



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

## Public Summary

<b>Summary for ARTG Entry:</b>	462432	PCO Balance
<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>	20/09/2024	
<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 . PCO Balance

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	26/11/2024
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#### 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
- Helps maintain/support healthy blood sugar/glucose
- Traditionally used in Western herbal medicine to maintain/support adrenal gland health
- Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support female healthy hormonal balance
- Maintain/support female healthy hormonal balance during the reproductive cycle
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
- Traditionally used in Chinese medicine to maintain/support/regulate healthy menstrual cycle
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual spasms/cramps
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea

#### Indication Requirements

- Product presentation must not imply or refer to any adrenal related diseases.
- Label statement: If symptoms persist, talk to your health professional.
- If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications



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No Specific Indications included on Record

#### Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

In rare cases, *Camellia sinensis* may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes, or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.

To be taken with food.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

#### Additional Product information

#### Pack Size/Poison information

Pack Size	Poison Schedule
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#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients

<b>Camellia sinensis leaf Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: <i>Camellia sinensis</i> (Dry)	1.625 g
<b>colecalfiferol</b>	<b>12.5 microgram</b>
<b>Glycyrrhiza glabra root Extract dry concentrate</b>	<b>156.25 mg</b>
Equivalent: <i>Glycyrrhiza glabra</i> (Dry)	1.25 g
<b>Mentha spicata leaf Extract dry concentrate</b>	<b>60 mg</b>
Equivalent: <i>Mentha spicata</i> (Dry)	600 mg
<b>Nigella sativa seed Extract dry concentrate</b>	<b>66.67 mg</b>
Equivalent: <i>Nigella sativa</i> (Dry)	1 g
<b>Paeonia lactiflora root Extract dry concentrate</b>	<b>62.5 mg</b>
Equivalent: <i>Paeonia lactiflora</i> (Dry)	1.25 g
<b>Trigonella foenum-graecum seed Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: <i>Trigonella foenum-graecum</i> (Dry)	1 g

#### Other Ingredients (Excipients)

Acacia  
carrageenan  
colloidal anhydrous silica  
dl-alpha-tocopherol  
hypromellose  
magnesium stearate  
maize starch  
maltodextrin  
microcrystalline cellulose  
mono- and di- glycerides  
potassium acetate  
purified water  
silicon dioxide  
sodium ascorbate  
sucrose

Public Summary

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