



Australian Government
Department of Health
 Therapeutic Goods Administration

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
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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

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	PP	9 Months	Store below 30 degrees Celsius	Neither child resistant closure nor restricted flow insert	Store at room temperature

Pack Size/Poison information

Pack Size

1 implant per package

Components

1.

Dosage Form

Implant

Route of Administration

Subcutaneous

Visual Identification

Product labelling

Active Ingredients

Naltrexone

1.86 g

Poison Schedule

(S1) This Schedule is intentionally blank

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