



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	282383	MediHerb Cramplex
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	11/11/2016	
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 Cramplex

Product Type	Single Medicine Product	Effective Date	14/04/2025
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Permitted Indications

Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
Traditionally used in Western herbal medicine to astringent/tightens tissues
Traditionally used in Western herbal medicine to decrease/reduce/relieve muscle cramps
Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
Traditionally used in Western herbal medicine to calmativ/nervous system relaxant
Traditionally used in Western herbal medicine to nervine/support nervous system
Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual spasms/cramps
Traditionally used in Western herbal medicine to decrease/reduce heavy menstruation/periods
Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea

Indication Requirements

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

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.

Additional Product information

Pack Size/Poison information



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Department of Health and Aged Care
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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Corydalis turtschaninovii tuber Extract dry concentrate	60 mg
Equivalent: Corydalis turtschaninovii (Dry)	600 mg
Dioscorea villosa root and rhizome Extract liquid	800 microlitre
Equivalent: Dioscorea villosa (Dry)	400 mg
Rubus idaeus leaf Extract liquid	800 microlitre
Equivalent: Rubus idaeus (Dry)	400 mg
Viburnum opulus stem bark Extract liquid	800 microlitre
Equivalent: Viburnum opulus (Dry)	400 mg
Zingiber officinale rhizome Extract liquid	800 microlitre
Equivalent: Zingiber officinale (Dry)	400 mg

Other Ingredients (Excipients)

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

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