



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

## Public Summary

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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/spasmolytic

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



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

Pack Size

Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

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