatment approach
- FDA approved for over 4 years
- Nasal spray formulation

**Indications:**

SPRAVATO® (esketamine) CII 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 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 their 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.

**Important Safety Information (continued)**

**CONTRAINDICATIONS**

SPRAVATO® is contraindicated in patients with:

- Any known acute or chronic (including thoracic and abdominal aortic, intracranial and peripheral arterial) vascular or cardiovascular 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 dissociation or loss of awareness (including in clinical trials, 48% to 51% 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.

(continued on page 4)

**The first head-to-head subanalysis of SPRAVATO® versus an oral antidepressant (continued)**

Patients with treatment-resistant depression (TRD) on SPRAVATO® were 65% more likely to achieve remission at Week 8 compared to QLE XR†.

**SPRAVATO® vs QLE XR Primary Endpoint: Rates of Remission at Week 8†**

Treatment	Remission Rate (%)
SPRAVATO® + oral AD	26.6%
QLE XR + oral AD	16.1%

Remission was defined as MADRS total score ≤10. Remission was defined as MADRS ≤10 in SPRAVATO®-treated patients and MADRS ≤10 in QLE XR-treated patients.

**Important Safety Information (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

**Increase in Blood Pressure:** (continued)

Closely monitor blood pressure with concurrent use of SPRAVATO® with psychostimulants (e.g., amphetamine, methylphenidate, modafinil, amantadine) or monoamine oxidase inhibitors (MAOIs).

**Cognitive Impairment:** (continued)

In a study in healthy volunteers, a single dose of SPRAVATO® caused cognitive performance decline 40 minutes post-dose. Compared to placebo-treated subjects,

REMS=Risk Evaluation and Mitigation Strategy.

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

