Public Summary

Summary for ARTG Entry: 167474 O'Neil Long Acting Naltrexone Implant Export Only

ARTG entry for Medicine Listed (Export Only)
Sponsor Go Medical Industries Pty Ltd
Postal Address 200 Churchill Avenue, SUBIACO, WA, 6008 Australia
ARTG Start Date 11/12/2009
Product category Medicine
Status Active
Approval area Export only Medicines

Conditions

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 sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1. O'Neil Long Acting Naltrexone Implant Export Only

Product Type Single Medicine Product
Effective date 2/05/2016

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
Alcohol Dependence (within treatment program); adjunctive therapy in maintenance of former opioid dependent patients

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>Syringe</td>
<td>PP</td>
<td>9 Months</td>
<td>Store below 30 degrees Celsius</td>
<td>Neither child resistant closure nor restricted flow insert</td>
<td>Store at room temperature</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 implant per package</td>
<td>(S1) This Schedule is intentionally blank</td>
</tr>
</tbody>
</table>

Components

1.

Dosage Form Implant
Route of Administration Subcutaneous
Visual Identification Product labelling

Active Ingredients
naltrexone 1.86 g