



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

Public Summary

**Summary for ARTG Entry:** 17649 GLYADE Gliclazide 80mg tablet bottle

**ARTG entry for** Medicine Registered  
**Sponsor** Alphapharm Pty Ltd  
**Postal Address** PO Box R1462, ROYAL EXCHANGE, NSW, 1225  
Australia  
**ARTG Start Date** 20/09/1991  
**Product Category** Medicine  
**Status** Active  
**Approval Area** Drug Safety Evaluation Branch

**Conditions**

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

**Products**

**1 . Glyade 80 mg tablet**

**Product Type** Single Medicine Product **Effective Date** 17/11/2008

**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**

INDICATIONS AS AT 3 November 1999: Diabetes mellitus of the maturity onset type, which cannot be controlled by diet alone.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	3 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule
100	(S4) Prescription Only Medicine

**Components**

**1 . Medicine Component**

**Dosage Form** Tablet, uncoated  
**Route of Administration** Oral  
**Visual Identification** 8mm flat bevelled edge white tablet marked GZ/80 on one side with a double score on reverse

**Active Ingredients**

**gliclazide** 80 mg

**Other Ingredients (Excipients)**

**lactose monohydrate**  
**magnesium stearate**  
**microcrystalline cellulose**  
**povidone**

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**purified talc**

**sodium starch glycollate**

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