



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	295977	MediHerb PhytoRegenex Tablets
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	7/11/2017	
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 PhytoRegenex Tablets

Product Type	Single Medicine Product	Effective Date	4/06/2021
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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 collagen health
- Traditionally used in Western herbal medicine to body tonic
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Helps enhance/promote healthy blood circulation in aging individuals
- Helps enhance/promote healthy blood circulation
- Maintain/support healthy blood circulation
- Helps enhance/improve/promote blood circulation to the peripheral areas of the body (legs, hands and feet)
- Helps enhance/improve/promote blood circulation to the peripheral areas of the body (legs, hands and feet) in aging individuals
- Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)
- Maintain/support blood capillary health
- Maintain/support blood vessel health
- Traditionally used in Western herbal medicine to maintain/support healthy digestive system function
- Traditionally used in Western herbal medicine to maintain/support digestive system health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
 - Linked indication - Relieve digestive discomfort
 - Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
 - Linked indication - Decrease/reduce/relieve flatulence/carminative
 - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to maintain/support healthy liver function
- Traditionally used in Western herbal medicine to maintain/support liver health
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress

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Support healthy stress response in the body
 Maintain/support cognitive function/mental function
 Maintain/support skin elasticity
 Helps protect skin elastin from breaking down

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to gastro oesophageal reflux disease.
 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

If symptoms persist, seek the advice of a healthcare professional.
 For practitioner dispensing only.
 Do not use if pregnant or likely to become pregnant (or words to that effect)

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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

Ginkgo biloba leaf Dry	30 mg
Equivalent: Ginkgo biloba (Dry)	1500 mg
Panax ginseng root Extract dry concentrate standardised	50 mg
Equivalent: Panax ginseng (Dry)	250 mg
Reynoutria japonica root Extract dry concentrate standardised	80 mg
Equivalent: Reynoutria japonica (Dry)	8 g
Silybum marianum seed Extract dry concentrate standardised	68.57 mg
Equivalent: Silybum marianum (Dry)	4.8 g
Vitis vinifera seed Extract dry concentrate standardised	40 mg
Equivalent: Vitis vinifera (Dry)	4.8 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
 colloidal anhydrous silica
 glucose monohydrate
 hypromellose
 magnesium stearate

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microcrystalline cellulose

sodium starch glycollate

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