Direct Healthcare Professional Communication

janssen Neuroscience
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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Spravato®▼(esketamine) nasal spray: patients required to be enrolled in the Register And Alert System before administration to mitigate the risk of drug abuse

Dear Healthcare Professional,

Janssen, in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA), would like to inform you of the following:

Spravato contains esketamine and may be subject to abuse and diversion - to minimise these risks, administration must be directly supervised by a healthcare professional and all patients enrolled to the Spravato Register And Alert System.

Summary

- From 1 April 2022 the Spravato® Register And Alert System will be available to mitigate the risk of drug abuse by enabling prescribers to identify patients who have received esketamine at other institutions/ hospitals (to mitigate the risk of doctor shopping).
- Individuals with a history of drug abuse or dependence may be at greater risk for abuse and misuse of esketamine.
- Prior to prescribing esketamine, 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.
- From 20 April 2022, all patients being prescribed Spravato (for any indication) must be enrolled onto the Spravato Register And Alert System at https://spravatoregister.clinpal.com.
- All patients must be enrolled before first prescription or within 24 hours of the first administration in case of the need for emergency administration or system technical issues preventing patient enrolment. Existing patients must be enrolled before their next prescription.
- Before registering for access to the System, please review the Healthcare Professional (HCP) Privacy Policy available at https://spravatoregister.clinpal.com. For your convenience, please find attached the copy of this policy.
- Before enrolling a patient onto the System, please inform the patient that personal information will be collected (name, surname, date of birth, treatment start date, treatment end date) and provide the patient with a copy of the Patient Privacy Policy which outlines how their information is collected and used (available within the Register). For your convenience, please find attached the copy of this policy.

Updated Risk Minimisation Materials

Important identified risks for Spravato include:

1. **Transient dissociative states and perception disorders**

   Dissociation describes a range of experiences, such as transient distortions of time and space, change in perception of what people feel, see or hear.

2. **Disturbances in consciousness**

   Disturbances in consciousness include a range of reported symptoms from sedation, altered state of consciousness, consciousness fluctuating, depressed level of consciousness and loss of consciousness, to lethargy, somnolence, sopor and stupor.

3. **Increased blood pressure**

   Esketamine can cause transient increases in systolic and/or diastolic blood pressure.

4. **Drug abuse**

   Signs of abuse may include attempted diversion (attempt to obtain more nasal sprays), drug-seeking behaviour (requesting more frequent or higher doses without medical need), and other symptoms of drug craving or withdrawal.

The newly updated Risk Minimisation Materials have been put in place to minimise these risks.

HCP Guide titled: 'Risk minimisation measures in patients treated with Spravato® (esketamine) nasal spray', EM-93062, March 2022

HCP Checklist titled: 'Spravato® (esketamine) nasal spray: Checklist for healthcare professionals', EM-93063, March 2022

Patient Guide titled: 'Spravato® (esketamine) nasal spray: What are the risks? A guide for patients', EM-93061, March 2022

Actions relating to the risk minimisation materials:

- Distribute the risk minimisation materials to healthcare professionals involved in the prescribing and administration of esketamine.
- Before administration of esketamine takes place, read the risk minimisation materials carefully.
- Share the patient guide with your patients before esketamine administration.
- Complete the Checklist for Healthcare Professionals for every patient before discharge after esketamine administration.

Background for introduction of the Spravato® Register And Alert System

Therapeutic Indications:

- Esketamine, 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.

- Esketamine, 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

Esketamine is classified as a Schedule 2 controlled substance in the UK. The evidence from an esketamine abuse potential trial in non-dependent, recreational polydrug users of perception-altering drugs (Trial 54135419TRD1015) suggests that the potential for abuse is similar to that of ketamine, a known drug of abuse recreationally. However, no evidence of drug-seeking behaviour was observed, and no confirmed cases of diversion were reported in clinical trials of esketamine.

To mitigate the risk of drug abuse the MHRA requested additional Risk Minimisation Measures including a Controlled Access Programme (including the Spravato® Register And Alert system).

Call for reporting

Spravato®▼(esketamine) nasal spray is subject to additional monitoring. This will allow quick identification of new safety information.

Please report ANY suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Drug dependency can be reported as an adverse drug reaction.

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Suspected adverse reactions should also be reported to Janssen-Cilag Limited, on tel: +44 (0)1494 567447, or by e-mail at dsafety@its.jnj.com.

Company contact points

If you have further questions or require additional information, please contact the Janssen Medical Information Department via e-mail at medinfo@its.jnj.com or by telephone at 0800 731 8450.

Yours Faithfully,

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