

Once you and your doctor have decided that SPRAVATO<sup>®</sup> is right for you, connect with your insurance provider and ask these questions:

- 1 Is SPRAVATO<sup>®</sup> medication covered under my medical or pharmacy benefit?
- 2 Are my SPRAVATO<sup>®</sup> visits covered under my medical plan or do I have a behavioral health benefit?
- 3 What is my co-pay or co-insurance amount?
- 4 Are the SPRAVATO<sup>®</sup>-certified treatment centers in my area in-network?

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**What is SPRAVATO<sup>®</sup> (esketamine) CIII nasal spray?**

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

- Adults with treatment-resistant depression (TRD)

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

It is not known if SPRAVATO<sup>®</sup> is safe and effective for use in preventing suicide or in reducing suicidal thoughts or actions. SPRAVATO<sup>®</sup> 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<sup>®</sup>.

It is not known if SPRAVATO<sup>®</sup> is safe and effective in children.

**IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about SPRAVATO<sup>®</sup>?**

**SPRAVATO<sup>®</sup> can cause serious side effects, including:**

- **Sedation and dissociation.** SPRAVATO<sup>®</sup> 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<sup>®</sup>. Your healthcare provider will decide when you are ready to leave the healthcare setting.
- **Respiratory depression** was observed with the use of SPRAVATO<sup>®</sup>; additionally, there were rare reports of respiratory arrest.
  - Your healthcare provider must monitor you for serious side effects for at least 2 hours (including pulse oximetry) after taking SPRAVATO<sup>®</sup>. Your healthcare provider will decide when you are ready to leave the healthcare setting.

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**Please see additional Important Safety Information in this guide. Please see full Prescribing Information, including **Boxed WARNINGS**, and Medication Guide for SPRAVATO<sup>®</sup> 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 physical and psychological dependence with SPRAVATO<sup>®</sup> treatment. Your healthcare provider should check you for signs of abuse and dependence before and during treatment with SPRAVATO<sup>®</sup>.
  - 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<sup>®</sup> Risk Evaluation and Mitigation Strategy (REMS).** Because of the risks for sedation, dissociation, respiratory depression, and abuse and misuse, SPRAVATO<sup>®</sup> is only available through a restricted program called the SPRAVATO<sup>®</sup> Risk Evaluation and Mitigation Strategy (REMS) Program. SPRAVATO<sup>®</sup> can only be administered at healthcare settings certified in the SPRAVATO<sup>®</sup> 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<sup>®</sup> 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

**Do not take SPRAVATO<sup>®</sup> 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<sup>®</sup>.

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

**Before you take SPRAVATO<sup>®</sup>, 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<sup>®</sup> may harm your baby. You should not take SPRAVATO<sup>®</sup> if you are pregnant.
  - Tell your healthcare provider right away if you become pregnant during treatment with SPRAVATO<sup>®</sup>.
  - If you are able to become pregnant, talk to your healthcare provider about methods to prevent pregnancy during treatment with SPRAVATO<sup>®</sup>.
  - There is a pregnancy registry for women who are exposed to SPRAVATO<sup>®</sup> during pregnancy. The purpose of the registry is to collect information about the health of women exposed to SPRAVATO<sup>®</sup> and their baby. If you become pregnant during treatment with SPRAVATO<sup>®</sup>, 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<sup>®</sup>.

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### IMPORTANT SAFETY INFORMATION (CONTINUED)

**Tell your healthcare provider about all the medicines that you take**, including prescription and over-the-counter medicines, vitamins and herbal supplements. Taking SPRAVATO<sup>®</sup> 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<sup>®</sup>?

- You will take SPRAVATO<sup>®</sup> 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<sup>®</sup> nasal spray device.
- Your healthcare provider will tell you how much SPRAVATO<sup>®</sup> you will take and when you will take it.
- Follow your SPRAVATO<sup>®</sup> treatment schedule exactly as your healthcare provider tells you to.
- During and after each use of the SPRAVATO<sup>®</sup> 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<sup>®</sup>.
- If you miss a SPRAVATO<sup>®</sup> treatment, your healthcare provider may change your dose and treatment schedule.
- Some people taking SPRAVATO<sup>®</sup> get nausea and vomiting. You should not eat for at least 2 hours before taking SPRAVATO<sup>®</sup> and not drink liquids at least 30 minutes before taking SPRAVATO<sup>®</sup>.
- If you take a nasal corticosteroid or nasal decongestant medicine take these medicines at least 1 hour before taking SPRAVATO<sup>®</sup>.

### What should I avoid while taking SPRAVATO<sup>®</sup>?

**Do not** drive, operate machinery, or do anything where you need to be completely alert after taking SPRAVATO<sup>®</sup>. **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<sup>®</sup>?”**

### What are the possible side effects of SPRAVATO<sup>®</sup>?

#### SPRAVATO<sup>®</sup> may cause serious side effects including:

- See **“What is the most important information I should know about SPRAVATO<sup>®</sup>?”**
- **Increased blood pressure.** SPRAVATO<sup>®</sup> 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<sup>®</sup> and for at least 2 hours after you take SPRAVATO<sup>®</sup>. 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<sup>®</sup>.
- **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<sup>®</sup> 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<sup>®</sup> and go away the same day.**

These are not all the possible side effects of SPRAVATO<sup>®</sup>.

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

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