



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	381295	MediHerb Wild Yam Complex
<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>	23/12/2021	
<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'.

All products containing *Cimicifuga racemosa* must comply with the following condition of listing by carrying the label statement - Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

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 Wild Yam Complex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/12/2021
---------------------	-------------------------	-----------------------	------------

#### Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve excessive perspiration/sweating
- Traditionally used in Western herbal medicine to decrease/reduce/relieve spontaneous sweating
- 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 help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of mild anxiety
- Traditionally used in Western herbal medicine to maintain/support nervous system health
- Traditionally used in Western herbal medicine to nervine/support nervous system
- Traditionally used in Western herbal medicine to maintain/support nervous system function
- Traditionally used in Western herbal medicine to support healthy emotional/mood balance
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve night sweats associated with menopause
- Traditionally used in Western herbal medicine to decrease/reduce/relieve hot flushes associated with menopause

#### 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.
- Product presentation must only refer to mild anxiety.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

Page 1 of 2

Produced at 05.12.2022 at 11:14:08 AEDT

**This is not an ARTG Certificate document.**

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

Visit [www.tga.gov.au](http://www.tga.gov.au) for contact information

Public Summary



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

No Specific Indications included on Record

**Warnings**

If symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.

Do not use if pregnant or likely to become pregnant (or words to that effect)

Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

**Additional Product information**

**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**

<b>Actaea racemosa root Extract liquid</b>	<b>200 microlitre</b>
Equivalent: Actaea racemosa (Dry)	100 mg
<b>Asparagus racemosus root Extract liquid</b>	<b>800 microlitre</b>
Equivalent: Asparagus racemosus (Dry)	400 mg
<b>Dioscorea villosa root and rhizome Extract liquid</b>	<b>800 microlitre</b>
Equivalent: Dioscorea villosa (Dry)	400 mg
<b>Hypericum perforatum herb top flowering Extract dry concentrate standardised</b>	<b>100 mg</b>
Equivalent: Hypericum perforatum (Dry)	600 mg
<b>Panax ginseng root Extract dry concentrate standardised</b>	<b>15 mg</b>
Equivalent: Panax ginseng (Dry)	75 mg
<b>Salvia officinalis leaf Extract liquid</b>	<b>580 microlitre</b>
Equivalent: Salvia officinalis (Dry)	290 mg

**Other Ingredients (Excipients)**

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

Public Summary

© 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>.