



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	351512	FemmeBalance
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	10/12/2020	
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 . FemmeBalance

Product Type	Single Medicine Product	Effective Date	10/12/2020
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Permitted Indications

- Temporarily relieve mild fluid retention
- Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal pain/discomfort
- Traditionally used in Chinese medicine to antispasmodic/spasmodolytic
- Maintain/support female healthy hormonal balance
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
- Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
- Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild fluid retention.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- Label statement: If fluid retention persists, seek medical advice (or words to that effect).
- Product presentation must not imply or refer to cardiovascular or renal conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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

Cinnamomum cassia stem bark Extract dry concentrate	66.67 mg
Equivalent: Cinnamomum cassia (Dry)	1 g
Glycyrrhiza glabra root Extract dry concentrate standardised	142.86 mg
Equivalent: Glycyrrhiza glabra (Dry)	2.5 g
inositol	200 mg
Paeonia lactiflora root Extract dry concentrate	150 mg
Equivalent: Paeonia lactiflora (Dry)	3 g
pyridoxal 5-phosphate monohydrate	39.18 mg
Equivalent: pyridoxine	25 mg
pyridoxine hydrochloride	30.39 mg
Equivalent: pyridoxine	25 mg
Taraxacum officinale leaf Extract dry concentrate	150 mg
Equivalent: Taraxacum officinale (Dry)	750 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dextrin
glucose monohydrate
hypromellose
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone

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