

# Medical Park Associates

## PATIENT SPRAVATO WELCOME PACKET

1103 Corporate Drive

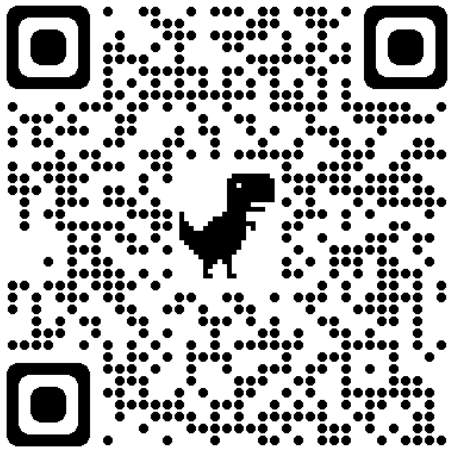
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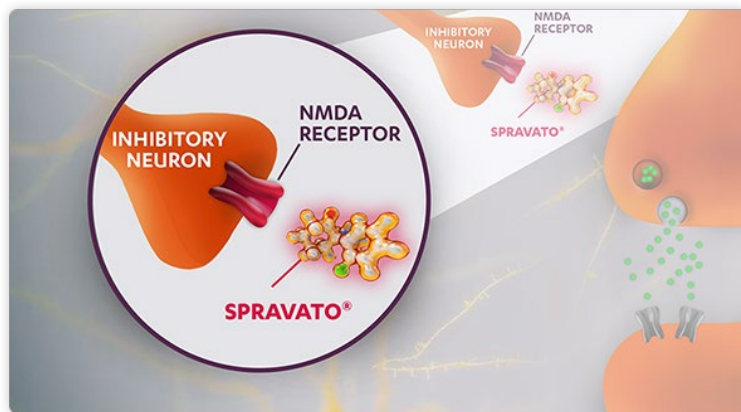
### **Indication**

Spravato is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression in adults.

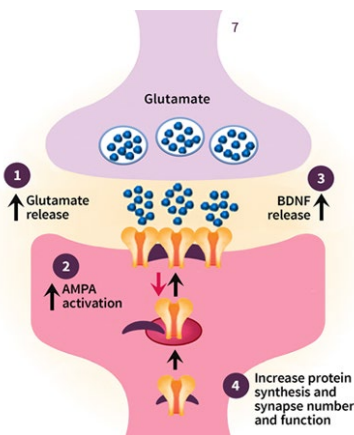


This is a QR link that shares other people's experiences with Spravato.

## How does Spravato work?



Spravato is an N-methyl-D-aspartate (NMDA) receptor agonist that is believed to work differently by acting on pathways in the brain affecting glutamate a chemical messenger in the brain. Glutamate affects memory, mood, and your ability to think clearly. The main antidepressant activity is not believed to directly involve inhibition of serotonin or norepinephrine reuptake.



-It's suggested in recent studies that glutamate transmission is not regulated normally in multiple parts of the brain in individuals with depression.

-Antagonism of the NMDA receptor and AMPA receptor activation cause release of BDNF and the activation of kinases.

-The presence of BDNF triggers neurogenesis and bring about synaptic excitability and change.

BDNF-brain derived neurotrophic factor

AMPA- a chemical messenger that mimics the affects of glutamate

## Informed Consent

I, \_\_\_\_\_ hereby give my consent to the following procedure.

### Spravato nasal treatment for depression

I understand the risks include but are not limited to: dissociation, dizziness, nausea, sedation, vertigo, headache, dysgeusia, hypoesthesia, anxiety, lethargy, increase in blood pressure, 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.

Furthermore, by signing below I am confirming that I have received a reviewed the pre-treatment instructions, post-treatment instructions and that I can fully comply.

\_\_\_\_ I understand that during my Spravato nasal treatment that I will be video monitored for my safety.

\_\_\_\_ I understand that I may not drive nor operate machinery for at least 12 hours after my nasal treatment is completed, and 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. By signing this document, I am giving my consent for such a series.

\_\_\_\_ I understand that Spravato nasal treatment is not a substitute for the continued behavioral medicine treatment. My provider will determine if any oral medications or other treatments may be stopped if my depression improves.

Patient name: Print \_\_\_\_\_

Date/time: \_\_\_\_\_

Patient Signature or Guardian: \_\_\_\_\_

Date/time: \_\_\_\_\_

Provider: \_\_\_\_\_

Date/time: \_\_\_\_\_

I have carefully explained the nature of Spravato nasal treatment to \_\_\_\_\_. I hereby certify that to the best of my knowledge, the individual signing this consent form understands the nature, conditions, risks and potential benefits involved in participating in Spravato nasal treatment. A medical problem or language or education barrier has not precluded a clear understanding of the subject's involvement in Spravato nasal treatment.

Witness: \_\_\_\_\_

Date/time: \_\_\_\_\_

Today's date: \_\_\_\_\_

Patient name: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

\_\_\_\_I have received a thorough explanation about the use of Spravato for major depression and I had the opportunity to ask all the relevant questions I felt necessary.

\_\_\_\_I voluntarily requested Susan Lally's team at Medical Park Associates to administer Spravato for the treatment of my condition.

\_\_\_\_I understand that I can revoke this content at any time including during treatment.

\_\_\_\_I understand that the duration of the treatment will be approximately two hours, and I understand that it will be necessary for me to stay in the office for a while after treatment ends, depending on my condition and readiness for discharge for my safety.

\_\_\_\_I am aware that potential side effects include: dissociation, dizziness, nausea, vomiting, sedation, vertigo, headache, dysgeusia, hypoesthesia, anxiety, lethargy, increased blood pressure, insomnia, and diarrhea.

\_\_\_\_I am aware that Spravato treatment is for the treatment of Major Depression and is approved by the Food and Drug Administration.

\_\_\_\_I am aware and understand that the Spravato nasal spray is indicated in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults.

Spravato is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after Spravato administration. Spravato must never be dispensed directly to a patient for home use.

Spravato is not approved as an anesthetic agent. The safety and effectiveness of Spravato as an anesthetic agent have not been established.

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

Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness Name (print) \_\_\_\_\_

## Frequently Asked Questions:

### Is Spravato safe?

Spravato is a very safe depression medication under the direction and observation of properly trained healthcare professionals. The appropriate dosage is determined by your physician, which is well below the dosage necessary to induce general anesthesia. Spravato is used to treat patients who experience treatment resistant depression.

### 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. Many drugs used in anesthesia practice have the potential for abuse, so Spravato is not unique in this respect. The key is to administer the right dose, to the right patient, in an appropriate setting.

### Is intranasal Spravato the only way to deliver Spravato for treatment resistant depression?

Spravato is only administered intranasally. The effectiveness and predictability of response and the overwhelming majority of scientific studies of Spravato for depression have been performed using intranasal Spravato.

### 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 significant, they often vary from patient to patient. Changes can be subtle and can take time to manifest. Our team will work closely with you to identify and evaluate changes or benefits as they occur.

### What should I expect during my first initial Spravato visit?

After we have received your medical and psychiatric history and completed acknowledgement of ongoing care by a mental health professional or general health care provider, we will schedule an initial consultation. At the initial consultation, we will discuss all your options regarding treatment for depression and assess if you are a good candidate for Spravato treatment. Once insurance benefits and authorizations have been completed and you have been enrolled in the Spravato REMS program, your first treatment can be scheduled.

You will need to plan to have someone drive you to and from the appointment. Plan to wear something comfortable and avoid eating anything up to 4 hours prior to your appointment. You may have clear liquids up to 2 hours before your appointment. You may bring something to read or listen to relaxing music from your phone, so don't forget your headphones or ear buds.

When you arrive at your appointment we will take you to a treatment room, take your blood pressure, heart rate and oxygen saturation levels. We will adjust your seat position into a recline at a 45 degree angle in one of our comfy recliners. After this we will help you administer the first dose. Depending on the amount you are taking we will wait 5 minutes between each dose. We will monitor you for approximately 120 minutes (2 hours) before you are assessed for discharge with your driver.

### How many intranasal administrations do I need?

The first phase of treatment (1-4 weeks) 2 visits per week to the office are required. From the 5<sup>th</sup> week to the 8<sup>th</sup> week only one visit per week is needed for treatment. The maintenance phase is from the 9<sup>th</sup> week on and treatment times may vary from patient to patient. The series of administration phases have proven much more effective to treat depression. We also recommend therapy in between treatments to help you process how you feel, because this is not a cure but a piece of a multi-modal approach.

### Can I continue to take my regular medications?

Yes, you should not stop your antidepressant medications in order to receive Spravato. However, all medications need to be reviewed prior to beginning treatments.

### Is Spravato addicting?

Spravato is not physically addicting, but could be psychologically addicting for those who use it recreationally at much higher doses and increased frequencies.

### How much does Spravato cost?

The cost of Spravato is dependent on your insurance plan. Janssen CarePath also works with your insurance plan to offer access and affordability options, as well.

### What if I miss a dose?

If you miss a dose and your depression symptoms worsen, give us a call to schedule an appointment.

## Patient Support:

The following link takes you to the *SPRAVATO withMe* program and can answer questions about affordability for people with commercial insurance, government insurance, and for those who are not insured.

<https://www.spravato.com/patient-support-program>

Below is the link for people who do not have health insurance. This program can help cover your medication costs.

[Medicines available through the Patient Assistance Program | Johnson & Johnson Patient Assistance Foundation, Inc \(jipaf.org\)](#)

Below is a FAQ page for the Johnson & Johnson patient assistance program:

[Questions? | Johnson & Johnson Patient Assistance Foundation, Inc \(jipaf.org\)](#)

*SPRAVATO withMe* Care Navigator can help you or your caregiver with understanding your insurance coverage or with challenges that may get in the way of your treatment.

To speak with a Care Navigator at [1-844-4S-WITHME \(1-844-479-4846\)](tel:1-844-4S-WITHME), Monday through Friday, from 8:00 AM to 8:00 PM ET. Multilingual phone support is available.

We hope this provides as much information as you need, but if you still have questions please call us at the office at 252-758-6080 or 252-864-6484.

