



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	310425	MediHerb Withania 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	16/10/2018	
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 Withania Complex

Product Type	Single Medicine Product	Effective Date	19/08/2021
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Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to balance Vata
- Traditionally used in Ayurvedic medicine to balance aggravated Vata
- Traditionally used in Ayurvedic medicine to enhance/promote energy levels
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence in elderly individuals
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence In older males
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence in healthy elderly individuals
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence In older females
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility In older females
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility In older males
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility in healthy elderly individuals
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility in elderly individuals
- Traditionally used in Western herbal medicine to body tonic
- Traditionally used in Ayurvedic medicine to longevity tonic
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support adrenal gland health
- Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to calms the mind
- Traditionally used in Western herbal medicine to calms the mind
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Ayurvedic medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety

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Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function
 Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall
 Traditionally used in Ayurvedic medicine to nerve tonic
 Traditionally used in Ayurvedic medicine to nerve tonic
 Traditionally used in Western herbal medicine to nerve tonic
 Traditionally used in Ayurvedic medicine to calmative/nervous system relaxant
 Traditionally used in Western herbal medicine to calmative/nervous system relaxant
 Traditionally used in Ayurvedic medicine to nervine/support nervous system
 Traditionally used in Western herbal medicine to nervine/support nervous system
 Traditionally used in Ayurvedic medicine to soporific/induces sleep
 Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
 Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness
 Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Label statement: If symptoms persist, talk to your health professional.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to any adrenal related diseases.
 Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

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

Glycyrrhiza glabra root Extract dry concentrate	107.15 mg
Equivalent: Glycyrrhiza glabra (Dry)	750 mg
Panax ginseng root Extract dry concentrate standardised	20 mg
Equivalent: Panax ginseng (Dry)	100 mg
Scutellaria lateriflora herb Extract liquid	940 microlitre
Equivalent: Scutellaria lateriflora (Dry)	470 mg
Withania somnifera root Extract dry concentrate	95 mg
Equivalent: Withania somnifera (Dry)	950 mg

Other Ingredients (Excipients)

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calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
glucose monohydrate
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
sodium starch glycollate

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