



Australian Government
Department of Health and Aged Care
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.

Products

1 . MediHerb PhytoRegenex Tablets

Product Type	Single Medicine Product	Effective Date	17/04/2025
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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
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
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) in aging individuals
Helps enhance/improve/promote blood circulation to the peripheral areas of the body (legs, hands and feet)
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
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Linked indication - Decrease/reduce/relieve flatulence/carminative
Linked indication - Relieve digestive discomfort
Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
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
Support healthy stress response in the body
Maintain/support cognitive function/mental function
Maintain/support skin elasticity



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Helps protect skin elastin from breaking down

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not imply or refer to serious cardiovascular conditions.

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 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
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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

microcrystalline cellulose

sodium starch glycollate



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