Public Summary

Summary for ARTG Entry:	107072 TRUVADA tenofovir disoproxil fumarate / emtricitabine 300/200 mg tablet bottle
ARTG entry for	Medicine Registered
Sponsor	Gilead Sciences Pty Ltd
Postal Address	Level 28, 385 Bourke Street, Melbourne, VIC, 3000 Australia
ARTG Start Date	22/09/2005
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 . TRUVADA tenofovir disoproxil fumarate / emtricitabine 300/200 mg tablet bottle

Product Type	Single Medicine Product	**Effective Date**	9/04/2024

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

Treatment of HIV-1 infection,TRUVADA is indicated for the treatment of HIV infected adults over the age of 18 years, in combination with other antiretroviral agents.,Pre-Exposure Prophylaxis
TRUVADA is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. This indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples (see CLINICAL STUDIES).

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions

Bottle	HDPE	48 Months	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
30 Tablets	(S4) Prescription Only Medicine

Components

1 . TRUVADA tenofovir disoproxil fumarate / emtricitabine 300/200 mg tablet bottle

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Blue, capsule shaped, film coated tablets debossed with "GILEAD" on one side of the tablet and "701" on the other.

Active Ingredients

emtricitabine	**200 mg**
tenofovir disoproxil fumarate	**300 mg**

Other Ingredients (Excipients)

croscarmellose sodium
hypromellose
indigo carmine aluminium lake
lactose monohydrate
magnesium stearate
microcrystalline cellulose
pregelatinised maize starch
titanium dioxide
triacetin

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