Public Summary

Summary for ARTG Entry:	237218 MediHerb PolyFem
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	6/05/2015
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'.

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 PolyFem

Product Type Single Medicine Product **Effective Date** 27/05/2021

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support general health and wellbeing

Anti-inflammatory/relieve inflammation

Traditionally used in Western herbal medicine to antispasmodic/spasmolytic in females

Traditionally used in Western herbal medicine to haemagogue/emmenagogue/promotes menstrual flow in females

Traditionally used in Western herbal medicine to improve menstrual flow in females

Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual spasms/cramps in females

Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea in females

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 abortifacient action.

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)

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

Actaea racemosa root Extract liquid	**600 microlitre**
Equivalent: Actaea racemosa (Dry)	300 mg
Glycyrrhiza glabra root Extract dry concentrate standardised	**121 mg**
Equivalent: Glycyrrhiza glabra (Dry)	847 mg
Paeonia lactiflora root Extract dry concentrate	**213 mg**
Equivalent: Paeonia lactiflora (Dry)	852 mg
Thuja occidentalis leaf Extract liquid	**1.25 mL**
Equivalent: Thuja occidentalis (Dry)	250 mg

Other Ingredients (Excipients)

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