

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 304900 Bergamot Cholesterol Care

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020

Australia

ARTG Start Date 21/06/2018

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.

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 . Bergamot Cholesterol Care

Product Type Single Medicine Product Effective Date 27/08/2025

Permitted Indications

Maintain/support general health and wellbeing

Helps maintain/support healthy cholesterol

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Indication Requirements

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

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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

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Citrus aurantium fruit juice Extract dry concentrate500 mgEquivalent: Citrus aurantium (Fresh)75 gCynara scolymus leaf Extract dry concentrate60 mgEquivalent: Cynara scolymus (Fresh)3 g

Other Ingredients (Excipients)

ascorbic acid

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

hypromellose

iron oxide red

macrogol 8000 magnesium stearate

microcrystalline cellulose

povidone

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