Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	342815 KALYDECO ivacaftor 25 mg granules sachet
ARTG entry for	Medicine Registered
Sponsor	Vertex Pharmaceuticals Australia Pty Ltd
Postal Address	Suite 3 Level 3 / 601 Pacific Highway, ST LEONARDS, NSW, 2065 Australia
ARTG Start Date	24/09/2021
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

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 . KALYDECO ivacaftor 25 mg granules sachet

Product Type	Single Medicine Product	**Effective Date**	13/06/2024

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

KALYDECO is indicated for the treatment of cystic fibrosis (CF) in patients aged 4 months and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data(see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE, and Section 5.1 PHARMACODYNAMIC PROPERTIES).

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Sachet	Other composite material	36 Months	Store below 30 degrees Celsius	Neither child resistant closure nor restricted	Not recorded

flow insert

Pack Size/Poison information

Pack Size	Poison Schedule
56 sachets (containing 4 individual wallets with 14 sachets per wallet)	(S4) Prescription Only Medicine

Components

1 . KALYDECO ivacaftor 25 mg granules sachet

Dosage Form	Granules
Route of Administration	Oral
Visual Identification	Granules are white to off-white, sweetened, unflavoured granules (approximately 2 mm in diameter) enclosed in unit dose sachets

Active Ingredients

ivacaftor	**25 mg**

Other Ingredients (Excipients)

croscarmellose sodium
hypromellose acetate succinate
lactose monohydrate
magnesium stearate
mannitol
silicon dioxide
sodium lauryl sulfate
sucralose