



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
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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
Helps maintain/support healthy heart function
Traditionally used in Western herbal medicine to helps maintain/support healthy heart function
Traditionally used in Western herbal medicine to maintain/support heart health
Maintain/support heart health
Maintain/support blood vessel health

Indication Requirements

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

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
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Components



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1 . Formulation 1

Dosage Form Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

Crataegus monogyna fruit Extract dry concentrate	375 mg
Equivalent: Crataegus monogyna (Dry)	1.5 g
Crataegus monogyna flower and leaf Extract dry concentrate	600 mg
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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