



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	20432	SERENACE (HALOPERIDOL 10 mg) Tablets
<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>	27/09/1991	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Export only Medicines	

**Conditions**

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 February 1992, 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 February 1992, other than condition No. 11.

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.

**Products**

**1 . SERENACE (Haloperidol 10 mg) tablets**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/07/2002
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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**

FOR THE CONTROL OF AGITATION, HOSTILITY, AGGRESSIVENESS, HALLUCINATION AND PARANOIA ASSOCIATED WITH ACUTE AND CHRONIC PSYCHOSES; MANIA; HYPOMANIA; SENILE DEMENTIA; DELIRIUM TREMENS; CHOREA; SEVERELY AGGRESSIVE AND HOSTILE CHILDREN AND FOR THE RARE GILLES DE LA TOURETTES SYNDROME. FOR ANXIETY NEUROSIS; NEUROLEPTANALGESIA; AS AN ANTI-EMETIC (EXCEPT IN PREGNANCY OR SUSPECTED PREGNANCY); FOR RADIATION SICKNESS AS AN ANTI-EMETIC AND ANXIOLYTIC IN MALIGNANT NEOPLASIA (LATE STAGE)

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	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 . Medicine Component**

<b>Dosage Form</b>	Tablet
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	Round, white, biconvex tablets. One side scored. Otherside stamped "searle". Diameter 8.7 mm.

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**Active Ingredients**

haloperidol

10 mg

**Other Ingredients (Excipients)**

Acacia

calcium hydrogen phosphate dihydrate

lactose monohydrate

magnesium stearate

maize starch

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