



# Feel like yourself again

SPRAVATO®, the only FDA-approved nasal spray for adults with treatment-resistant depression, reduces depression symptoms when two or more oral antidepressants haven't worked.

SPRAVATO® can be taken with or without an oral antidepressant.

**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, dissociation, and respiratory depression.** SPRAVATO® may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation), breathing problems (respiratory depression and respiratory arrest)
  - 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.

Please see additional Important Safety Information continued on the next page.

Please see full [Prescribing Information](#), including Boxed WARNINGS, and [Medication Guide](#) for SPRAVATO® and discuss any questions you may have with your healthcare provider.

## IMPORTANT SAFETY INFORMATION (continued)

- **Abuse and misuse.** There is a risk for abuse and misuse with SPRAVATO®, which may lead to physical and psychological dependence. Your healthcare provider should check you for signs of abuse, misuse, and dependence before and during treatment.
  - 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 in drug addiction.
- **SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS).** Because of the risks for sedation, dissociation, respiratory depression, 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 (such as 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.

Please see Important Safety Information on pages 19-23.

Please see full [Prescribing Information](#), including Boxed WARNINGS, and [Medication Guide](#) for SPRAVATO® and discuss any questions you may have with your healthcare provider.

- **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, or if you develop suicidal thoughts or actions.
  - 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 or get emergency help right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:**

◦ thoughts about suicide or dying	◦ suicide attempts
◦ new or worse depression	◦ new or worse anxiety
◦ feeling very agitated or restless	◦ panic attacks
◦ trouble sleeping (insomnia)	◦ new or worse irritability
◦ acting aggressive, being angry or violent	◦ acting on dangerous impulses
◦ an extreme increase in activity and talking (mania)	◦ other unusual changes in behavior or mood

### What is SPRAVATO® (esketamine) CIII nasal spray?

SPRAVATO® is a prescription medicine used:

- with or without an antidepressant taken by mouth, to treat adults with treatment-resistant depression (TRD)
- with an antidepressant taken by mouth, to treat 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 SPRVATO® is safe or effective as an anesthetic medicine.

It is not known if SPRVATO® is safe and effective for use in preventing suicide or in reducing suicidal thoughts or actions. SPRVATO® 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 SPRVATO®. It is not known if SPRVATO® is safe and effective in children.

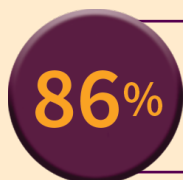
**Spravato®**  
(esketamine) CIII  
28 mg nasal spray



# Oral antidepressants may not work for everyone.



**1 in 3 people did not experience a reduction** in their depression symptoms when taking oral antidepressants alone.



Based on a clinical study, **86% of patients do not achieve remission** from depression symptoms by their third oral antidepressant.

**If you've taken 2 or more oral antidepressants and still experience symptoms of depression, you may have treatment-resistant depression**



Please see Important Safety Information on pages 19-23.

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**SPRAVATO®** offers a **different** approach

**SPRAVATO® is the only FDA-approved nasal spray for adults with treatment-resistant depression that can be taken with or without an oral antidepressant, giving you more options and flexibility.**

- SPRAVATO® reduces depression symptoms when oral antidepressants haven't worked
- SPRAVATO® works differently by acting on glutamate
- Glutamate is a chemical messenger found in the brain that is thought to help balance well-being and depression
- The exact way SPRAVATO® works is unknown



Data rates may apply.

Scan here to watch top healthcare providers answer questions about SPRAVATO®

Visit [SPRAVATO.com/asktheexperts](https://www.spravato.com/asktheexperts)

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# Is there proof that SPRAVATO® can help?

Here's a snapshot of what SPRAVATO® achieved in short- and long-term clinical trials of patients who had inadequate response to 2 or more oral antidepressants.

## Short-Term Study Results

### IN COMBINATION WITH AN ORAL ANTIDEPRESSANT

In a 4-week clinical study, patients were given either SPRAVATO® in combination with an oral antidepressant or a placebo nasal spray plus an oral antidepressant. The study showed:

- Rapid and superior reduction in depression symptoms at 4 weeks for more patients using SPRAVATO® in combination with an oral antidepressant compared with those who received placebo plus an oral antidepressant\*
- Most of the reduction in depression symptoms was seen at 24 hours
- Continued improvement between 24 hours and 4 weeks for both groups; the difference in improvement between the groups did not appear to increase through 4 weeks

\*Based on an overall score on a standardized rating scale.

### ALONE

Patients were given either SPRAVATO® alone or a placebo nasal spray alone in a randomized clinical study. The study showed:

- Rapid and superior reduction in depression symptoms at ~4 weeks and 24 hours for patients using SPRAVATO® alone compared with those who received a placebo nasal spray alone

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## Long-Term Study Results

### IN COMBINATION WITH AN ORAL ANTIDEPRESSANT

An 18-month SPRAVATO® study to see if the effect of treatment was maintained over time showed:

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



Data rates may apply.

Scan here to learn more  
at [SPRAVATO.com](https://www.spravato.com)

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# What are the possible side effects of SPRAVATO®?

SPRAVATO® may cause serious side effects, including sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation), and breathing problems (respiratory depression and respiratory arrest).

Scan the QR code for Important Safety Information  
Visit [SPRAVATO.com/important-safety-information](https://spravato.com/important-safety-information)



Data rates may apply.

## The Most Common Side Effects of SPRAVATO®:

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

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



In clinical studies, patients on SPRAVATO® experienced a **low incidence of sexual dysfunction** compared with placebo. Sexual dysfunction was not seen in ≥2% or more of patients.

Please see Important Safety Information on pages 19-23.

Please see full [Prescribing Information](#), including Boxed WARNINGS, and [Medication Guide](#) for SPRAVATO® and discuss any questions you may have with your healthcare provider.

## Where Do I Receive SPRAVATO®?



SPRAVATO® is administered under the supervision of a healthcare provider at a treatment center that is certified in the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS) Program. This could be at a different location than your usual healthcare provider's office. Work with your healthcare provider to locate a treatment center that is right for you.

### My Treatment Center:

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# You've decided to try SPRAVATO®. What's next?

After you and your healthcare provider have decided SPRAVATO® is right for you – and you understand the benefits and risks – you can start planning for treatment at a certified treatment center.

## 1: Treatment Plan



Your healthcare provider will work with you to determine if SPRAVATO® should be taken with or without an oral antidepressant.



For the first month, you'll take SPRAVATO® twice per week, then once per week for the second month. After that, you and your provider will determine if treatment should be continued and will have the flexibility to decide your treatment frequency.



You may start treatment as soon as your second visit to the SPRAVATO® treatment center.



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## Your First Visit to a Treatment Center

Your first visit to a 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 confirm SPRAVATO® is an appropriate option.



Verify your insurance information as part of the eligibility confirmation.



Make sure to follow up with your healthcare provider after your treatment plan is built if you have questions.

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# What happens on your first day of treatment?

## 2: Treatment Days



You will administer SPRAVATO® nasal spray yourself under the supervision of a healthcare provider at a certified SPRAVATO® treatment center.



After you administer SPRAVATO®, there will be an observation period of at least 2 hours, during which you will rest comfortably while a healthcare provider at the treatment center monitors you for possible side effects.



Because of possible side effects affecting mental alertness and motor coordination, you won't be able to drive, operate machinery, or do anything where you need to be completely alert until the next day, following a restful sleep.

**You'll need to plan for rides on treatment days.**



Please see Important Safety Information on pages 19-23.

Please see full [Prescribing Information](#), including Boxed WARNINGS, and [Medication Guide](#) for SPRAVATO® and discuss any questions you may have with your healthcare provider.

## Tips to Prepare for Treatment Days



Avoid eating 2 hours before, and drinking liquids 30 minutes before, the treatment session. Some patients taking SPRAVATO® may experience nausea or vomiting.



If you take a nasal corticosteroid or nasal decongestant medicine, take these medicines at least 1 hour before taking SPRAVATO®.



Many people spend the observation time relaxing, listening to music, reading, or resting.



Keep in mind, your referring healthcare provider will continue to be involved with your care during SPRAVATO® treatment even if they are not present during your treatment sessions. Both your referring physician and treatment center will be available to answer questions or address concerns as you start and progress through treatment.



Data rates may apply.

Watch these stories to hear about the SPRAVATO® patient experience

[Visit SPRAVATO.com/patientstories](https://spravato.com/patientstories)

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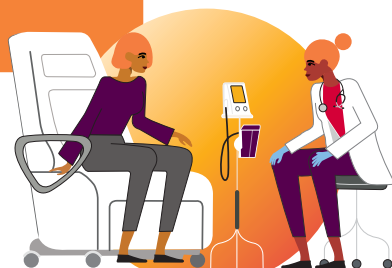
# What should you know about ongoing SPRAVATO® treatment?

## 3: Ongoing Treatment



For the first month, you'll take SPRAVATO® twice per week, then once per week for the second month. After that, you and your provider will determine if treatment should be continued and will have the flexibility to decide your treatment frequency.

In a long-term clinical study, patients who stayed on SPRAVATO® were less likely to relapse.



Please see Important Safety Information on pages 19-23.

Please see full [Prescribing Information](#), including Boxed WARNINGS, and [Medication Guide](#) for SPRAVATO® and discuss any questions you may have with your healthcare provider.

## SPRAVATO® Timeline

### INDUCTION PHASE

  
Weeks  
1-4



**Two times  
per week**

### MAINTENANCE PHASE

  
Weeks  
5-8



**Once per week**

  
Ongoing



**Once per week  
or every 2 weeks**

Dosing strength based on clinical judgment

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# Is support available for people who take SPRAVATO®?

Once you and your healthcare provider have decided that SPRAVATO® is right for you, sign up for:

## Spravato withMe

The support program designed with you in mind



We're here to give you the help you may need on your SPRAVATO® treatment journey. SPRAVATO withMe offers flexible support to help you start and stay on therapy.

- Cost Support
- Dedicated Care Navigator
- Treatment Prep & Ongoing Support



### Sign Up Over the Phone

1-844-4S-WITHME (1-844-479-4846)  
Monday – Friday, 8:00 AM – 8:00 PM ET



When you sign up for SPRAVATO withMe, you'll get a free Patient Starter Kit with resources to help you start your SPRAVATO® treatment.

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Actor portrayal.

**Have commercial or private insurance? You have 2 ways to save. Take advantage of both of the programs below and maximize your savings**

### Pay as little as \$10 per treatment for your SPRAVATO® medication

#### SPRAVATO withMe Savings Program

Treatment may include up to three devices administered on the same day. There are quantity limits and a maximum program benefit per calendar year. Offer subject to change or end without notice. Program does not cover the cost of treatment observation. Participate without sharing your income information. See program requirements at [Spravato.com/SavingsRequirements](https://Spravato.com/SavingsRequirements)

### Pay \$0 after rebate for observation of each treatment

#### SPRAVATO withMe Observation Rebate Program

There is a limit to savings each year. Offer subject to change or end without notice. Not valid for residents of MA, MI, MN, or RI. Participate without sharing your income information.

See program requirements at [Spravato.com/Observation](https://Spravato.com/Observation)

If insurance doesn't cover all of your costs, or if you have no insurance, SPRAVATO withMe can provide information about other cost support options.



Data rates may apply.

Scan here to learn more about support offerings from SPRAVATO withMe

[Visit SPRAVATO.com/patientsupport](https://Spravato.com/patientsupport)

The support and resources provided by SPRAVATO withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

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## Can SPRAVATO® help with depression symptoms in adults with MDD with suicidal thoughts or actions (MDSI)?



In clinical studies of adults with MDSI, those who took SPRAVATO® and an oral antidepressant experienced a greater reduction of depression symptoms at 24 hours compared with those who received a placebo plus an oral antidepressant.\*

### Limitations of Use

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®.

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.



Help is available 24/7. If you're struggling with suicidal thoughts, call 988 Suicide & Crisis Lifeline

\*Based on an overall score on a standardized rating scale.

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## IMPORTANT SAFETY INFORMATION

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

#### SPRAVATO® can cause serious side effects, including:

- **Sedation, dissociation, and respiratory depression.** SPRAVATO® may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation), breathing problems (respiratory depression and respiratory arrest)
  - 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 misuse with SPRAVATO®, which may lead to physical and psychological dependence. Your healthcare provider should check you for signs of abuse, misuse, and dependence before and during treatment.
  - 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 in drug addiction.
- **SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS).** Because of the risks for sedation, dissociation, respiratory depression, 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 (such as medical offices and clinics) must be enrolled in the program.

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• **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, or if you develop suicidal thoughts or actions.

◦ 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 or get emergency help right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:**

- |   |   |
|---|---|
| ◦ thoughts about suicide or dying                     | ◦ suicide attempts                          |
| ◦ new or worse depression                             | ◦ new or worse anxiety                      |
| ◦ feeling very agitated or restless                   | ◦ panic attacks                             |
| ◦ trouble sleeping (insomnia)                         | ◦ new or worse irritability                 |
| ◦ acting aggressive, being angry or violent           | ◦ acting on dangerous impulses              |
| ◦ an extreme increase in activity and talking (mania) | ◦ other unusual changes in behavior or mood |

**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 unborn 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/>.

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**IMPORTANT SAFETY INFORMATION** (continued)

- are breastfeeding or plan to breastfeed. SPRAVATO® passes into your breast milk. 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) medicine. 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.
- 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® include:**

- |   |                                 |
|---|---------------------------------|
| • feeling disconnected from yourself, your thoughts, feelings and things around you | • feeling anxious               |
| • dizziness   | • lack of energy                |
| • nausea  | • increased blood pressure      |
| • feeling sleepy  | • vomiting                      |
| • spinning sensation  | • feeling drunk                 |
| • decreased feeling of sensitivity (numbness)                                       | • headache                      |
|   | • 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 Johnson & Johnson at 1-800-526-7736, or to the FDA at 1-800-FDA-1088.

**Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO® and discuss any questions you may have with your healthcare provider.**

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