Uptown Psych

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Spravato (Esketamine Nasal Spray)

Consent for Nasal Spray Esketamine (Spravato)

1. For the treatment of Treatment-Resistant Depression, I have agreed to receive the following procedure:

2. My doctor, _____has explained to me:
   a. The treatment process
   b. Potential benefits and risks of this treatment
   c. Possible side effects, complications, and contraindications to the use of esketamine
   d. Risks and benefits of other treatment options, including not receiving this treatment
   e. How likely it is that the desired outcome of the procedure will be achieved
   f. I do not have any of the conditions that would prevent me from receiving the procedure
   g. The information contained in this consent form is also described in the Spravato Patient Brochure, Frequently Asked Questions, and Guide to Understanding Treatment-Resistant Depression all of which are included in the Welcome folder and available from your doctor.

3. I understand that;
   a. SPRAVATO™ (esketamine) CIII Nasal Spray is indicated, in conjunction with an oral antidepressant (AD), for the treatment of treatment-resistant depression (TRD) in adults. SPRAVATO™ is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO™ as an anesthetic agent have not been established.
   b. Effectiveness: According to the literature, efficiency emerged within the first 24 hours following administration in about 70% of the cases and the effects typically last for about 2 weeks. Longer or shorter duration of action is possible. Like all medical treatments, I understand that there is no guarantee Spravato Nasal Spray, or any treatment modality, will be successful.

c. Procedure: Use the SPRAVATO™ nasal spray myself under the direct observation of a healthcare provider with a 2-hour monitor after each administration until the healthcare provider determines I am ready to leave the healthcare setting. The Day 1 starting dose of SPRAVATO™ nasal spray is 56 mg (2 devices). A single-use device delivers a total of
28 mg of SPRAVATO™ (each device contains 2 sprays, 1 spray in each nostril). Day 1 starting dose: 56 mg and Subsequent doses: 56 mg or 84 mg twice a week for 4 weeks, then 56 mg or 84 mg once weekly from week 5 to week 8. From week 9 on, 56 mg or 84 mg every 2 weeks then once a month or as recommended by the prescriber.

d. Complications and side effects may occur. Risk for sedation and dissociation after administration. I agree to receive counseling on the risks and the need for monitoring for resolution of sedation and dissociation, and for any changes in my vital signs. Sedation and dissociation can result from treatment with SPRAVATO™ and I must stay after each treatment until these effects resolve. I may feel: sleepy and/or distortion of time and space and illusions, disconnected from myself, my thoughts, feelings and things around me.), derealization, and depersonalization. My blood pressure may increase and may need to be monitored or treated. DRUG INTERACTIONS CNS depressants (e.g.. benzodiazepines, opioids, alcohol): Concomitant use may increase sedation.
Psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil)or monoamine oxidase inhibitors (MAOIs): Concomitant use may increase blood pressure.

e. Potential for abuse and misuse.

f. Ulcerative or Interstitial Cystitis: Cases of ulcerative or interstitial cystitis have been reported in individuals with long-term off-label use or misuse/abuse of ketamine. In clinical studies with SPRAVATO™ nasal spray, there was a higher rate of lower urinary tract symptoms (pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) in SPRAVATO™-treated patients than in placebo-treated patients. No cases of esketamine-related interstitial cystitis were observed in any of the studies, which involved treatment for up to a year. Let your healthcare provider know if you experience any urinary tract and bladder symptoms during the course of treatment with SPRAVATO™ and you may be referred to an appropriate healthcare provider as clinically warranted.

g. A single dose of SPRAVATO™ caused cognitive performance to decline 40 minutes post-dose.

h. Pregnancy: SPRAVATO™ may cause embryo-fetal harm when administered to a pregnant woman. Let us know if you are pregnant or planning to become pregnant during the treatment course.

Initial (if applicable):_____

i. Esketamine is contraindicated in Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation or history of intracerebral hemorrhage or hypersensitivity to esketamine, ketamine, or any of the excipients

j. I should make arrangements to safely leave the healthcare setting and get home.
k. I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO™.
l. I should contact my doctor or inform him/her at my next visit if I believe I have a side effect or reaction from SPRAVATO™.
m. In order to receive SPRAVATO™, I am required to be enrolled in the REMS, and my information will be stored in a database of all patients who receive SPRAVATO™ in the United States. Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me via phone, mail, fax, or email to support administration of the REMS. Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may use, disclose, and share my personal health information for the purpose of the operations of the REMS, including enrolling me into the REMS and administering the REMS, coordinating the dispensing of SPRAVATO™, and releasing and disclosing my personal health information to the Food and Drug Administration (FDA), as necessary, and as otherwise required by law. Further information, including a list of certified pharmacies, is available at www.SPRAVATOrems.com or 1-855-382-6022.

4. You may refuse the medication. If you consent, you may withdraw it at any time by stating such intention to any member of the treating staff.

5. Reasonable alternative treatments are available. In general, alternative treatments for depression include antidepressant medication, transcranial magnetic stimulation and/or electroconvulsive therapy.

6. I have understood and am satisfied with my understanding of the risks and benefits of the procedure as well as the risks and benefits of the alternatives as explained to me. Therefore, I give my consent for the procedure. I authorize the above-named clinician(s) and his or her associates to:

a. Perform the above-described procedure as well as any additional services which are considered needed to treat or correct conditions discovered during the treatment.
b. Determine the need for and allow persons, including interns and personnel in the procedure room during my procedure for medical and/or educational purposes.

_____

_____

Signature of Patient or Authorized Representative Specify Relationship of Authorized Representative

_____

_____

Print Name Date and Time

_____

_____

Witness to the Signature (Not MD/DO) Print Name

_____

Signature of Provider

_____

Print Name, Date and Time