



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	171891	GEN-CLOZAPINE Tablets 50 mg
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Alphapharm Pty Ltd	
Postal Address	PO Box R1462, ROYAL EXCHANGE, NSW, 1225 Australia	
ARTG Start Date	31/05/2010	
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.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . GEN-CLOZAPINE Tablets 50 mg

Product Type	Single Medicine Product	Effective Date	31/05/2010
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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

No Specific Indications included on Record

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

Pack Size	Poison Schedule
100	(S1) This Schedule is intentionally blank

Components

1 .

Dosage Form	Tablet, uncoated
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Route of Administration Oral
Visual Identification 8.5 mm flat bevel edged pale yellow tablet debossed "CZ over 50" on one side and "G/G" (pressure sensitive bisect) on the other.

Active Ingredients

clozapine **50 mg**

Other Ingredients (Excipients)

colloidal anhydrous silica
lactose monohydrate
magnesium stearate
maize starch
povidone
purified talc

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