17 October 2019
EMA/557804/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Spravato

esketamine

On 17 October 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Spravato, intended for combination treatment in adults with treatment-resistant major depressive disorder. The applicant for this medicinal product is Janssen-Cilag International N.V.

Spravato will be available as a 28 mg nasal spray solution. The active substance of Spravato is esketamine, a Psychoanaleptic, Other antidepressants (ATC code: N06AX27). The antidepressant effect of esketamine is mediated via its antagonist activity on N-methyl-D-aspartate receptor (NMDAR) which produces a transient increase in glutamate release.

The benefits with Spravato are its ability to reduce a broad range of depressive symptoms in patients with a moderate to severe depressive episode that has not responded to at least two different treatments with antidepressants. The most common side effect are dizziness, nausea, dissociation, headache, somnolence and vertigo.

The full indication is: “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”. Treatment with Spravato should be initiated by psychiatrists to ensure a correct diagnosis of treatment-resistant major depressive disorder.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union