Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

# Public Summary

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| **Summary for ARTG Entry:** | 291923 | BIKTARVY bictegravir (as sodium) 50 mg, emtricitabine 200 mg, tenofovir alafenamide (as fumarate) 25 mg fixed-dose combination tablets bottle |

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|---|---|
| **ARTG entry for** | Medicine Registered |
| **Sponsor** | Gilead Sciences Pty Ltd |
| **Postal Address** | Level 28, 385 Bourke Street, Melbourne, VIC, 3000<br>Australia |
| **ARTG Start Date** | 12/07/2018 |
| **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 . BIKTARVY bictegravir (as sodium) 50 mg, emtricitabine 200 mg, tenofovir alafenamide (as fumarate) 25 mg fixed-dose combination tablets bottle

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|---|---|---|---|
| **Product Type** | Single Medicine Product | **Effective Date** | 22/04/2024 |

**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**

BIKTARVY is indicated for the treatment of HIV-1 infection in adults and paediatric patients weighing at least 25 kg who are antiretroviral therapy (ART)-naïve or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen at the start of therapy with no history of treatment failure, and no known substitutions associated with resistance to the individual components of BIKTARVY.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

*This product is included in the Black Triangle Scheme*

Public Summary

## Container information

| Type | Material | Life Time | Temperature | Closure | Conditions |
|---|---|---|---|---|---|
| Bottle | HDPE | 36 Months | Store below 30 degrees Celsius | Child resistant closure | Not recorded |

## Pack Size/Poison information

| Pack Size | Poison Schedule |
|---|---|
| 30 | (S4) Prescription Only Medicine |

## Components

**1 . BIKTARVY bictegravir (as sodium) 50 mg, emtricitabine 200 mg, tenofovir alafenamide (as fumarate) 25 mg fixed-dose combination tablets bottle**

| | |
|---|---|
| **Dosage Form** | Tablet, film coated |
| **Route of Administration** | Oral |
| **Visual Identification** | Capsule-shaped, film-coated purplish-brown, debossed with GSI on one side of the tablet and 9883 on the other side |

### Active Ingredients

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|---|---|
| **bictegravir sodium** | **52.45 mg** |
| Equivalent: bictegravir | 50 mg |
| **emtricitabine** | **200 mg** |
| **tenofovir alafenamide fumarate** | **28.04 mg** |
| Equivalent: tenofovir alafenamide | mg |

### Other Ingredients (Excipients)

**croscarmellose sodium**
**iron oxide black**
**iron oxide red**
**macrogol 3350**
**magnesium stearate**
**microcrystalline cellulose**
**polyvinyl alcohol**
**purified talc**
**titanium dioxide**