



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	81087	CLOZAPINE 100mg tablet bulk (AF)
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Alphapharm Pty Ltd	
Postal Address	PO Box R1462, ROYAL EXCHANGE, NSW, 1225 Australia	
ARTG Start Date	28/11/2001	
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 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 . CLOZAPINE 100mg tablet bulk (AF)

Product Type	Single Medicine Product	Effective Date	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

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
Not Required	Not scheduled. Not considered by committee

Components

1 . tablet

Dosage Form	Tablet, uncoated
Route of Administration	Oral
Visual Identification	Pale yellow, uncoated 10mm flat bevel edged tablet debossed "CZ over 100" on one side and "G over G" (pressure sensitive bisect) on the other.

Active Ingredients

clozapine	100 mg
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Other Ingredients (Excipients)

colloidal anhydrous silica

lactose monohydrate

magnesium stearate

maize starch

povidone

purified talc

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