Public Summary

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

ARTG entry for Medicine Registered
Sponsor Apotex Pty Ltd
Postal Address PO Box 280, NORTH RYDE BC, NSW, 1670 Australia
ARTG Start Date 26/11/2003
Product Category Medicine
Status Active
Approval Area Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11.

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.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1. SIMVASTATIN ARW simvastatin 10 mg tablet blister pack

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Medicine Product</td>
<td>8/09/2021</td>
</tr>
</tbody>
</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
SIMVASTATIN ARW is indicated as an adjunct to diet for treatment of hypercholesterolaemia. Prior to initiating therapy with SIMVASTATIN ARW, 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. SIMVASTATIN ARW 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 SIMVASTATIN ARW 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

Produced at 29.08.2023 at 06:07:58 AEST

This is not an ARTG Certificate document.

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
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. SIMVASTATIN ARW simvastatin 10 mg tablet blister pack

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Tablet, film coated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>Oral</td>
</tr>
<tr>
<td>Visual Identification</td>
<td>Peach coloured, oval shaped, film-coated tablet, coded with ‘E33’ on one side and plain on the other side.</td>
</tr>
</tbody>
</table>

Active Ingredients

- simvastatin 10 mg

Other Ingredients (Excipients)

- ascorbic acid
- butylated hydroxyanisole
- citric acid monohydrate
- hyprolose
- hypromellose
- iron oxide red
- iron oxide yellow
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- pregelatinised maize starch
- purified talc
- titanium dioxide