




Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	392350	SUNLENCA lenacapavir (as sodium) 300 mg film coated tablet blister pack
ARTG entry for	Medicine Registered	
Sponsor	Gilead Sciences Pty Ltd	
Postal Address	Level 28, 385 Bourke Street, Melbourne, VIC, 3000 Australia	
ARTG Start Date	27/03/2023	
Product Category	Medicine	
Status	Active	
Approval Area	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) 300 mg film coated tablet blister pack

Product Type	Single Medicine Product	Effective Date	28/11/2023
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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
Blister Pack	PVC/Al	36 Months	Store below 30 degrees Celsius	Child resistant closure	Store in Original Container

Pack Size/Poison information

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

Components

1 . SUNLENCA lenacapavir (as sodium) 300 mg film coated tablet blister pack

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	LEN tablets are beige, capsule-shaped, filmcoated tablet, debossed with GSI on one side and 62L on the other side

Active Ingredients

lenacapavir sodium	306.8 mg
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Equivalent: lenacapavir

300 mg

Other Ingredients (Excipients)

copovidone
croscarmellose sodium
iron oxide black
iron oxide red
iron oxide yellow
macrogol 3350
magnesium stearate
mannitol
microcrystalline cellulose
poloxamer
polyvinyl alcohol
purified talc
titanium dioxide

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