



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

## Public Summary

<b>Summary for ARTG Entry:</b>	237217	MediHerb EndoFem
<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>	6/05/2015	
<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 EndoFem

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/03/2021
---------------------	-------------------------	-----------------------	-----------

### Permitted Indications

- Traditionally used in Western herbal medicine to astringent/tightens tissues
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to improve menstrual flow
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
- Traditionally used in Western herbal medicine to maintain/support/regulate healthy menstrual cycle
- 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.

### 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.

### Additional Product information

### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

### Components

Public Summary



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

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Alchemilla vulgaris herb Extract liquid</b>	<b>1.3 mL</b>
Equivalent: Alchemilla vulgaris (Dry)	650 mg
<b>Angelica polymorpha root Extract dry concentrate</b>	<b>118 mg</b>
Equivalent: Angelica polymorpha (Dry)	826 mg
<b>Calendula officinalis flower Extract liquid</b>	<b>800 microlitre</b>
Equivalent: Calendula officinalis (Dry)	400 mg
<b>Paeonia lactiflora root Extract dry concentrate</b>	<b>206 mg</b>
Equivalent: Paeonia lactiflora (Dry)	824 mg

**Other Ingredients (Excipients)**

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary