



## Step 1: Identify appropriate adult patients for SPRAVATO<sup>®</sup>



Adult patients with TRD are those with challenging-to-treat major depressive disorder (MDD) who have not adequately responded to at least 2 different oral antidepressants of adequate dose and duration in their current depressive state.<sup>1</sup>

### Important Safety Information (continued)

#### CONTRAINDICATIONS

**SPRAVATO<sup>®</sup> is contraindicated in patients with:**

- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation.
- History of intracerebral hemorrhage.
- Hypersensitivity to esketamine, ketamine, or any of the excipients.

#### WARNINGS AND PRECAUTIONS

**Sedation:** SPRAVATO<sup>®</sup> may cause sedation or loss of consciousness. In some cases, patients

may display diminished or less apparent breathing. In clinical trials, 48% to 61% of SPRAVATO<sup>®</sup>-treated patients developed sedation and 0.3% to 0.4% of SPRAVATO<sup>®</sup>-treated patients experienced loss of consciousness.

Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting. Closely monitor for sedation with concomitant



## Step 2: Educate patients about SPRAVATO<sup>®</sup>

Consider these points when setting expectations about the treatment experience and SPRAVATO<sup>®</sup>:

- SPRAVATO<sup>®</sup> nasal spray can only be administered at a REMS-certified treatment center
- Review the benefits and risks associated with SPRAVATO<sup>®</sup>, including Boxed WARNINGS for sedation, dissociation, abuse and misuse, and suicidal thoughts and behaviors<sup>1</sup>
- SPRAVATO<sup>®</sup> is administered by patients under the direct observation of a healthcare provider who will continue to monitor them for at least 2 hours after administration for side effects<sup>1</sup>
- All patients treated at an outpatient setting must enroll in the REMS program (done at the treatment center)<sup>1</sup>
- Provide your patients with a copy of the **Medication Guide**<sup>1</sup>
- For additional information, patients can go to [spravato.com/trd/preparing-for-treatment](https://spravato.com/trd/preparing-for-treatment)



use of SPRAVATO<sup>®</sup> with CNS depressants (e.g., benzodiazepines, opioids, alcohol).

**Dissociation:** The most common psychological effects of SPRAVATO<sup>®</sup> were dissociative or perceptual changes (including distortion of time, space and illusions), derealization and depersonalization (61% to 84% of SPRAVATO<sup>®</sup>-treated patients developed dissociative or perceptual changes). Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering SPRAVATO<sup>®</sup>; treatment should be initiated only if the benefit outweighs the risk.

Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

**Respiratory Depression:** In postmarketing experience, respiratory depression was observed with the use of SPRAVATO<sup>®</sup>. In addition, there were rare reports of respiratory arrest.

Because of the risks of respiratory depression, patients must be monitored for changes in