Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	111819 SERENACE HALOPERIDOL 20mg 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 partry 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 20mg 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

Acute & chronic schzophrenia, mania &hypomania, organic psychoses agitation in psychotic illness, explosive hyperexcitability & extreme hyperactivity in children, motorics & vocal utterances of Gile De La Tourette's syndrome, anxiety neurosis & tension states, mixed neurosis where features of depression acompany anxiety.

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
Route of Administration	Oral
Visual Identification	Round blue biconex tablets one side scored other side debossed "SEARLE" diameter 8.7mm

Active Ingredients	
haloperidol	**20 mg**

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate
indigo carmine aluminium lake
lactose monohydrate
magnesium stearate
maize starch