



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	147593	GEMFITRIL gemfibrozil 600mg tablet bottle
<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>	23/04/2008	
<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 . GEMFITRIL gemfibrozil 600mg tablet bottle**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/09/2011
---------------------	-------------------------	-----------------------	-----------

**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**

Gemfibrozil is indicated as an adjunct to diet and other therapeutic measures for the following: \* Severe hypertriglyceridaemia (Types IV and V) in persons who present a risk of pancreatitis and who do not respond adequately to a determined dietary effort to control them. \* Dyslipidaemia associated with diabetes. \* Reduction of risk of coronary heart disease in patients with Type IIa and IIb hypercholesterolaemia. \* Because of potential toxicity such as malignancy, gall bladder disease, abdominal pain leading to appendectomy and other abdominal surgeries, an increased incidence in noncoronary mortality, and the 29% increase in all-cause mortality seen with the chemically and pharmacologically related drug clofibrate, the potential benefits of gemfibrozil in treating Type IIa patients with elevations of LDL cholesterol only is not likely to outweigh the risks. In a subgroup analysis of patients in the Helsinki Heart Study with above median HDL cholesterol values at baseline (greater than 1.2mmol/L), the incidence of serious coronary events was similar for gemfibrozil and placebo subgroups. NOTE: Gemfibrozil is indicated when exercise, weight loss and specific dietary or other non-drug measures such as limiting alcohol intake have failed. Other medical disorders such as hypothyroidism and diabetes should be controlled as much as possible. Periodic determinations of serum lipids should be obtained during treatment with gemfibrozil. The drug should be withdrawn or additional therapy instituted if the lipid response is deemed inadequate after three months.

**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	Protect from Light Protect from Moisture

**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>	

Public Summary



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

Oral

**Visual Identification** White, film coated, elliptical, biconvex, tablets engraved with 600, breakline & dp logo on one face and plain on the other.

**Active Ingredients**

**gemfibrozil** 600 mg

**Other Ingredients (Excipients)**

calcium stearate  
colloidal anhydrous silica  
hypromellose  
hypromellose  
indigo carmine  
macrogol 4000  
microcrystalline cellulose  
polysorbate 80  
pregelatinised maize starch  
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