Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 340591 TIVICAY PD dolutegravir (as sodium) 5 mg dispersible tablet bottle

ARTG entry for	Medicine Registered
Sponsor	ViiV Healthcare Pty Ltd
Postal Address	PO Box 18095, MELBOURNE CITY MC, VIC, 8001 Australia
ARTG Start Date	20/09/2021
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 . TIVICAY PD dolutegravir (as sodium) 5 mg dispersible tablet bottle

Product Type Single Medicine Product **Effective Date** 13/09/2023

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

TIVICAY and TIVICAY PD are indicated for the treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in adults and children of at least 4 weeks in age or older and weighing 3 kg or more (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE, Dual regimens).

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

Bottle	HDPE	36 Months	Store below 30 degrees Celsius	Child resistant closure	Store in Original Container Protect from Moisture

Pack Size/Poison information

Pack Size	Poison Schedule
60 tablets	(S4) Prescription Only Medicine

Components

1 . TIVICAY PD dolutegravir (as sodium) 5 mg dispersible tablet bottle

Dosage Form	Tablet, dispersible
Route of Administration	Oral
Visual Identification	White, round, biconvex tablets debossed with SV H7S on one side and 5 on the other side

Active Ingredients

dolutegravir sodium	**5.26 mg**
Equivalent: dolutegravir	5 mg

Other Ingredients (Excipients)

calcium sulfate dihydrate
crospovidone
Flavour
hypromellose
macrogol 400
mannitol
microcrystalline cellulose
povidone
purified water
silicified microcrystalline cellulose
sodium starch glycollate
sodium stearylfumarate
sucralose
titanium dioxide

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