



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 235128 Hawthorn 4500

**ARTG entry for** Medicine Listed  
**Sponsor** Herbs of Gold Pty Ltd  
**Postal Address** PO Box 3143, KIRRAWEE, NSW, 2232  
Australia  
**ARTG Start Date** 17/03/2015  
**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 . Hawthorn 4500

**Product Type** Single Medicine Product **Effective Date** 1/02/2021

### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support healthy blood circulation  
Maintain/support cardiovascular system health  
Traditionally used in Western herbal medicine to maintain/support cardiovascular system health  
Traditionally used in Western herbal medicine to cardiogenic/strengthen heart  
Traditionally used in Western herbal medicine to helps maintain/support healthy heart function  
Helps maintain/support healthy heart function  
Maintain/support heart health  
Traditionally used in Western herbal medicine to maintain/support heart health  
Maintain/support blood vessel health

### Indication Requirements

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

### 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



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**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Crataegus monogyna fruit Extract dry concentrate</b>	<b>375 mg</b>
Equivalent: Crataegus monogyna (Dry)	1.5 g
<b>Crataegus monogyna flower and leaf Extract dry concentrate</b>	<b>600 mg</b>
Equivalent: Crataegus monogyna (Dry)	3 g

**Other Ingredients (Excipients)**

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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Public Summary