Public Summary

Summary for ARTG Entry:	181978 Sativex Oromucosal Spray, nabiximols 80 mg/mL pump actuated metered dose aerosol
ARTG entry for	Medicine Registered
Sponsor	Chiesi Australia Pty Ltd
Postal Address	Suite 3 22 Gillman Street, Hawthorn East, VIC, 3123 Australia
ARTG Start Date	26/11/2012
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Conditions

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.

Products

1 . Sativex Oromucosal Spray, nabiximols 80 mg/mL pump actuated metered dose aerosol

Product Type	Single Medicine Product	**Effective Date**	4/08/2021

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

Sativex is indicated as treatment, for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Aerosol - Pump Actuated Metered Dose	Glass Type I Coloured	24 Months	Store at 2 to 8 degrees Celsius	Restricted flow insert	Refrigerate Store Upright Replace the cover firmly after use

Pack Size/Poison information

Pack Size	Poison Schedule
10 mL	(S8) Controlled Drug

Components

1 . Sativex Oromucosal Spray, nabiximols 80 mg/mL pump actuated metered dose aerosol

Dosage Form	Spray, solution
Route of Administration	Oromucosal
Visual Identification	Yellow/brown solution in a brown, plastic-coated glass spray container

Active Ingredients

nabiximols	**80 mg/mL**

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Other Ingredients (Excipients)

ethanol absolute

Peppermint Oil

propylene glycol

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