Public Summary

Summary for ARTG Entry: 61598 XENICAL orlistat 120mg capsule blister pack

ARTG entry for Medicine Registered
Sponsor Roche Products Pty Ltd
Postal Address PO Box 255, DEE WHY, NSW, 2099 Australia
ARTG Start Date 11/04/2000
Product category Medicine
Status Active
Approval area Non-Prescription Medicines

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. XENICAL orlistat 120mg capsule blister pack

Product Type Single Medicine Product
Effective date 18/06/2015

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

Xenical is indicated for the treatment of obese patients with a body mass index (BMI) >= 30, and overweight patients with a BMI >= 27 in the presence of other risk factors, in conjunction with a mildly hypocaloric diet.

Warnings
No Warnings included on Record

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>Not recorded</td>
<td>3 Years</td>
<td>Store below 25 degrees Celsius</td>
<td>Not recorded</td>
<td>Protect from Light</td>
</tr>
<tr>
<td>Blister Pack</td>
<td>Not recorded</td>
<td>3 Years</td>
<td>Store below 25 degrees Celsius</td>
<td>Not recorded</td>
<td>Protect from Heat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Protect from Moisture</td>
</tr>
</tbody>
</table>

Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 capsules</td>
<td>(S3) Pharmacist Only Medicine</td>
</tr>
<tr>
<td>84 capsules</td>
<td>(S3) Pharmacist Only Medicine</td>
</tr>
<tr>
<td>42 capsules</td>
<td>(S3) Pharmacist Only Medicine</td>
</tr>
<tr>
<td>9 capsules</td>
<td>(S3) Pharmacist Only Medicine</td>
</tr>
</tbody>
</table>

Components

1.

Dosage Form Capsule, hard
Route of Administration Oral
Visual Identification Hard gelatin capsule, opaque turquoise, imprinted with black ink "XENICAL Roche 120".