



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	214424	MediHerb Horsechestnut Complex
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	11/09/2013	
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.

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27) as in force or existing from time to time. This condition does not apply to powdered or dried leaf.

Products

1 . MediHerb Horsechestnut Complex

Product Type	Single Medicine Product	Effective Date	10/03/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support healthy blood circulation
- Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of haemorrhoids
- Traditionally used in Western herbal medicine to decrease/reduce/relieve discomfort associated with haemorrhoids
- Traditionally used in Western herbal medicine to decrease/reduce/relieve itching associated with haemorrhoids
- Traditionally used in Western herbal medicine to decrease/reduce/relieve swelling associated with haemorrhoids
- Decrease/reduce/relieve symptoms of mild varicose veins
 - Linked indication - Decrease/reduce/relieve pain associated with mild varicose veins
 - Linked indication - Decrease/reduce/relieve aching/tired legs/leg heaviness associated with mild varicose veins
 - Linked indication - Decrease/reduce/relieve itchy legs associated with mild varicose veins
 - Linked indication - Decrease/reduce/relieve leg swelling associated mild varicose veins

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild varicose veins.
- 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

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

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(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, enteric coated

Route of Administration Oral

Visual Identification

Active Ingredients

Aesculus hippocastanum seed Extract dry concentrate standardised	200 mg
Equivalent: Aesculus hippocastanum (Dry)	1200 mg
Ginkgo biloba leaf Dry	30.5 mg
Equivalent: Ginkgo biloba (Dry)	1525 mg
Ruscus aculeatus root and rhizome Extract dry concentrate standardised	200 mg
Equivalent: Ruscus aculeatus (Extract dry concentrate standardised)	800 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
carmellose sodium
colloidal anhydrous silica
ethylcellulose
liquid glucose
magnesium stearate
maltodextrin
medium chain triglycerides
microcrystalline cellulose
oleic acid
polydextrose
purified talc
purified water
sodium starch glycollate
strong ammonia solution

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