



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	111844	SERENACE HALOPERIDOL 0.5mg tablet bottle.
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Proqualix Pty Ltd - in Administration	
Postal Address	59 Lisbon Street, FAIRFIELD, NSW, 2165 Australia	
ARTG Start Date	7/10/2004	
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 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

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.

Products

1 . SERENACE HALOPERIDOL 0.5mg tablet bottle.

Product Type	Single Medicine Product	Effective Date	7/10/2004
---------------------	-------------------------	-----------------------	-----------

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

Antipsychotic

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	5 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
Not Required	Not scheduled. Not considered by committee

Components

1 . UNCOATED TABLET

Dosage Form	Tablet, uncoated
--------------------	------------------



Australian Government
Department of Health
Therapeutic Goods Administration

Route of Administration Oral

Visual Identification Round green biconex tablets one side scored other side debossed 'SEARLE' diameter 6.35mm

Active Ingredients

haloperidol .5 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate
green S
lactose monohydrate
magnesium stearate
maize starch
quinoline yellow

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary