




**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	386895	SUNLENCA lenacapavir (as sodium) 463.5 mg/1.5 mL solution for injection vial
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Gilead Sciences Pty Ltd	
<b>Postal Address</b>	Level 28, 385 Bourke Street, Melbourne, VIC, 3000 Australia	
<b>ARTG Start Date</b>	27/03/2023	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Drug Safety Evaluation Branch	

  
**Medicine under  
additional monitoring**

### Conditions

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.

### Products

#### 1 . SUNLENCA lenacapavir (as sodium) 463.5 mg/1.5 mL solution for injection vial

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	17/10/2023
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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

SUNLENCA, in combination with other antiretrovirals, is indicated for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.

#### 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
Vial	Glass Type I Clear	36 Months	Store below 30 degrees Celsius	Child resistant closure	Protect from Light

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
2 x 1.5 mL vials	(S4) Prescription Only Medicine

#### Components

##### 1 . SUNLENCA lenacapavir (as sodium) 463.5 mg/1.5 mL solution for injection vial

<b>Dosage Form</b>	Injection, solution
<b>Route of Administration</b>	Subcutaneous
<b>Visual Identification</b>	Lenacapavir (LEN) injection, 463.5 mg/1.5mL, is a sterile, preservative-free, clear, yellow to brown solution for subcutaneous administration

#### Active Ingredients

<b>lenacapavir sodium</b>	<b>473.1 mg</b>
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Equivalent: lenacapavir

463.5 mg

**Other Ingredients (Excipients)**

macrogol 300

water for injections

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