



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

## Public Summary

<b>Summary for ARTG Entry:</b>	387381	BioFem
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biomedica Nutraceuticals Pty Ltd	
<b>Postal Address</b>	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	22/04/2022	
<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 . BioFem

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/04/2022
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### Permitted Indications

Maintain/support energy production  
Maintain/support general health and wellbeing  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Aid/assist thyroid hormone production  
Maintain/support muscle function  
Support healthy stress response in the body  
Maintain/support nervous system health  
Maintain/support nervous system function  
Support healthy emotional/mood balance in premenstrual woman  
Support healthy emotional/mood balance  
Maintain/support female healthy hormonal balance  
Maintain/support female healthy hormonal balance during the reproductive cycle  
Maintain/support female reproductive system health  
Traditionally used in Western herbal medicine to haemagogue/emmenagogue/promotes menstrual flow  
Decrease/reduce/relieve menstrual cycle irregularity/irregular periods  
Maintain/support/regulate healthy menstrual cycle  
Decrease/reduce/relieve hot flushes associated with menopause  
Maintain/support skin health

### Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to abortifacient action.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.



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#### 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].

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).

#### Additional Product information

#### Pack Size/Poison information

##### Pack Size

##### Poison Schedule

#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

##### Visual Identification

##### Active Ingredients

<b>Crocus sativus stigma Dry</b>	<b>13.5 mg</b>
Equivalent: Crocus sativus (Dry)	45 mg
<b>magnesium amino acid chelate</b>	<b>250 mg</b>
Equivalent: magnesium	50 mg
<b>potassium iodide</b>	<b>98.1 microgram</b>
Equivalent: iodine	75 microgram
<b>pyridoxine hydrochloride</b>	<b>60.78 mg</b>
Equivalent: pyridoxine	50 mg
<b>selenomethionine</b>	<b>186.3 microgram</b>
Equivalent: selenium	75 microgram
<b>Vitex agnus-castus fruit Extract dry concentrate standardised</b>	<b>100 mg</b>
Equivalent: Vitex agnus-castus (Dry)	1000 mg
<b>zinc amino acid chelate</b>	<b>25 mg</b>
Equivalent: zinc	5 mg

##### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
dextrin  
hypromellose  
magnesium stearate  
maltodextrin  
microcrystalline cellulose