



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	282317	IB-Pro
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	10/11/2016	
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 . IB-Pro

Product Type	Single Medicine Product	Effective Date	20/08/2025
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Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
Traditionally used in Western herbal medicine to relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Traditionally used in Western herbal medicine to maintain/support healthy digestive system function
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal pain/discomfort
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of nervous indigestion
Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms
Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
Traditionally used in Western herbal medicine to support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist or worsen talk to your medical practitioner.

Label statement: If symptoms persist, talk to your health professional.
Product presentation must only refer to medically diagnosed IBS.
Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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Do not use if pregnant or likely to become pregnant (or words to that effect)
Do not use while breastfeeding.
Use in children under 12 years is not recommended.

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

Carum carvi seed Extract dry concentrate	150 mg
Equivalent: Carum carvi (Dry)	600 mg
Cynara scolymus leaf Extract dry concentrate	40 mg
Equivalent: Cynara scolymus (Fresh)	2 g
Foeniculum vulgare seed Extract dry concentrate	40 mg
Equivalent: Foeniculum vulgare (Dry)	400 mg
Matricaria chamomilla flower Extract dry concentrate	200 mg
Equivalent: Matricaria chamomilla (Dry)	2 g
Melissa officinalis leaf Extract dry concentrate	200 mg
Equivalent: Melissa officinalis (Dry)	2 g

Other Ingredients (Excipients)

calcium hydrogen phosphate
colloidal anhydrous silica
hypromellose
maltodextrin
microcrystalline cellulose
purified water
silicon dioxide
sorbitol

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