Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311827 SPRAVATO esketamine (as hydrochloride) 28 mg per 2 actuations nasal spray solution
ARTG entry for	Medicine Registered
Sponsor	Janssen-Cilag Pty Ltd
Postal Address	Locked Bag 2070, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date	9/03/2021
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Medicine under additional monitoring

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . SPRAVATO esketamine (as hydrochloride) 28 mg per 2 actuations nasal spray solution

Product Type Single Medicine Product **Effective Date** 21/09/2022

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

SPRAVATO is indicated for treatment resistant depression (Major Depressive Disorder in adults who have not responded adequately to at least two different antidepressants of adequate dose and duration to treat the current moderate to severe depressive episode).,SPRAVATO is to be initiated in conjunction with a newly initiated oral antidepressant.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

Container information

Type	Material	Life Time	Temperature	Closure	Conditions

Aerosol - Pump Actuated Metered Dose	Glass Type I Clear	36 Months	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded
Aerosol - Pump Actuated Metered Dose	Plastic	36 Months	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
2 Nasal Spray (vial and device combination)	(S8) Controlled Drug
1 Nasal Spray (vial and device combination)	(S8) Controlled Drug
3 Nasal Spray (vial and device combination)	(S8) Controlled Drug

Components

1 . SPRAVATO esketamine (as hydrochloride) 28 mg per 2 actuations nasal spray solution

Dosage Form	Spray, nasal
Route of Administration	Nasal
Visual Identification	Clear colourless to slightly yellowish aqueous solution packaged in Type 1 glass vial, rubber stopper and assemble inside a single use nasal spray device

Active Ingredients

esketamine hydrochloride	**32.3 mg**
Equivalent: esketamine	28 mg

Other Ingredients (Excipients)

citric acid monohydrate

disodium edetate

sodium hydroxide

water for injections