Summary for ARTG Entry: 95949 SIMVAR 10 simvastatin 10 mg tablet blister pack

ARTG entry for Medicine Registered
Sponsor Arrow Pharma Pty Ltd
Postal Address 15 - 17 Chapel Street, Cremorne, VIC, 3121, Australia
ARTG Start Date 26/11/2003
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. SIMVAR 10 simvastatin 10 mg tablet blister pack

Product Type Single Medicine Product
Effective date 18/09/2018

Permitted Indications
No Indication Requirements included on Record

Indication Requirements
No Standard Indications included on Record

Standard Indications
No Standard Indications included on Record

Specific Indications
SIMVAR 10 is indicated as an adjunct to diet for treatment of hypercholesterolaemia. Prior to initiating therapy with SIMVAR 10, secondary causes of hypercholesterolaemia (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, other drug therapy, alcoholism) should be identified and treated. SIMVAR is indicated in patients at high risk of CHD (with or without hypercholesterolaemia), including patients with diabetes, history of stroke or other cerebrovascular disease, peripheral vessel disease, or with existing CHD to reduce the risk of cardiovascular death, major cardiovascular events including stroke, and hospitalisation due to angina pectoris. These effects do not replace the need to independently control known causes of cardiovascular mortality and morbidity such as hypertension, diabetes and smoking. SIMVAR is indicated as an adjunct to diet in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with heterozygous familial hypercholesterolaemia (HeFH). Prior to initiating therapy with SIMVAR secondary causes of hypercholesterolaemia (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, other drug therapy, alcoholism) should be identified and treated.

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>Blister Pack</td>
<td>PVC/PE/PVDC/Al</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>30</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
<tr>
<td>5 tablets</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

Components

1. SIMVAR 10 simvastatin 10 mg tablet blister pack

Dosage Form Tablet, film coated
Route of Administration Oral
Visual Identification Peach coloured, oval shaped, film-coated tablet, coded with 'E33' on one side and plain on the other side.

Active Ingredients