



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|---------------------------|
| Summary for ARTG Entry: | 304900 | Bergamot Cholesterol Care |
| ARTG entry for | Medicine Listed | |
| Sponsor | Herbs of Gold Pty Ltd | |
| Postal Address | PO Box 3143, KIRRAWEE, NSW, 2232 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 | 2/02/2021 |
|---------------------|-------------------------|-----------------------|-----------|

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 concentrate | 500 mg |
| Equivalent: Citrus aurantium (Fresh) | 75 g |
| Cynara scolymus leaf Extract dry concentrate | 60 mg |
| Equivalent: 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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