



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

## Public Summary

<b>Summary for ARTG Entry:</b>	115137	GLUCOMET metformin hydrochloride 850mg tablet blister pack
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Strides Pharma Science Pty Ltd	
<b>Postal Address</b>	5/148-152 Spit Road, Mosman, NSW, 2088 Australia	
<b>ARTG Start Date</b>	4/04/2005	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 850mg tablet blister pack

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/01/2011
---------------------	-------------------------	-----------------------	------------

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

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
60 tablets	(S4) Prescription Only Medicine

#### Components

##### 1 . Medicine Component

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	White to off-white, capsule shaped, biconvex, film-coated tablets 850 debossed on one side and plain on the other side.

#### Active Ingredients

<b>metformin hydrochloride</b>	<b>850 mg</b>
--------------------------------	---------------

#### Other Ingredients (Excipients)

Public Summary



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

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