



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	40742	CARAFATE sucralfate 1g/5mL oral liquid bottle
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Viatrix Pty Ltd	
<b>Postal Address</b>	Level 1 30 The Bond, 30-34 Hickson Road, Millers Point, NSW, 2000 Australia	
<b>ARTG Start Date</b>	6/08/1992	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Non-Prescription Medicines	

**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 . CARAFATE**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/07/2002
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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**

For the treatment of gastric & duodenal ulcers. To prevent the reoccurrence of duodenal ulcers. Symptomatic relief and treatment in mild to moderate gastro-oesophageal reflux disease.

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

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

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
250mL	Not scheduled. Not considered by committee

**Components**

**1 . Medicine Component**

<b>Dosage Form</b>	Oral Liquid, suspension
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	Off-white, homogenous suspension characterised by an aniseed/caramel aroma.

**Active Ingredients**

sucralfate	200 mg/mL
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**Other Ingredients (Excipients)**

Flavour

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glycerol  
monobasic sodium phosphate  
purified water  
saccharin sodium  
sodium methyl hydroxybenzoate  
sodium propyl hydroxybenzoate  
xanthan gum

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