



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** 21/06/2019

Permitted Indications

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	48 Months	Store below 30 degrees Celsius	Not recorded	Store at room temperature

Pack Size/Poison information

Pack Size 28 Tablets, Bottle **Poison Schedule** (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
sofosbuvir 400 mg

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