

**Australian Government** 

## **Department of Health**

# Therapeutic Goods Administration

**Public Summary** 

Summary for ARTG Entry:	286616	MediHerb Stealth Complex
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthca	are Australia Pty Ltd
Postal Address	PO Box 4854, E Australia	IGHT MILE PLAINS, QLD, 4113
ARTG Start Date	10/03/2017	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	3
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 Stealth Complex						
Product Type	Single Medicine Product	Effective Date	20/08/2021			
Permitted Indication	ons					
Traditionally used in	Western herbal medicine to alterative/blood	l cleanser/depurative/purifier				
Traditionally used in	Western herbal medicine to aids/assists bo	dy waste elimination				
Traditionally used in	Western herbal medicine to body tonic					
Traditionally used in	Western herbal medicine to helps enhance	/promote general health and wellbeir	ng			
Traditionally used in	Western herbal medicine to maintain/support	ort general health and wellbeing				
Traditionally used in	Western herbal medicine to decrease/redu	ce/relieve mild rheumatic aches and	pains			
Traditionally used in	Western herbal medicine to decrease/redu	ce/relieve symptoms of mild psoriasis	S			
Indication Require	ments					
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.						
Product presentation	on must only refer to detoxification in relation	to natural body processes.				
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.						
Product presentation	on must not imply or refer to drugs/alcohol.					

Product presentation must only refer to mild rheumatic aches/pains. Label statement: If symptoms persist, talk to your health professional. Product presentation must only refer to mild psoriasis

#### **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**

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**Department of Health** Therapeutic Goods Administration

Pack Size/Poison information				
Pack Size		Poison Schedule	Poison Schedule	
Components				
1. Formulation 1				
Dosage Form	Tablet, film coated			
Route of Administration Oral				
Visual Identification				
Active Ingredients				
Artemisia annua herb Extract dry concentrate		266.66 mg		
Equivalent: Artemisia annua (Dry)		8 g		
Smilax officinalis root Extract dry concentrate		200 mg		
Equivalent: Smilax officina	alis (Dry)	800 mg		
Other Ingredients (Excipie	ents)			
calcium hydrogen phosph	nate dihydrate			
colloidal anhydrous silica	l .			
croscarmellose sodium				
hypromellose				
magnesium stearate				
maltodextrin				
microcrystalline cellulose	•			
sodium starch glycollate				

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