



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	62002 SUNCOSMOS CHOLESTEROL-LES tablet bottle
ARTG entry for	Medicine Listed (Export Only)
Sponsor	Suncosmos Pty Ltd
Postal Address	Unit B / 15 Rodborough Road, FRENCHS FOREST, NSW, 2086 Australia
ARTG Start Date	30/10/1997
Product Category	Medicine
Status	Active
Approval Area	Export only 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 February 1992, other than condition No. 8 and condition No. 9.

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 February 1992, other than condition No. 11.

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

A copy of a signed and dated certificate of analysis, which is not more than six months old, for the first batch of goods manufactured is to be provided to the Head, Listing Treaties & Export Section, Chemical & Non Prescription Drug Branch within six months of the date of supply of the goods.

Products

1 . SUNCOSMOS CHOLESTEROL-LES tablet bottle

Product Type	Single Medicine Product	Effective Date	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

Is made from Red Koji which is carefully produced by a unique monascus treatment process. It contains natural substances that have many health benefits. Cholesterol-les is a dietary supplement that may help lower cholesterol & triglyceride levels.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	3 Years	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
bulk	Not scheduled. Not considered by committee
30,50,60,90,100,120,180,200,250,500,1000 tablets	Not scheduled. Not considered by committee

Components

1 . tablet	
Dosage Form	Tablet, uncoated
Route of Administration	Oral

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Visual Identification Pink, 12.7mm round, biconvex tablet

Active Ingredients

fermented (red koji) rice starch 500 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
lecithin
soy polysaccharide
stearic acid

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