



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 211019 SOVALDI sofosbuvir 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** 30/06/2014  
**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. SOVALDI sofosbuvir 400 mg tablet bottle**

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective date</b> | 30/08/2019 |
|---------------------|-------------------------|-----------------------|------------|

**Permitted Indications**

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

SOVALDI is indicated for the treatment of adults with chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. (see CLINICAL TRIALS and DOSAGE AND ADMINISTRATION section for detailed information on the studied combinations, dose regimens, and treatment durations for different subgroups of CHC patients)

**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     | 5 Years   | Store below 30 degrees Celsius | Child resistant closure | Store at room temperature |

**Pack Size/Poison information**

|                  |                                 |
|------------------|---------------------------------|
| <b>Pack Size</b> | <b>Poison Schedule</b>          |
| 28 tablets       | (S4) Prescription Only Medicine |

**Components**

1. SOVALDI sofosbuvir 400 mg tablet bottle

**Dosage Form**

Tablet

**Route of Administration**

Oral

**Visual Identification**

Film coated, yellow, capsule shaped tablet with 'GSI' on one side and '7977' on the other side

**Active Ingredients**

sofosbuvir **400 mg**

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.