EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Spravato

esketamine

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AUTHORISED
This medicine is authorised for use in the European Union.

Overview

Spravato is a medicine used to treat adults with major depression that is resistant to treatment. It is used in combination with an SSRI or SNRI medicine (other antidepressants) when at least two other treatments have failed.

Spravato contains the active substance esketamine.

How is Spravato used?

Spravato is available as a nasal spray to be used by the patient in a clinic or doctor's office, under the direct supervision of a healthcare professional.

The recommended starting dose is one or two sprays in each nostril (depending on the patient's age) on the first day. This is followed by 1, 2 or 3 sprays in each nostril twice a week for 4 weeks. Afterwards, if the patient's depression improves, Spravato should be used once a week for the next 4 weeks and then once every 1 or 2 weeks for at least 6 months.

Because Spravato can increase blood pressure, patients' blood pressure should be measured before and after using Spravato. Patients with serious respiratory or heart problems should only use Spravato where facilities for resuscitating patients are immediately available.

Spravato can only be obtained with a prescription and the decision to start treatment should be taken by a psychiatrist. For more information about using Spravato, see the package leaflet or contact your doctor or pharmacist.

How does Spravato work?

The active substance in Spravato, esketamine, is an antidepressant. It acts on receptors (targets) in the brain for a substance called NMDA. NMDA regulates the transmission of signals between cells in brain areas involved in the regulation of mood. By acting on these NMDA receptors, esketamine can help improve the symptoms of depression.

What benefits of Spravato have been shown in studies?

Studies in around 1,800 patients have shown that Spravato taken with an SSRI or SNRI relieves symptoms of treatment-resistant depression as measured using a standard scoring system known as MADRS.

In a 4-week study, MADRS symptoms scores improved by 3.5 points more in patients treated with Spravato (plus an SSRI or SNRI) than in those treated with placebo (also with an SSRI or SNRI), a difference that is considered clinically relevant. Similar improvements were achieved in two other short-term studies, although the results were not as robust. The results of the three studies taken together convincingly showed that, overall, Spravato was more effective than placebo.

In a fourth long-term study, Spravato was shown to be effective at preventing relapses of depression. The proportion of patients given Spravato (plus an SSRI or SNRI) who relapsed during the study was 27%, compared with 45% in the placebo group (also given an SSRI or SNRI). A fifth study lasting around 1 year showed that the benefits of Spravato (plus an SSRI or SNRI) were maintained long-term.

What are the risks associated with Spravato?

The most common side effects with Spravato (which may affect up to 3 in 10 people) are dizziness, nausea (feeling sick), dissociation (feeling of being disconnected from physical surroundings and emotions), headache, sleepiness, vertigo (a spinning sensation), dysgeusia (taste disturbances), hypoaesthesia (reduced sense of touch) and vomiting. For the full list of side effects of Spravato, see the package leaflet.

Spravato must not be used in patients with weaknesses in blood vessel walls that might rupture if blood pressure goes up, patients who have had bleeding in the brain and patients who recently had a heart attack. For the full list of restrictions, see the package leaflet.

Why is Spravato authorised in the EU?

Studies showed that Spravato, added to SSRI or SNRI antidepressants, improves symptoms of major depression that have not improved with other treatment, both in the short- and in the long-term. Furthermore, the safety of Spravato was considered acceptable and its side effects manageable.

Because of risk of patients misusing this medicine or becoming addicted to it, Spravato will only be available under a special prescription and must be taken under direct supervision of a healthcare professional. The European Medicines Agency concluded that with these restrictions in place the benefits of Spravato are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Spravato?

The company that markets Spravato will provide educational material for doctors and a guide for patients with important information about Spravato's side effects, its risks and how to use the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Spravato have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Spravato are continuously monitored. Side effects reported with Spravato are carefully evaluated and any necessary action taken to protect patients.

Other information about Spravato

Spravato received a marketing authorisation valid throughout the EU on 18 December 2019.

Spravato : EPAR - Medicine overview (PDF/123.14 KB)

First published: 19/12/2019
EMA/578240/2019

Available languages (22)

Spravato : EPAR - Risk-management-plan summary (PDF/160.48 KB)

First published: 19/12/2019
Last updated: 06/07/2021

This EPAR was last updated on 14/07/2023

Authorisation details

Name
Spravato
Agency product number
EMEA/H/C/004535
Active substance
esketamine hydrochloride
International non-proprietary name (INN) or common name
esketamine
Therapeutic area (MeSH)

Depressive Disorder

Anatomical therapeutic chemical (ATC) code

N06AX27

Additional monitoring ▼

This medicine is under additional monitoring, meaning that it is monitored even more intensively than other medicines. For more information, see Medicines under additional monitoring.

Marketing-authorisation holder

Janssen-Cilag International NV

Revision

8

Date of issue of marketing authorisation valid throughout the European Union

18/12/2019

Contact address

Turnhoutseweg 30
B-2340 Beerse
Belgium

Product information

04/07/2023 Spravato - EMEA/H/C/004535 - IB/0019/G

Spravato : EPAR - Product Information (PDF/1.82 MB)

First published: 19/12/2019
Last updated: 14/07/2023

Available languages (24)

This medicine's product information is available in all **official EU languages**.

Select 'available languages' to access the language you need.

Product information documents contain:

- summary of product characteristics (annex I);
- manufacturing authorisation holder responsible for batch release (annex IIA);
- conditions of the marketing authorisation (annex IIB);
- labelling (annex IIIA);
- package leaflet (annex IIIB).

You can find product information documents for centrally authorised human medicines on this website. For centrally authorised veterinary medicines authorised or updated from February 2022, see the Veterinary Medicines Information website.

Spravato : EPAR - All Authorised presentations (PDF/35.26 KB)

First published: 19/12/2019
Last updated: 31/08/2022

Available languages (24)

Spravato : EPAR - Conditions imposed on member states for safe and effective use (PDF/62.69 KB)

First published: 08/03/2021

Available languages (24)

Pharmacotherapeutic group

Other antidepressants

Therapeutic indication

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.

Assessment history

Changes since initial authorisation of medicine

Spravato : EPAR - Procedural steps taken and scientific information after authorisation (PDF/174.98 KB)

First published: 29/10/2020
Last updated: 14/07/2023

Spravato-H-C-PSUSA-00010825-202203 : EPAR - Scientific Conclusion (PDF/116.87 KB)

Adopted

First published: 01/03/2023
EMA/97281/2023

Spravato-H-C-4535-II-0001-G : EPAR - Assessment report - Variation (PDF/3.32 MB)

Adopted

First published: 08/03/2021
EMA/141382/2021

CHMP post-authorisation summary of positive opinion for Spravato (II-0001-G) (PDF/132.48 KB)

Adopted

First published: 11/12/2020
EMA/CHMP/654550/2020

Initial marketing-authorisation documents

Spravato : EPAR - Public assessment report (PDF/3.37 MB)

Adopted

First published: 19/12/2019
EMA/614876/2019

CHMP summary of positive opinion for Spravato (PDF/69.11 KB)

Adopted

First published: 18/10/2019
EMA/557804/2019

News

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 7-10 December 2020
  11/12/2020
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 14-17 October 2019
  18/10/2019

Related content

- Spravato: Paediatric investigation plan

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