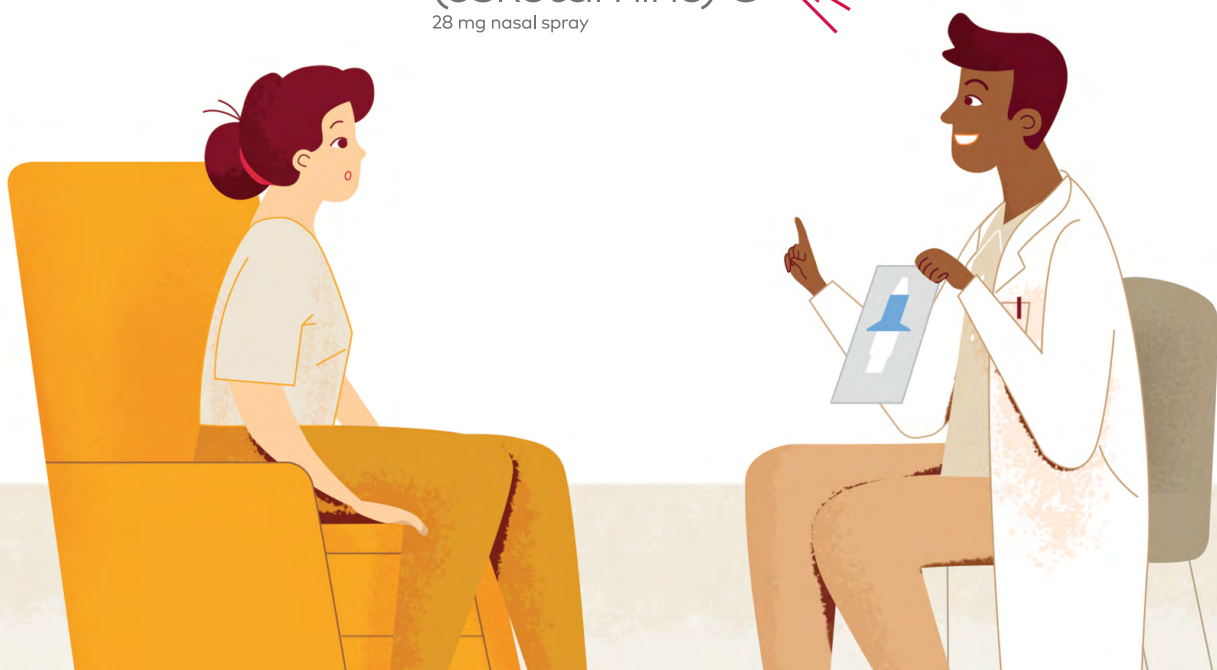


Conversation Guide



What is SPRAVATO®?

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.

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information](#), including [Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

IMPORTANT SAFETY INFORMATION

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

SPRAVATO® can cause serious side effects, including:

- **Sedation and dissociation.** SPRAVATO® may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation).
 - Tell your healthcare provider right away if you feel like you cannot stay awake or if you feel like you are going to pass out.
 - Your healthcare provider must monitor you for serious side effects for at least 2 hours after taking SPRAVATO®. Your healthcare provider will decide when you are ready to leave the healthcare setting.
- **Abuse and misuse.** There is a risk for abuse and physical and psychological dependence with SPRAVATO® treatment. Your healthcare provider should check you for signs of abuse and dependence before and during treatment with SPRAVATO®.
 - Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
 - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- **SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS).** Because of the risks for sedation, dissociation, and abuse and misuse, SPRAVATO® is only available through a restricted program called the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS) Program. SPRAVATO® can only be administered at healthcare settings certified in the SPRAVATO® REMS Program. Patients treated in outpatient healthcare settings (e.g., medical offices and clinics) must be enrolled in the program.
- **Increased risk of suicidal thoughts and actions.** Antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed.**
SPRAVATO® is not for use in children
 - Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a higher risk of having suicidal thoughts or actions. These include people who have (or have a family history of) depression or a history of suicidal thoughts or actions.
- **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
 - Pay close attention to any changes, especially sudden changes, in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
 - Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.
- **Tell your healthcare provider right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:**
 - suicide attempts
 - thoughts about suicide or dying
 - worsening depression
 - other unusual changes in behavior or mood

- ▶ Click or tap to see additional [Important Safety Information](#)
- ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
- ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

How to use this guide



This guide is intended to help you discuss your treatment goals with your healthcare provider and decide together if SPRAVATO® nasal spray is an appropriate treatment option for you.

Your healthcare provider is here to answer your questions about treatment, support, safety, and helping you move toward your treatment goals.

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information](#), including [Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

Click below to learn more about

Treatment-Resistant
Depression



Click below to learn more about

Depressive Symptoms in Adults
with Major Depressive Disorder
with Suicidal Thoughts or Actions



-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

Spravato®
(esketamine) 
28 mg nasal spray 

Table of contents

Click below to go
to each section



About SPRAVATO[®]



What is SPRAVATO[®]?



Considerations before taking SPRAVATO[®]



How is SPRAVATO[®] different?



Your first treatment center visit



Side effects



SPRAVATO[®] dosing



How often will I receive treatment?



What should I expect on treatment days?



Patient stories



Cost support



Getting started on SPRAVATO[®]



Important Safety Information



-
- ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO[®]](#)

Discuss any questions you may have with your healthcare provider.



About SPRAVATO®

Treatment-resistant depression



-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



**Click here for
cost support**

Spravato®
(esketamine) 
28 mg nasal spray



What is SPRAVATO®?

Treatment-resistant depression

- SPRAVATO® is the first FDA-approved nasal spray medication, taken with an oral antidepressant, for treatment-resistant depression in adults
- If you've tried two or more antidepressants* without sufficient relief, talk to your healthcare provider to see if you may have treatment-resistant depression

*Of adequate dose and duration in your current episode.

- SPRAVATO® is **not** for use:
 - As a medicine to prevent or relieve pain (anesthetic)
 - To prevent suicide, reduce suicidal thoughts or actions, or replace hospitalization, even if there is improvement after the first dose
- SPRAVATO® is **not** for use in children

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support



28 mg nasal spray



Things to discuss with your healthcare provider before taking SPRAVATO®

Do NOT take SPRAVATO® if any of the following applies to you:

- You have a blood vessel disease (aneurysm)
- You have an abnormal connection between your blood vessels (arteriovenous malformation)
- You have a history of bleeding in the brain
- You are allergic to esketamine or a similar medicine called ketamine used for anesthesia or any of the other ingredients in SPRAVATO®

Be sure to tell your healthcare provider if:

- You have heart, brain or liver problems
- You have ever had psychosis (see, feel, or hear things that are not there, or believe in things that are not true)
- You are pregnant or breastfeeding. You should not take SPRAVATO® if you are pregnant or breastfeeding
- You are taking prescription or over-the-counter medicines, including vitamins or herbal supplements

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



**Click here for
cost support**





How is SPRAVATO® different?

How does SPRAVATO® work?

SPRAVATO® targets the N-methyl-D-aspartate (NMDA) receptor and is believed to work differently than currently available oral antidepressants. The exact way that SPRAVATO® works is unknown.



-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray



Your first treatment center visit

Your healthcare provider will continue to be involved with your care during SPRAVATO® treatment and will be available to answer questions or address concerns as you undergo treatment. Your first visit to the certified SPRAVATO® treatment center will be a consultation.

The treatment center will:

- Receive your medical information from your healthcare provider
- Conduct its own assessment to determine if SPRAVATO® may be right for you
- Verify your insurance information as part of the eligibility confirmation

If SPRAVATO® is recommended, the treatment center will build a treatment plan with you and enroll you in the SPRAVATO® REMS Program.

Remember: Make sure to follow up with your healthcare provider regarding your treatment plan.

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray

What should I know about the side effects of SPRAVATO®?

SPRAVATO® may cause serious side effects including:

- Feeling sleepy (sedation)
- Feeling disconnected from yourself, your thoughts, feelings and things around you (dissociation)
- Abuse and misuse
- Increased risk of suicidal thoughts and behavior
- Temporary increase in blood pressure that may last about four hours after a dose
- Problems with thinking clearly
- Bladder problems

This is a summary of serious side effects for SPRAVATO®. Read the complete information about these serious side effects [here](#).

Most common side effects:

- Dissociation
- Dizziness
- Nausea
- Feeling sleepy
- Spinning sensation
- Numbness
- Feeling anxious
- Lack of energy
- Increased blood pressure
- Vomiting
- Feeling drunk
- Feeling very happy or excited

If these common side effects occur, they usually happen right after taking SPRAVATO® and go away the same day.

These are not all the possible side effects of SPRAVATO®. See SPRAVATO® [Medication Guide](#) for additional safety information.



SPRAVATO® is only available at a REMS-certified SPRAVATO® treatment center under the supervision of a healthcare provider.

- ▶ Click or tap to see [Important Safety Information](#)
- ▶ Click or tap for full [Prescribing Information](#), including [Boxed WARNINGS](#)
- ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for cost support

Spravato®
(esketamine) 
28 mg nasal spray 

SPRAVATO® dosing

Adults with treatment-resistant depression



-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



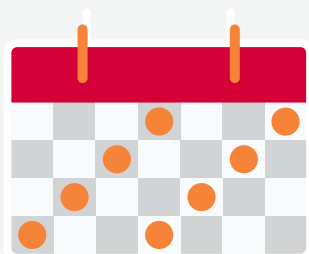
**Click here for
cost support**

Spravato®
(esketamine) 
28 mg nasal spray



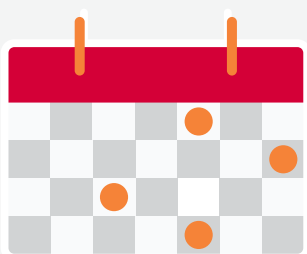
How often will I receive treatment?

Treatment-resistant depression



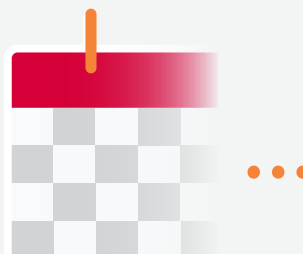
Weeks 1–4

Twice weekly



Weeks 5–8

Once weekly



Weeks 9+

Once every
week or two

You and your healthcare provider will decide how long you stay on SPRAVATO® based on:

- How you respond to it
- How stable your response is

After eight weeks of treatment:

- Your healthcare provider will determine the dosing frequency based on how you feel

SPRAVATO® is taken with an oral antidepressant.

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray

What should I expect on treatment days?



You will not be able to drive, so plan transportation for treatment days.



You will administer the nasal spray yourself under the supervision of a healthcare provider.



You'll be monitored for side effects for at least two hours.



Your healthcare provider will tell you when it's okay to leave.



Do not drive, operate machinery or do anything where you need to be completely alert until the day after a treatment session, following a restful sleep.

Get help paying for SPRAVATO®



- ▶ Click or tap to see [Important Safety Information](#)
- ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
- ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



**Click here for
cost support**

Spravato®
(esketamine) 
28 mg nasal spray



Patient stories

What a real patient with treatment-resistant depression is saying about SPRAVATO®



Nicole P., 23 – St. Peters, MO
Real patient with
treatment-resistant depression

See Nicole's full story at
SPRAVATO.com/TRD/patient-stories

Individual results may vary. Testimonial shared in 2018. Nicole is a real patient with treatment-resistant depression and has been compensated for her time by Janssen Pharmaceuticals, Inc.

Get help paying for SPRAVATO®



-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



**Click here for
cost support**

Spravato®
(esketamine) 
28 mg nasal spray 

Table of contents

Click below to go
to each section



About SPRAVATO[®]



What is SPRAVATO[®]?



Considerations before taking SPRAVATO[®]



How is SPRAVATO[®] different?



Side effects



SPRAVATO[®] dosing



How often will I receive treatment?



What should I expect on treatment days?



Cost support



Getting started on SPRAVATO[®]



Important Safety Information



▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)

▶ Click or tap for the [Medication Guide for SPRAVATO[®]](#)

Discuss any questions you may have with your healthcare provider.



About SPRAVATO®

Depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions



-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray

What is SPRAVATO®?



Depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions

- SPRAVATO® is the first FDA-approved nasal spray medication, taken with an oral antidepressant, that treats depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions
- SPRAVATO® is **not** for use:
 - As a medicine to prevent or relieve pain (anesthetic)
 - To prevent suicide, reduce suicidal thoughts or actions, or replace hospitalization, even if there is improvement after the first dose
- SPRAVATO® is **not** for use in children

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray



Things to discuss with your doctor before taking SPRAVATO®

Do NOT take SPRAVATO® if any of the following applies to you:

- You have a blood vessel disease (aneurysm)
- You have an abnormal connection between your blood vessels (arteriovenous malformation)
- You have a history of bleeding in the brain
- You are allergic to esketamine or a similar medicine called ketamine used for anesthesia or any of the other ingredients in SPRAVATO®

Be sure to tell your healthcare provider if:

- You have heart, brain or liver problems
- You have ever had psychosis (see, feel, or hear things that are not there, or believe in things that are not true)
- You are pregnant or breastfeeding. You should not take SPRAVATO® if you are pregnant or breastfeeding
- You are taking prescription or over-the-counter medicines, including vitamins or herbal supplements

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



**Click here for
cost support**

How is SPRAVATO® different?

How does SPRAVATO® work?

SPRAVATO® targets the N-methyl-D-aspartate (NMDA) receptor and is believed to work differently than currently available oral antidepressants. The exact way that SPRAVATO® works is unknown.



- ▶ Click or tap to see [Important Safety Information](#)
- ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
- ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray

What should I know about the side effects of SPRAVATO®?

SPRAVATO® may cause serious side effects including:

- Feeling sleepy (sedation)
- Feeling disconnected from yourself, your thoughts, feelings and things around you (dissociation)
- Abuse and misuse
- Increased risk of suicidal thoughts and behavior
- Temporary increase in blood pressure that may last about four hours after a dose
- Problems with thinking clearly
- Bladder problems

This is a summary of serious side effects for SPRAVATO®. Read the complete information about these serious side effects [here](#).

Most common side effects:

- Dissociation
- Dizziness
- Nausea
- Feeling sleepy
- Spinning sensation
- Numbness
- Feeling anxious
- Lack of energy
- Increased blood pressure
- Vomiting
- Feeling drunk
- Feeling very happy or excited

If these common side effects occur, they usually happen right after taking SPRAVATO® and go away the same day.

These are not all the possible side effects of SPRAVATO®. See SPRAVATO® [Medication Guide](#) for additional safety information.



SPRAVATO® is only available at a REMS-certified SPRAVATO® treatment center under the supervision of a healthcare provider.

- ▶ Click or tap to see [Important Safety Information](#)
- ▶ Click or tap for full [Prescribing Information](#), including [Boxed WARNINGS](#)
- ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for cost support

Spravato®
(esketamine) 
28 mg nasal spray



SPRAVATO® dosing

Depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions



-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information](#), including [Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

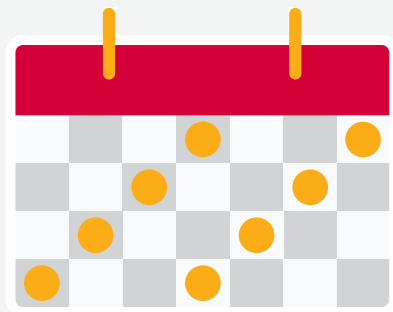


Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray

How often will I receive treatment?

Depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions



Four Weeks

Twice weekly

- After four weeks, you and your healthcare provider will determine if continued treatment with SPRAVATO® is necessary. Treatment beyond four weeks has not been studied

SPRAVATO® is taken with an oral antidepressant.

- ▶ Click or tap to see [Important Safety Information](#)
- ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
- ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray

What should I expect on treatment days?



You will not be able to drive, so plan transportation for treatment days.



You will administer the nasal spray yourself under the supervision of a healthcare provider.



You'll be monitored for side effects for at least two hours.



Your healthcare provider will tell you when it's okay to leave.



Do not drive, operate machinery or do anything where you need to be completely alert until the day after a treatment session, following a restful sleep.

Get help paying for SPRAVATO®



- ▶ Click or tap to see [Important Safety Information](#)
- ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
- ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



**Click here for
cost support**

Spravato®
(esketamine) 
28 mg nasal spray

Where can I get support for SPRAVATO®?



Get support for SPRAVATO®

Once you and your healthcare provider have decided that SPRAVATO® is right for you, Janssen CarePath will help you find the resources you may need to help get started and stay on track.



Paying for SPRAVATO®

At Janssen, we don't want cost to get in the way of treatment you need. We can help you explore options to lower your out-of-pocket cost for SPRAVATO®. No matter what type of coverage you have – or even if you don't have coverage – Janssen CarePath can help explain your medication insurance coverage and potential out-of-pocket costs and help find programs that may help you pay for SPRAVATO®.

If you have commercial or private health insurance and need help paying for SPRAVATO®, the Janssen CarePath Savings Program may be able to help.*

If you don't have commercial or private health insurance, Janssen CarePath can provide information about other resources that may help with your out-of-pocket medication costs. You may also find help from the programs and resources found on our website.†

*See next page.

†For a summary of websites and phone contact information, [please see page 27.](#)

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

Janssen CarePath Savings Program for SPRAVATO®

If you use commercial or private health insurance to pay for your medication:
Janssen CarePath Savings Program for SPRAVATO®



Eligible commercially-insured patients **pay \$10 per treatment** for SPRAVATO® medication costs, with a \$7,150 maximum program benefit per calendar year.

Treatment may include up to three devices administered on the same day. Program limits apply. Depending on how your insurance covers SPRAVATO®, there is a program benefit limit of list price of medication and a quantity limit of three devices per day or 23 devices in a 24-day period. There is a quantity limit of 24 devices in a 24-day period for one use per lifetime. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medications. Terms expire at the end of each calendar year and may change. Program does not cover the cost to give you your treatment. See full eligibility requirements at

[Spravato.JanssenCarePathSavings.com](https://spravato.janssencarepathsavings.com)

- ▶ Click or tap to see [Important Safety Information](#)
- ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
- ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

How to enroll in the Janssen CarePath Savings Program for SPRAVATO® or get cost support



If you use commercial or private health insurance to pay for your medication:

Enroll in the Savings Program at
MyJanssenCarePath.com/express
to get a card for use at your
healthcare provider's office or pharmacy.

Create a Janssen CarePath Account
at **MyJanssenCarePath.com** to check your
insurance coverage for SPRAVATO®;
enroll in the Janssen CarePath Savings Program
and manage program benefits; and sign up for
treatment support.



If you are using a government-funded
healthcare program to pay for SPRAVATO®
or have no insurance coverage and need help
paying for your medication, go to:

JanssenCarePath.com



**Call a Janssen CarePath Care Coordinator
at 877-CarePath (877-227-3728),
Monday–Friday, 8 AM to 8 PM ET
for more information.**

-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

How do I get started with SPRAVATO®?

SPRAVATO® is only available at certified SPRAVATO® treatment centers under the supervision of a healthcare provider who will:

- Determine if SPRAVATO® is right for you
- Discuss your full medical and depression treatment history with you



-
- ▶ Click or tap to see [Important Safety Information](#)
 - ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.



Click here for
cost support

Spravato®
(esketamine) 
28 mg nasal spray

IMPORTANT SAFETY INFORMATION

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

SPRAVATO® can cause serious side effects, including:

- **Sedation and dissociation.** SPRAVATO® may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation).
 - Tell your healthcare provider right away if you feel like you cannot stay awake or if you feel like you are going to pass out.
 - Your healthcare provider must monitor you for serious side effects for at least 2 hours after taking SPRAVATO®. Your healthcare provider will decide when you are ready to leave the healthcare setting.
- **Abuse and misuse.** There is a risk for abuse and physical and psychological dependence with SPRAVATO® treatment. Your healthcare provider should check you for signs of abuse and dependence before and during treatment with SPRAVATO®.
 - Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
 - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- **SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS).** Because of the risks for sedation, dissociation, and abuse and misuse, SPRAVATO® is only available through a restricted program called the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS) Program. SPRAVATO® can only be administered at healthcare settings certified in the SPRAVATO® REMS Program. Patients treated in outpatient healthcare settings (e.g., medical offices and clinics) must be enrolled in the program.
- **Increased risk of suicidal thoughts and actions.** Antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed.**
SPRAVATO® is not for use in children
 - Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a higher risk of having suicidal thoughts or actions. These include people who have (or have a family history of) depression or a history of suicidal thoughts or actions.
- **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
 - Pay close attention to any changes, especially sudden changes, in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
 - Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.
- **Tell your healthcare provider right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:**
 - suicide attempts
 - thoughts about suicide or dying
 - worsening depression
 - other unusual changes in behavior or mood

continued on next page

▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)

▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

IMPORTANT SAFETY INFORMATION

continued

Do not take SPRAVATO® if you:

- have blood vessel (aneurysmal vascular) disease (including in the brain, chest, abdominal aorta, arms and legs)
- have an abnormal connection between your veins and arteries (arteriovenous malformation)
- have a history of bleeding in the brain
- are allergic to esketamine, ketamine, or any of the other ingredients in SPRAVATO®.

If you are not sure if you have any of the above conditions, talk to your healthcare provider before taking SPRAVATO®.

Before you take SPRAVATO®, tell your healthcare provider about all of your medical conditions, including if you:

- have heart or brain problems, including:
 - high blood pressure (hypertension)
 - slow or fast heartbeats that cause shortness of breath, chest pain, lightheadedness, or fainting
 - history of heart attack
 - history of stroke
 - heart valve disease or heart failure
 - history of brain injury or any condition where there is increased pressure in the brain
- have liver problems
- have ever had a condition called “psychosis” (see, feel, or hear things that are not there, or believe in things that are not true).
- are pregnant or plan to become pregnant. SPRAVATO® may harm your baby. You should not take SPRAVATO® if you are pregnant.
 - Tell your healthcare provider right away if you become pregnant during treatment with SPRAVATO®.
 - If you are able to become pregnant, talk to your healthcare provider about methods to prevent pregnancy during treatment with SPRAVATO®.
 - There is a pregnancy registry for women who are exposed to SPRAVATO® during pregnancy. The purpose of the registry is to collect information about the health of women exposed to SPRAVATO® and their baby. If you become pregnant during treatment with SPRAVATO®, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>.
- are breastfeeding or plan to breastfeed. You should not breastfeed during treatment with SPRAVATO®.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Taking SPRAVATO® with certain medicine may cause side effects.

Especially tell your healthcare provider if you take central nervous system (CNS) depressants, psychostimulants, or monoamine oxidase inhibitors (MAOIs) medicines. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How will I take SPRAVATO®?

- You will take SPRAVATO® nasal spray yourself, under the supervision of a healthcare provider in a healthcare setting. Your healthcare provider will show you how to use the SPRAVATO® nasal spray device.
- Your healthcare provider will tell you how much SPRAVATO® you will take and when you will take it.
- Follow your SPRAVATO® treatment schedule exactly as your healthcare provider tells you to.

continued on next page

-
- ▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)
 - ▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

Spravato®
(esketamine) 
28 mg nasal spray



IMPORTANT SAFETY INFORMATION

continued

How will I take SPRAVATO®? (continued)

- During and after each use of the SPRAVATO® nasal spray device, you will be checked by a healthcare provider who will decide when you are ready to leave the healthcare setting.
- You will need to plan for a caregiver or family member to drive you home after taking SPRAVATO®.
- If you miss a SPRAVATO® treatment, your healthcare provider may change your dose and treatment schedule.
- Some people taking SPRAVATO® get nausea and vomiting. You should not eat for at least 2 hours before taking SPRAVATO® and not drink liquids at least 30 minutes before taking SPRAVATO®.
- If you take a nasal corticosteroid or nasal decongestant medicine take these medicines at least 1 hour before taking SPRAVATO®.

What should I avoid while taking SPRAVATO®?

Do not drive, operate machinery, or do anything where you need to be completely alert after taking SPRAVATO®. **Do not** take part in these activities until the next day following a restful sleep. See “**What is the most important information I should know about SPRAVATO®?**”

What are the possible side effects of SPRAVATO®?

SPRAVATO® may cause serious side effects including:

- See “**What is the most important information I should know about SPRAVATO®?**”
- **Increased blood pressure.** SPRAVATO® can cause a temporary increase in your blood pressure that may last for about 4 hours after taking a dose. Your healthcare provider will check your blood pressure before taking SPRAVATO® and for at least 2 hours after you take SPRAVATO®. Tell your healthcare provider right away if you get chest pain, shortness of breath, sudden severe headache, change in vision, or seizures after taking SPRAVATO®.
- **Problems with thinking clearly.** Tell your healthcare provider if you have problems thinking or remembering.
- **Bladder problems.** Tell your healthcare provider if you develop trouble urinating, such as a frequent or urgent need to urinate, pain when urinating, or urinating frequently at night.

The most common side effects of SPRAVATO® when used along with an antidepressant taken by mouth include:

- | | |
|---|---|
| • feeling disconnected from yourself, your thoughts, feelings and things around you | • decreased feeling of sensitivity (numbness) |
| • dizziness | • feeling anxious |
| • nausea | • lack of energy |
| • feeling sleepy | • increased blood pressure |
| • spinning sensation | • vomiting |
| | • feeling drunk |
| | • feeling very happy or excited |

If these common side effects occur, they usually happen right after taking SPRAVATO® and go away the same day.

These are not all the possible side effects of SPRAVATO®.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

cp-170363v1

▶ Click or tap for full [Prescribing Information, including Boxed WARNINGS](#)

▶ Click or tap for the [Medication Guide for SPRAVATO®](#)

Discuss any questions you may have with your healthcare provider.

© Janssen Pharmaceuticals, Inc. 2022 05/22 cp-204181v3