



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	343209	MediHerb Rhodiola & Schisandra
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	9/09/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 Rhodiola & Schisandra

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/01/2021
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Traditionally used in Chinese medicine to calm/stabilise/settle/regulate shen  
Traditionally used in Chinese medicine to decrease/reduce/relieve excessive perspiration/sweating  
Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating  
Maintain/support general health and wellbeing  
Support healthy stress response in the body  
Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit  
Maintain/support cognitive function/mental function  
Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep

### Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Label statement: If symptoms persist, talk to your health professional.  
If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

### 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).  
For practitioner dispensing only.  
If symptoms persist, seek the advice of a healthcare professional.

### Additional Product information



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**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**

<b>Rhodiola rosea root Extract dry concentrate standardised</b>	<b>150 mg</b>
Equivalent: Rhodiola rosea (Dry)	600 mg
<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>110 mg</b>
Equivalent: Schisandra chinensis (Dry)	660 mg

**Other Ingredients (Excipients)**

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

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