Public Summary

Summary for ARTG Entry: 338419 VEKLURY remdesivir 100 mg powder for injection vial

ARTG entry for Medicine Registered (Provisional)
Sponsor Gilead Sciences Pty Ltd
Postal Address Level 6 / 417 St Kilda Road, MELBOURNE, VIC, 3004 Australia
ARTG Start Date 10/07/2020
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. VEKLURY remdesivir 100 mg powder for injection vial

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Single Medicine Product</th>
<th>Effective Date</th>
<th>10/07/2020</th>
</tr>
</thead>
</table>

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

Provisionally Registered Indications

VEKLURY has provisional approval for the treatment of Coronavirus Disease 2019 (COVID-19) in adults and adolescents (aged 12 years and older weighing at least 40 kg) with pneumonia, requiring supplemental oxygen. The decision to approve this medicine has been made based on limited data. More comprehensive evidence is required to be submitted.

Provisionally Registered Conditions

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

<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>Vial</td>
<td>Glass Type I Clear</td>
<td>3 Years</td>
<td>Store below 30 degrees Celsius</td>
<td>Not recorded</td>
<td>Not recorded</td>
</tr>
</tbody>
</table>

Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 vial</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

Components

1. VEKLURY remdesivir 100 mg powder for injection vial

Dosage Form
Injection, powder for

Route of Administration
Intravenous Infusion

Produced at 20.09.2020 at 04:23:57 AEST

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information
### Visual Identification
white to off-white to yellow lyophilized solid

### Active Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>remdesivir</td>
<td>100 mg</td>
</tr>
</tbody>
</table>

### Other Ingredients (Excipients)
sulfobutyl betadex sodium

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