



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	476358	Cramp Bark Complex
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	22/01/2025	
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 . Cramp Bark Complex

Product Type	Single Medicine Product	Effective Date	22/01/2025
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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
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Chinese medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Western herbal medicine to astringent/tightens tissues
- Traditionally used in Western herbal medicine to helps enhance/improve/promote blood circulation to the peripheral areas of the body (legs, hands and feet)
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant
- Traditionally used in Western herbal medicine to nervine/support nervous system
- Maintain/support nervous system function
- Traditionally used in Western herbal medicine to maintain/support female reproductive system health
- Traditionally used in Chinese medicine to maintain/support female reproductive system health
- Traditionally used in Chinese medicine to relieves mid-cycle menstrual pain
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual spasms/cramps
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual spasms/cramps
- Traditionally used in Western herbal medicine to decrease/reduce heavy menstruation/periods
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menstruation
- Traditionally used in Chinese medicine to female tonic

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Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 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 mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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

Alchemilla vulgaris herb top flowering Extract dry concentrate	75 mg
Equivalent: Alchemilla vulgaris (Dry)	1.5 g
Angelica polymorpha root Extract dry concentrate	28.15 mg
Equivalent: Angelica polymorpha (Dry)	563 mg
Corydalis turtschaninovii rhizome Extract dry concentrate	62.5 mg
Equivalent: Corydalis turtschaninovii (Dry)	1.25 g
d-alpha-tocopheryl acid succinate	103.21 mg
Equivalent: d-alpha-tocopherol	125 IU
Matricaria chamomilla flower Extract dry concentrate	37.5 mg
Equivalent: Matricaria chamomilla (Dry)	750 mg
thiamine hydrochloride	31.775 mg
Equivalent: thiamine	25 mg
Viburnum opulus stem bark Extract dry concentrate	56.3 mg
Equivalent: Viburnum opulus (Dry)	563 mg
Zingiber officinale rhizome Extract dry concentrate	12.5 mg
Equivalent: Zingiber officinale (Dry)	250 mg

Other Ingredients (Excipients)

carrageenan
 colloidal anhydrous silica
 hypromellose
 magnesium stearate
 maltodextrin
 potassium acetate
 purified water

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