




Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	328860	EPIDYOLEX cannabidiol 100 mg/mL oral liquid solution bottle
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	21/09/2020	
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 party 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 . EPIDYOLEX cannabidiol 100 mg/mL oral liquid solution bottle

Product Type	Single Medicine Product	Effective Date	15/09/2023
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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

EPIDYOLEX is indicated for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) for patients 2 years of age and older.

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
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Bottle Glass Type III 2 Years Store below 25 degrees Celsius Child resistant closure and restricted flow insert Not recorded

Pack Size/Poison information

Pack Size 100 mL
Poison Schedule (S4) Prescription Only Medicine

Components

1 . EPIDYOLEX cannabidiol 100 mg/mL oral liquid solution bottle

Dosage Form Oral Liquid, solution
Route of Administration Oral
Visual Identification Clear, colourless to yellow solution

Active Ingredients

cannabidiol 100 mg/mL

Other Ingredients (Excipients)

ethanol absolute
Flavour
sesame oil
sucralose

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