



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	162956	Blackmores Cholesterol Health
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	30/06/2009	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Blackmores Cholesterol Health

Product Type	Single Medicine Product	Effective Date	21/05/2020
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Permitted Indications

Maintain/support general health and wellbeing
Helps reduce intestinal absorption of cholesterol from dietary sources
Helps maintain/support healthy cholesterol

Indication Requirements

Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

There is no benefit from taking more than 3g/day of phytosterols from all sources
Not recommended for use by pregnant and lactating women (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, soft
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Route of Administration Oral

Visual Identification

Active Ingredients

betacarotene	1.5 mg
vegetable oil phytosterol esters	1 g

Other Ingredients (Excipients)

ascorbyl palmitate
ethanol
Gelatin
glycerol
iron oxide red
mixed (low-alpha type) tocopherols concentrate
purified water
Soya Oil

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