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

**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