



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	147410	GLUCOMET metformin hydrochloride 1000 mg tablet blister pack
ARTG entry for	Medicine Registered	
Sponsor	Strides Pharma Science Pty Ltd	
Postal Address	5/148-152 Spit Road, Mosman, NSW, 2088 Australia	
ARTG Start Date	13/01/2009	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

Conditions

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.

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.

Products

1 . GLUCOMET metformin hydrochloride 1000 mg tablet blister pack

Product Type	Single Medicine Product	Effective Date	11/03/2011
---------------------	-------------------------	-----------------------	------------

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

Treatment of type 2 diabetes mellitus in adults, particularly in over weight patients, when dietary management and exercise alone, does not result in adequate glycaemic control. Metformin may be used as initial treatment, or in sulphonylurea failures, either alone or in combination with a sulphonylurea and other oral agents or as adjuvant therapy in insulin dependent diabetes.

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/PVDC/Al	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
90 tablets	(S4) Prescription Only Medicine
60 tablets	(S4) Prescription Only Medicine
30 tablets	(S4) Prescription Only Medicine
10 tablets	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	White capsule-shaped, biconvex film-coated tablet with a central breakline on one side.

Active Ingredients

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

metformin hydrochloride

1000 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

macrogol 6000

magnesium stearate

maize starch

povidone

propylene glycol

purified talc

sodium starch glycollate

titanium dioxide

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary