



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	20589	SERENACE (HALOPERIDOL 0.5 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>	30/09/1991	
<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 0.5 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**

CHRONIC THERAPY: THE MANAGEMENT OF MANIFESTATIONS OF PSYCHOTIC DISORDERS SUCH AS SCHIZOPHRENIA, PSYCHOSIS DUE TO ORGANIC BRAIN DAMAGE OR MENTAL DEFICIENCY, SENILE PSYCHOSIS, THE MANIC PHASE OF MANIC DEPRESSIVE ILLNESS, GILLES DE LA TOURETTE SYNDROME. SHORT TERM THERPAY: THE TREATMENT OF ACUTE ALCOHOLISM FOR THE RELIEF OF DELUSIONS, HALLUCINATIONS AND CONFUSED STATES, AND FOR THE CONTROL OF ACCOMPANYING TREMULOUSNESS AND AGGRESSIVE BEHAVIOUR. IN THE TREATMENT OF INTRACTABLE NAUSEA AND VOMITING ASSOCIATED WITH RADIATION OR MALIGNANCY AND NOT RESPONDING TO OTHER THERAPY

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	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, yellow, biconvex tablet, one side scored, the otherside stamped "searle". Diameter 6.5 mm.



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**Active Ingredients**

haloperidol .5 mg

**Other Ingredients (Excipients)**

Acacia  
calcium hydrogen phosphate dihydrate  
lactose monohydrate  
magnesium stearate  
maize starch  
tartrazine

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Public Summary