



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 Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	10/03/2017	
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 Stealth Complex

Product Type	Single Medicine Product	Effective Date	20/08/2021
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Permitted Indications

- Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
- Traditionally used in Western herbal medicine to aids/assists body waste elimination
- Traditionally used in Western herbal medicine to body tonic
- Traditionally used in Western herbal medicine to helps enhance/promote general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- 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 symptoms of mild psoriasis

Indication Requirements

- Product presentation must not imply or refer to drugs/alcohol.
- 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 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 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

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

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

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 officinalis (Dry)	800 mg

Other Ingredients (Excipients)

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

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