



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	347237	MediHerb Hemidesmus Complex
<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>	4/11/2020	
<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 Hemidesmus Complex**

Product Type	Effective Date
Single Medicine Product	13/02/2021

**Permitted Indications**

- Traditionally used in Ayurvedic medicine to alterative/blood cleanser/depurative/purifier
- Traditionally used in Chinese medicine to regulate/soothe/smooth/disperse the flow of liver-qi/liver
- Traditionally used in Chinese medicine to soothe liver Qi
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild rheumatic aches and pains
- Traditionally used in Western herbal medicine to decrease/reduce/relieve headache symptoms
- Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of headaches
- Traditionally used in Western herbal medicine to helps reduce occurrence of mild migraines
- Traditionally used in Chinese medicine to decrease/reduce/relieve chills associated with common cold
- Traditionally used in Ayurvedic medicine to soothe/relieve skin inflammation
- Traditionally used in Ayurvedic medicine to maintain/support skin health

**Indication Requirements**

- Product presentation must only refer to detoxification in relation to natural body processes.
- Product presentation must not imply or refer to drugs/alcohol.
- 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.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- Product presentation must only refer to mild migraine.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- Label statement: Not to be used in children under 5 years.
- Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
- Product presentation must only refer to mild rheumatic aches/pains.

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**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

For practitioner dispensing only.

If symptoms persist, seek the advice of a healthcare professional.

**Additional Product information**

**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>Bupleurum falcatum root Extract liquid</b>	<b>1.4 mL</b>
Equivalent: Bupleurum falcatum (Dry)	700 mg
<b>Hemidesmus indicus root Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Hemidesmus indicus (Dry)	500 mg
<b>Rehmannia glutinosa root Extract liquid</b>	<b>1.75 mL</b>
Equivalent: Rehmannia glutinosa (Dry)	350 mg
<b>Tanacetum parthenium herb Dry</b>	<b>33 mg</b>
Equivalent: Tanacetum parthenium ( )	165 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
croscarmellose sodium  
hydrogenated vegetable oil  
hypromellose  
magnesium stearate  
microcrystalline cellulose

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