



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

## Public Summary

<b>Summary for ARTG Entry:</b>	81086	CLOZAPINE 25mg tablet bulk (AF)
<b>ARTG entry for</b>	Medicine Listed (Export Only)	
<b>Sponsor</b>	Alphapharm Pty Ltd	
<b>Postal Address</b>	PO Box R1462, ROYAL EXCHANGE, NSW, 1225 Australia	
<b>ARTG Start Date</b>	28/11/2001	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 25mg tablet bulk (AF)

<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

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

<b>Pack Size</b>	<b>Poison Schedule</b>
Not Required	Not scheduled. Not considered by committee

#### Components

##### 1 . tablet

<b>Dosage Form</b>	Tablet, uncoated
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	Pale yellow, uncoated 6.5mm flat bevel edged tablet debossed "CZ over 25" on one side and "G over G" (pressure sensitive bisect on the other

#### Active Ingredients

clozapine	25 mg
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**Other Ingredients (Excipients)**

colloidal anhydrous silica

lactose monohydrate

magnesium stearate

maize starch

povidone

purified talc

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