



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	17650	GLYADE Gliclazide 80mg tablet blister pack
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 . Gliclazide 80mg tablet

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

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
Blister Pack	PVC/Al	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 double score mark on reverse

Active Ingredients

gliclazide	80 mg
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Other Ingredients (Excipients)

lactose monohydrate
magnesium stearate
microcrystalline cellulose
povidone

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purified talc

sodium starch glycollate

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