Spravato®
速開朗®

Check Your Patients' Suitability for SPRAVATO®

Eligibility[1]

- ☑ 18 year-old or above
- ☑ Not responded to at least two different antidepressants in the current moderate to severe depressive episode (Treatment-resistant depression)
- ☑ Baseline blood pressure <140/90 mmHg for patients <65 years of age and <150/90 mmHg for patients ≥65 years of age

Contraindications[1]

- ☒ Hypersensitivity to the active substance, ketamine, or to any of the excipients
- ☒ Patients for whom an increase in blood pressure or intracranial pressure poses a serious risk:
  - Patients with aneurysmal vascular disease (including intracranial, thoracic, or abdominal aorta, or peripheral arterial vessels)
  - Patients with history of intracerebral haemorrhage
  - Recent (within 6 weeks) cardiovascular event, including myocardial infarction (MI)

Check if your patients have below conditions

Clinically significant or unstable cardiovascular or respiratory conditions[1]

Examples of conditions which should be considered include, but are not limited to:

- Significant pulmonary insufficiency, including COPD
- Sleep apnoea with morbid obesity (BMI ≥35);
- Patients with uncontrolled brady- or tachyarrhythmias that lead to haemodynamic instability;
- Patients with a history of an MI. These patients should be clinically stable and cardiac symptom free prior to administration;
- Haemodynamically significant valvular heart disease or heart failure (NYHA Class III-IV)

Only Initiate Treatment if BENEFIT OUTWEIGHS RISK

Other conditions that require caution

- Presence or history of psychosis
- Presence or history of mania or bipolar disorder
- Hyperthyroidism that has not been sufficiently treated
- History of brain injury, hypertensive encephalopathy, intrathecal therapy with ventricular shunts, or any other condition associated with increased intracranial pressure

Only Initiate Treatment if BENEFIT OUTWEIGHS RISK

ASSESS PATIENTS' CONDITIONS carefully before prescribing

Special populations[1]

Severe (Child-Pugh class C) hepatic impairment:
Use of SPRAVATO® is not recommended

Pregnancy and breast-feeding:
Use of SPRAVATO® is not recommended

Patients with prior elevated blood pressure*:
Initiate treatment only if the benefit outweighs the risk

*General guide for elevated baseline blood pressure: >140/90 mmHg for patients <65 years of age and >150/90 mmHg for patients ≥65 years of age

Medicinal products that might interact with SPRAVATO®[1]

- Concomitant use of SPRAVATO® with CNS depressants may increase sedation
- Blood pressure should be closely monitored if SPRAVATO® is used concomitantly with psychostimulants and other medicinal products that may increase blood pressure

PLEASE REFER TO THE FULL PRESCRIBING INFORMATION FOR FURTHER SAFETY DETAILS BEFORE PRESCRIBING.

Reference: 1. SPRAVATO® Hong Kong Prescribing Information P02.

SPRAVATO®
ABBREVIATED PRESCRIBING INFORMATION
ACTIVE INGREDIENT(S): esketamine (as hydrochloride) **INDICATION(S):** Spravato, in combination with a SSRI or SNRI, is indicated for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode. Spravato, co-administered with oral antidepressant therapy, is indicated in adults with a moderate to severe episode of Major Depressive Disorder, as acute short-term treatment, for the rapid reduction of depressive symptoms, which according to clinical judgement constitute a psychiatric emergency. **DOSAGE & ADMINISTRATION:** The decision to prescribe Spravato should be determined by a psychiatrist. Spravato is intended to be self-administered by the patient under the direct supervision of a healthcare professional. Assessment before treatment - Prior to dosing with Spravato blood pressure should be assessed. Post-administration observation - After dosing with Spravato, blood pressure should be reassessed at approximately 40 minutes and subsequently as clinically warranted. Recommended dosing for Spravato in adults <65 years with treatment-resistant Major Depressive Disorder - Induction phase, Weeks 1-4: Starting day 1 dose: 56 mg; Subsequent doses: 56 mg or 84 mg twice a week); Maintenance phase, Weeks 5-8: 56 mg or 84 mg once weekly; From Week 9: 56 mg or 84 mg every 2 weeks or once weekly. Recommended dosing for Spravato in adults ≥65 years with treatment-resistant Major Depressive Disorder - Induction phase, Weeks 1-4: Starting day 1 dose: 28 mg; Subsequent doses: 28 mg, 56 mg or 84 mg twice a week* ; Maintenance phase, Weeks 5-8: 28 mg, 56 mg or 84 mg once weekly* ; From Week 9: 28 mg, 56 mg or 84 mg every 2 weeks or once weekly* (*All dose changes should be in 28 mg increments.) Evidence of therapeutic benefit should be evaluated at the end of induction phase to determine need for continued treatment. The need for continued treatment should be reexamined periodically. After depressive symptoms improve, treatment is recommended for at least 6 months. Acute short-term treatment of psychiatric emergency due to Major Depressive Disorder - Recommended dosage of Spravato for adult patients (<65 years) is 84 mg twice per week for 4 weeks. Dosage reduction to 56 mg should be made based on tolerability. After 4 weeks of treatment with Spravato, the oral antidepressant (AD) therapy should be continued, per clinical judgement. Patients should be advised not to eat for at least 2 hours before administration and not to drink liquids at least 30 minutes prior to administration. Patients who require a nasal corticosteroid or nasal decongestant on a dosing day should be advised not to administer these medicinal products within 1 hour before Spravato administration. Patients who have missed treatment session(s) during the first 4 weeks of treatment should continue with their current dosing schedule. For patients with treatment-resistant Major Depressive Disorder who miss treatment session(s) during maintenance phase and have worsening of depression symptoms, per clinical judgement, consider returning to the previous dosing schedule. Efficacy of Spravato in Japanese patients has been studied, but not established. Method of administration - For nasal use only. Do not prime before use. **CONTRAINDICATIONS:** Hypersensitivity to the active substance, ketamine, or to any of the excipients listed in the full prescribing information. Patients for whom an increase in blood pressure or intracranial pressure poses a serious risk: Patients with aneurysmal vascular disease (including intracranial, thoracic, or abdominal aorta, or peripheral arterial vessels); Patients with history of intracerebral haemorrhage; Recent (within 6 weeks) cardiovascular event, including myocardial infarction (MI). **SPECIAL WARNINGS & PRECAUTIONS:** Suicide/suicidal thoughts or clinical worsening - Effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behaviour has not been demonstrated. Use of Spravato does not preclude the need for hospitalisation if clinically warranted, even if patients experience improvement after an initial dose of Spravato. Close supervision of patients especially in early treatment and following dose changes. Patients and caregivers should be alerted to the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour and to seek medical advice immediately if these symptoms present. Patients with a history of suicide-related events or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts and should receive careful monitoring during treatment. Neuropsychiatric and motor impairments - Spravato has been reported to cause somnolence, sedation, dissociative symptoms, perception disturbances, dizziness, vertigo and anxiety during the clinical trials. At each treatment session, patients should be monitored under the supervision of a healthcare professional to assess when the patient is considered stable based on clinical judgement. Respiratory depression - Respiratory depression may occur at high doses following rapid intravenous injection of esketamine or ketamine when used for anaesthesia. Close monitoring is required for sedation and respiratory depression. Effect on blood pressure - Spravato can cause transient increases in systolic and/or diastolic blood pressure which peak at approximately 40 minutes after administration of the medicinal product and last approximately 1-2 hours. A substantial increase in blood pressure could occur after any treatment session. Spravato is contraindicated in patients for whom an increase in blood pressure or intracranial pressure poses a serious risk. Before prescribing Spravato, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of Spravato outweigh its risks. In patients whose blood pressure prior to dose administration is judged to be elevated, it is appropriate to adjust lifestyle and/or pharmacologic therapies to reduce blood pressure before starting treatment with Spravato. If blood pressure is elevated prior to Spravato administration a decision to delay Spravato therapy should take into account the balance of benefit and risk in individual patients. Blood pressure should be monitored after dose administration. Blood pressure should be measured around 40 minutes post-dose and subsequently as clinically warranted until values decline. If blood pressure remains elevated for a prolonged period of time, assistance should promptly be sought from practitioners experienced in blood pressure management. Patients who experience symptoms of a hypertensive crisis should be referred immediately for emergency care. Patients with clinically significant or unstable cardiovascular or respiratory conditions - Only initiate treatment with Spravato in patients with clinically significant or unstable cardiovascular or respiratory conditions if the benefit outweighs the risk. Spravato should be administered in a setting where appropriate resuscitation equipment and healthcare professionals with training in cardiopulmonary resuscitation are available. Refer to the full prescribing information for examples of conditions. Drug abuse, dependence, withdrawal - Individuals with a history of drug abuse or dependence may be at greater risk for abuse and misuse of Spravato. Prior to prescribing Spravato, each patient's risk for abuse or misuse should be assessed and patients receiving esketamine should be monitored for the development of behaviours or conditions of abuse or misuse, including drug seeking behaviour, while on therapy. Dependence and tolerance have been reported with prolonged use of ketamine. In individuals who were dependent on ketamine, withdrawal symptoms of cravings, anxiety, shaking, sweating and palpitations have been reported upon discontinuing ketamine. Ketamine, the racemic mixture of arketamine and esketamine, is a medicinal product that has been reported to be abused. The potential for abuse, misuse and diversion of Spravato is minimised due to the administration taking place under the direct supervision of a healthcare professional. Spravato contains esketamine and may be subject to abuse and diversion. Other populations at risk - Use with caution in patients with the following conditions. These patients should be carefully assessed before prescribing Spravato and treatment initiated only if the benefit outweighs the risk: (i) Presence or history of psychosis; (ii) Presence or history of mania or bipolar disorder; (iii) Hyperthyroidism that has not been sufficiently treated; (iv) History of brain injury, hypertensive encephalopathy, intrathecal therapy with ventricular shunts, or any other condition associated with increased intracranial pressure. Elderly (65 years of age and older) - May have a greater risk of falling once mobilised, therefore, these patients should be carefully monitored. Severe hepatic impairment - Due to expected increase in exposure and lack of clinical experience, Spravato is not recommended in patients with Child-Pugh class C (severe) hepatic impairment. Hepatotoxicity has been reported with chronic ketamine use, so the potential for such an effect due to long-term use of Spravato cannot be excluded. Urinary tract symptoms - Urinary tract and bladder symptoms have been reported with Spravato use. Recommended to monitor for urinary tract and bladder symptoms during the course of treatment and refer to an appropriate healthcare provider when symptoms persist. **SIDE EFFECTS:** The most commonly observed adverse reactions in treatment resistant depression patients treated with Spravato were dizziness, nausea, dissociation, headache, somnolence, vertigo, dysgeusia, hypoaesthesia, and vomiting. Refer to the full prescribing information for other side effects. **PREGNANCY & LACTATION:** Spravato is not recommended during pregnancy and in women of childbearing potential not using contraception. There are no or limited data on the use of esketamine in pregnant women. If a woman becomes pregnant while being treated with Spravato, treatment should be discontinued, and the patient should be counselled about the potential risk to the foetus and clinical/therapeutic options as soon as possible. It is unknown whether esketamine is excreted in human milk. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from Spravato therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. **INTERACTIONS:** Concomitant use of Spravato with CNS depressants (e.g., benzodiazepines, opioids, alcohol) may increase sedation, which therefore should be closely monitored. Blood pressure should be closely monitored when Spravato is used concomitantly with psychostimulants (e.g., amphetamines, methylphenidate, modafanil, armodafinil) or other medicinal products that may increase blood pressure (e.g. xanthine derivatives, ergometrine, thyroid hormones, vasopressin, or MAOIs, such as, tranylcypromine, selegiline, phenelzine). **PLEASE REFER TO FULL PRESCRIBING INFORMATION BEFORE PRESCRIBING.** Spravato aPI ver.2.0

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