

**Australian Government** 

### **Department of Health**

## Therapeutic Goods Administration

**Public Summary** 

| Summary for ARTG Entry: | 166317                        | Blooms Horse Chestnut 1500 mg |
|-------------------------|-------------------------------|-------------------------------|
| ARTG entry for          | Medicine Listed               |                               |
| Sponsor                 | Phytologic Holdi              | ings Pty Limited              |
| Postal Address          | 16-20 Baker Stre<br>Australia | eet, Banksmeadow, NSW, 2019   |
| ARTG Start Date         | 26/10/2009                    |                               |
| Product Category        | Medicine                      |                               |
| Status                  | Active                        |                               |
| Approval Area           | Listed Medicines              | S                             |
| 0                       |                               |                               |

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 . Blooms Horse Chestnut 1500 mg  |  |                                       |            |  |  |  |
|--|--|---------------------------------------|------------|--|--|--|
| Product Type   | Single Medicine Product                        | Effective Date                        | 19/07/2022 |  |  |  |
| Permitted Indications  |  |                                       |            |  |  |  |
| Helps reduce/decrease free radical damage to body cells  |  |                                       |            |  |  |  |
| Anti-inflammatory/r  | elieve inflammation                            |                                       |            |  |  |  |
| Relieve mild tissue  | oedema   |                                       |            |  |  |  |
| Decrease/reduce/relieve symptoms of soft tissue trauma   |  |                                       |            |  |  |  |
| Maintain/support healthy blood circulation   |  |                                       |            |  |  |  |
| Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)   |  |                                       |            |  |  |  |
| Maintain/support bl  | ood capillary health                           |                                       |            |  |  |  |
| Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of haemorrhoids  |  |                                       |            |  |  |  |
| Decrease/reduce/relieve symptoms of mild varicose veins  |  |                                       |            |  |  |  |
| Decrease/reduce appearance of mild varicose veins  |  |                                       |            |  |  |  |
| Decrease/reduce/ | elieve aching/tired legs/leg heaviness assoc   | iated with mild varicose veins        |            |  |  |  |
| Decrease/reduce/ | elieve itchy legs associated with mild varicos | se veins                              |            |  |  |  |
| Decrease/reduce/relieve pain associated with mild varicose veins   |  |                                       |            |  |  |  |
| Decrease/reduce/relieve leg swelling associated mild varicose veins  |  |                                       |            |  |  |  |
| Traditionally used in Western herbal medicine to helps decrease/reduce/relieve leg cramps  |  |                                       |            |  |  |  |
| Traditionally used in Western herbal medicine to aid/assist/helps in the management of muscle sprain/strain  |  |                                       |            |  |  |  |
| Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea   |  |                                       |            |  |  |  |
| Indication Requirements  |  |                                       |            |  |  |  |
| Product presentation must not imply or refer to serious cardiovascular conditions.   |  |                                       |            |  |  |  |
| Product presentation must only refer to mild varicose veins.   |  |                                       |            |  |  |  |
| Label statement: If symptoms persist, talk to your health professional.  |  |                                       |            |  |  |  |
| Product procontati   | on must not imply or refer to circulatory disc | rdors/discosos/conditions o.g. thromh | ocic       |  |  |  |

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

#### **Standard Indications**

No Standard Indications included on Record

### **Specific Indications**

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**Department of Health** 

# Therapeutic Goods Administration

No Specific Indications included on Record

### Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

# Additional Product information

| Pack Size/Poison information | ation |
|------------------------------|-------|
|------------------------------|-------|

| Pack Size  |               | Poison Schedule |        |  |
|--|---------------|-----------------|--------|--|
| Components   |               |                 |        |  |
| 1. Formulation 1   |               |                 |        |  |
| Dosage Form  | Capsule, hard |                 |        |  |
| Route of Administration  | Oral          |                 |        |  |
| Visual Identification  |               |                 |        |  |
| Active Ingredients   |               |                 |        |  |
| Aesculus hippocastanum seed Extract dry concentrate standardised |               |                 | 250 mg |  |
| Equivalent: Aesculus hippocastanum (Dry)                         |               |                 | 1.5 g  |  |
| Other Ingredients (Excipients)                                   |               |                 |        |  |
| Gelatin  |               |                 |        |  |
| magnesium stearate   |               |                 |        |  |
| microcrystalline cellulose                                       |               |                 |        |  |

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