



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	97900	SODEN naproxen sodium 275mg tablet blister pack
ARTG entry for	Medicine Registered	
Sponsor	Southern Cross Pharma Pty Ltd	
Postal Address	Suite 5 118 Church Street, HAWTHORN, VIC, 3122 Australia	
ARTG Start Date	3/11/2003	
Product Category	Medicine	
Status	Active	
Approval Area	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 . SODEN naproxen sodium 275mg tablet blister pack

Product Type	Single Medicine Product	Effective Date	3/11/2003
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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 temporary relief of pain associated with primary dysmenorrhoea, migraine headache, minor aches, arthritis and rheumatic pain where inflammation is present.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	2 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
Carton containing 2 blisters of 12 tablets each for a total of 24 tablets per pack	(S2) Pharmacy Medicine

Components

1 . Medicine Component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Oval, blue film-coated and shallow, convex tablets with score line.

Active Ingredients

naproxen sodium	275 mg
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Other Ingredients (Excipients)

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carmoisine
hypromellose
indigo carmine
lactose monohydrate
magnesium stearate
povidone
propylene glycol
sodium starch glycollate
titanium dioxide

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