



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	111859	SERENACE HALOPERIDOL 5mg tablet bottle.
<b>ARTG entry for</b>	Medicine Listed (Export Only)	
<b>Sponsor</b>	Proqualix Pty Ltd - in Administration	
<b>Postal Address</b>	59 Lisbon Street, FAIRFIELD, NSW, 2165 Australia	
<b>ARTG Start Date</b>	7/10/2004	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 5mg tablet bottle.**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/10/2004
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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**

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**

<b>Pack Size</b>	<b>Poison Schedule</b>
Not Required	Not scheduled. Not considered by committee

**Components**

**1 . UNCOATED TABLET**

<b>Dosage Form</b>	Tablet, uncoated
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**Route of Administration** Oral

**Visual Identification** Red biconvex tablet one side scored other side debossed 'SEARLE' diameter 7.9mm

**Active Ingredients**

**haloperidol** 5 mg

**Other Ingredients (Excipients)**

**Acacia**

**brilliant scarlet 4R**

**calcium hydrogen phosphate**

**lactose monohydrate**

**magnesium stearate**

**maize starch**

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Public Summary