



# BEACHES TMS & BRAIN HEALTH

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## **CONSENT FOR TREATMENT AND SPRAVATO FAQ'S**

### **WHAT IS KETAMINE?**

Ketamine is made up of a 50:50 mixture of two differently oriented versions of the same molecule, known as enantiomers (or optical isomers). The two enantiomers of ketamine are known as S-ketamine (Esketamine) and R-ketamine (arketamine). Ketamine has been approved by the FDA for use in anesthesia and as a pain reliever during medical procedures. Studies have shown that ketamine may be helpful in the treatment of depression.

### **WHAT IS ESKETAMINE?**

Esketamine, the molecule found in ketamine. Studies have shown that Esketamine is more potent than ketamine. Because it's more potent, it can be used at a lower dose and may have fewer side effects. While other antidepressants modulate a group of chemicals in the brain called monoamines, esketamine targets glutamate, which is found to be in abundance in the brains of people with depression.

### **HOW DOES ESKETAMINE WORK?**

Esketamine is working on the glutamatergic system, and that's thought to create synapses in the brain. When we have depression, sometimes we don't have as many connections or synapses within the brain cells, so those synapses go away. Esketamine is thought to create these synapses, or connections, between our brain cells again.

### **IS SPRAVATO SAFE?**

SPRAVATO is a very safe depression medication in the hands of properly trained healthcare professionals. SPRAVATO is used along with an antidepressant taken by mouth to treat Adults with treatment-resistant depression (TRD) and depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions. The appropriate dosage is determined by your physician and is below those necessary to induce general anesthesia.

### **IS SPRAVATO A RECREATIONAL DRUG?**

SPRAVATO is esketamine, however Ketamine has been abused as a recreational drug. Street drug use is in doses vastly higher than the sub-anesthetic doses used for the treatment of depression and other mental health conditions. As mentioned above, SPRAVATO is used legally and safely and is a very safe medication in experienced hands. Incidentally, many of the drugs used in anesthesia practice have the potential for abuse, so SPRAVATO is not unique in this respect. The key is administering the right dose to the right patient in the right setting.

### **IS INTRANASAL SPRAVATO THE ONLY WAY TO DELIVER SPRAVATO FOR TREATMENT RESISTANT DEPRESSION?**

SPRAVATO is only administered intranasal. Unfortunately, the effectiveness and predictability of response and the overwhelming majority of scientific studies of SPRAVATO for depression and mental health conditions have been performed using intranasal SPRAVATO. In short, intranasal SPRAVATO is the gold standard route for SPRAVATO administration.

### **CAN SPRAVATO HELP ME?**

Research over the last 5-10 years has shown that Intranasal administration of SPRAVATO in sub-anesthetic doses remarkably benefits 70% of people suffering from severe depression. While the benefits can truly be remarkable, they often occur in ways that differ from some patients' expectations. That is, the changes produced by SPRAVATO can be subtle, and while they occur quickly, they do not always manifest themselves immediately. This phenomenon stands in contrast to some patients' expectations of a benevolent "thunderbolt" response from SPRAVATO treatment. With this in mind, we will work closely with you to identify and evaluate the benefits of SPRAVATO as a depression medication.

## **HOW MANY INTRANASAL ADMINISTRATIONS DO I NEED?**

The standard SPRAVATO protocol for depression that has resulted from scientific trials and clinical experience around the U.S. is about 2 times per week for the first 4 weeks, and then weekly for 2-4 weeks and then maintenance (usually once every 2 weeks). It has been shown that serial Intranasal administrations are more effective than single Intranasal administrations, and many patients who respond to SPRAVATO treatment require maintenance Intranasal administrations on an ongoing basis following the initial series. The frequency of these maintenance Intranasal administrations varies greatly from person to person. It is important to note that SPRAVATO Intranasal administrations should not be viewed as a cure for depression, but rather a depression treatment that is a piece of a multi-modal approach that may include ongoing mental health therapy or other depression medication.

## **CAN I CONTINUE TO TAKE MY REGULAR MEDICATIONS?**

Yes, you should not stop your antidepressant medications in order to receive SPRAVATO. It is essential that we review your current medication list prior to beginning SPRAVATO treatments.

## **IS SPRAVATO ADDICTING?**

SPRAVATO is not physically addicting but it could be psychologically addicting in those using it recreationally at much higher doses and in far greater frequencies than we will use. There is potential for abuse and misuse. All patients will be monitored for signs and symptoms of abuse and misuse.

## **OTHER SPRAVATO FAQ'S**

### **IS THERE A DIFFERENCE BETWEEN SPRAVATO NASAL SPRAY AND KETAMINE INFUSIONS?**

SPRAVATO™(esketamine) is the s-enantiomer of racemic ketamine. There are no head-to-head studies comparing esketamine and ketamine infusion. SPRAVATO™ (esketamine) is delivered in a nasal spray form and ketamine is delivered intravenously.

### **HOW MUCH DOSE SPRAVATO COST?**

The cost of SPRAVATO™ to your patients is dependent on their insurance plan. Janssen CarePath offers access and affordability options for your patients, depending on their plan.

### **CAN SPRAVATO BE TAKEN WITH OTHER MEDICATIONS FOR DEPRESSION?**

SPRAVATO™ should be administered in conjunction with an oral antidepressant (AD). The new open-label oral AD initiated during Study 1 (short-term) was an SSRI in 32% of patients and an SNRI in 68% of patients.

### **WHAT IF A PATIENT MISSES A DOSE OF SPRAVATO?**

If a patient misses treatment session, and depression symptoms worsen, consider returning your patient to their previous dosing schedule (ie, every 2 weeks to once weekly, once or twice per week), per clinical judgment.

### **CAN MY PATIENTS PICK UP SPRAVATO AND SELF-ADMINISTER AT HOME?**

No, under the REMS, SPRAVATO™ must be administered in a certified healthcare setting. Due to the possibility of delayed or prolonged sedation or dissociation in some cases, patients should be monitored by a healthcare professional for at least 2 hours following each treatment session, or until the clinician determines the patient is safe to leave.

### **HOW SOON CAN MY PATIENTS DRIVE AFTER TAKING SPRAVATO?**

Caution patients that SPRAVATO™ may impair their ability to drive or operate machinery. 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 after a restful sleep.

## **WHAT SHOULD I EXPECT DURING MY FIRST INITIAL SPRAVATO VISIT?**

This assessment is a two-part process that involves a review of your medical history and then a second visit for your initial treatment. Your first appointment will last about an hour. The initial assessment, or consultation, will be used to evaluate the appropriateness of Spravato/esketamine in treating your depression. Dr Galliano-Pardo, your Spravato prescribing psychiatrist, will use the assessment to determine a diagnosis and the risks and benefits of Spravato compared to other available treatments for your diagnosis.

The doctor will also want details about previous treatment for your depression including counseling history, names of medications and maximum dosage, duration of treatment, and reasons treatment was discontinued, such as lack of benefit or side effects. You should be prepared to complete formal medical history evaluations and sign consent forms.

There is also a chance that Dr Galliano -Pardo will request a physical examination from your primary care physician. This is not always the case, though, and will vary from patient to patient. If a physical examination is requested, it will most likely be used to carefully screen patients for the presence of medical conditions that are contraindicated with Spravato.

At the end of the assessment, Dr. Galliano-Pardo will decide if you are a candidate for Spravato. If Spravato is right for you, she will create a treatment plan for you. Your next appointment will be your first treatment. Your first evaluation will be about 1 hours long. Your intake with a staff member will take about 15 minutes followed by a 45 minute to an hour meeting with Dr. Galliano-Pardo.

Prior to administering SPRAVATO, your blood pressure will be recorded to ensure SPRAVATO can be safely administered. Then we will begin the intranasal administration while you are seated with your head at a 45-degree incline. Afterwards, we will monitor you for approximately 120 minutes (2hours) before you are released with a friend or relative who can drive you safely home.

During the treatment, occasionally people experience nausea, mild non-threatening hallucinations, or dizziness. You will be awake during the treatment and able to interact with those around you. It is best to relax quietly or listen to relaxing music during the session. Please feel free to bring a blanket or anything else that makes you feel comfortable. Although the effects of SPRAVATO wear off quickly, we ask that you refrain from driving until the day after the treatment. Please do not eat solid foods, milk, pulp-filled juices or soup for 4-hours prior to your appointment. You may have clear liquids such as water, Gatorade, apple juice, black coffee or tea up to two hours prior to your appointment



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## **INFORMED CONSENT: SPRAVATO TREATMENT FOR DEPRESSION**

- I understand the risks include but are not limited to: Dissociation, Dizziness, Nausea, Sedation, Vertigo, Headache, Dysgeusia, Hypoesthesia, Anxiety, Lethargy, Blood pressure increased, Vomiting, Insomnia, and Diarrhea. I also understand that the potential side effects from Spravato nasal treatment may include: Nasal discomfort, Throat irritation, feeling drunk, Dry mouth, Hyperhidrosis, Euphoric mood, Dysarthria, Tremor, Oropharyngeal pain, Mental impairment, Constipation, Pollakiuria, Feeling abnormal, and Tachycardia.
- I agree to remain abstinent from any illegal drugs, alcohol, and controlled medications that I am not prescribed. If I cannot remain abstinent from these substances, I agree to inform the office prior to my treatment session, as this could jeopardize my safety and affect my ability to continue treatment. While undergoing treatment, I am fully aware that I may be monitored for compliance with random Urine Drug Screens (UDS).
- I understand that I may not drive nor operate machinery for at least 12 hours after my nasal treatment is completed. And that I will only be discharged to the care of a responsible adult.
- I understand that good results are expected but not guaranteed. My depression may not improve with Spravato treatment even if I follow the complete treatment protocol.
- I understand that to achieve the desired results that a series of nasal treatments are needed, and it is my full intent to complete the course of treatment.
- I understand that Spravato nasal treatment is not a substitute for continued behavioral medicine treatment. My psychiatrist or family doctor will determine if any oral medications or other treatments may be stopped if my depression improves.
- I have been explained thoroughly about the use of Spravato for Major Depression and I had the opportunity to ask all the relevant questions I felt necessary. I am confirming that I have received and reviewed the pre-treatment instructions, post treatment instructions and that I can fully comply
- I voluntarily request Beaches TMS & Brain Health to administer SPRAVATO for the treatment of my condition.
- I understand that I can revoke this consent at any time including during treatment.
- I understand that SPRAVATO nasal spray is indicated and FDA approved, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression in adults.
- I fully consent and agree to Beaches Deep TMS & Brain Health bill my insurance company for services rendered. I am aware that I bear full financial responsibility for monies not received by Beaches Deep TMS & Brain Health from my insurance company

**Patient Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Patient Signature:** \_\_\_\_\_