Public Summary

Summary for ARTG Entry: 96427  EMTRIVA emtricitabine 200mg capsule blister pack

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 7/01/2005
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. EMTRIVA emtricitabine 200mg capsule blister pack

Product Type Single Medicine Product  Effective date 6/07/2016

Warnings

See Product Information and Consumer Medicine Information for this product

Standard Indications

Emtriva is indicated for the treatment of HIV in combination with other antiretroviral agents in adults and paediatric patients 12 years of age and older, weighing more than 33 kg. Evidence to support this claim is based on surrogate markers (plasma HIV RNA and CD4 count) in antiretroviral naive individuals and in antiretroviral experienced individuals with virological suppression (See Clinical Trials).

Specific Indications

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>Blister Pack</td>
<td>PVC/PE/PCTFE (Aclar)/Al</td>
<td>2 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>
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</thead>
<tbody>
<tr>
<td>30 Capsules</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

Components

1. EMTRIVA emtricitabine 200mg capsule blister pack

Dosage Form Capsule, hard
Route of Administration Oral
Visual Identification Hard Gelatin Capsule with “200 mg” printed on a blue cap and “GILEAD” and corporate logo printed on a white body

Active Ingredients

Emtricitabine 200 mg

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