



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

## Public Summary

<b>Summary for ARTG Entry:</b>	282383	MediHerb Cramplex
<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>	11/11/2016	
<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 Cramplex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/05/2021
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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 calmative/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

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

#### 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

#### Pack Size/Poison information



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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**

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