Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: BLACKMORES SUPER STRENGTH COQ10 300mg 298346

ARTG entry for Medicine Listed

Blackmores Ltd Postal Address PO Box 1725, WARRIEWOOD, NSW, 2102

9/01/2018 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

Conditions

Sponsor

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.

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 SUPER STRENGTH COQ10 300mg

Product Type Effective Date 2/10/2025 Single Medicine Product

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support energy levels

Helps in the maintenance of healthy blood lipids/blood fats

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Maintain/support blood vessel health

Helps enhance/promote blood vessel health

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Do not take while on warfarin therapy without medical advice.

Additional Product information

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Department of Health, Disability and Ageing

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Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

ubidecarenone 300 mg

Other Ingredients (Excipients)

Gelatin

glycerol

hydrogenated vegetable oil

iron oxide black

iron oxide red

lecithin

medium chain triglycerides

purified water

Soya Oil

yellow beeswax

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