



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	222848	HARVONI ledipasvir/sofosbuvir 90 mg/400 mg tablet bottle
ARTG entry for	Medicine Registered	
Sponsor	Gilead Sciences Pty Ltd	
Postal Address	Level 6 / 417 St Kilda Road, MELBOURNE, VIC, 3004 Australia	
ARTG Start Date	13/05/2015	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

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 . HARVONI ledipasvir/sofosbuvir 90 mg/400 mg tablet bottle

Product Type	Single Medicine Product	Effective Date	13/04/2021
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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

HARVONI (ledipasvir/sofosbuvir fixed-dose combination) is indicated for the treatment of chronic hepatitis C (CHC) infection in adults. (see PRECAUTIONS and CLINICAL TRIALS sections for information on the available data for HCV patients of each genotype, see DOSAGE AND ADMINISTRATION section for recommended regimens and treatment durations for different patient subgroups).

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	72 Months	Store below 30 degrees Celsius	Child resistant closure	Store at room temperature

Pack Size/Poison information

Pack Size	Poison Schedule
28 Tablets, Bottle	(S4) Prescription Only Medicine

Components

1 . HARVONI ledipasvir/sofosbuvir 90 mg/400 mg tablet bottle

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Film coated, orange, diamond shaped tablet with "GSI" on one side and "7985" on the other side

Active Ingredients

ledipasvir acetone solvate	95.9 mg
Equivalent: ledipasvir	90 mg

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sofosbuvir

400 mg

Other Ingredients (Excipients)

croscarmellose sodium

lactose monohydrate

macrogol 3350

magnesium stearate

microcrystalline cellulose

polyvinyl alcohol

purified talc

silicon dioxide

sunset yellow FCF aluminium lake

titanium dioxide

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