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

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Material</th>
<th>Life Time</th>
<th>Temperature</th>
<th>Closure</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottle</td>
<td>HDPE</td>
<td>48 Months</td>
<td>Store below 30 degrees Celsius</td>
<td>Not recorded</td>
<td>Store at room temperature</td>
</tr>
</tbody>
</table>

Pack Size/Poison Information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
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</thead>
<tbody>
<tr>
<td>28 Tablets, Bottle</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>ledipasvir acetone solvate</th>
<th>95.9 mg</th>
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</thead>
<tbody>
<tr>
<td>sofosbuvir</td>
<td>400 mg</td>
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</table>