



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	341032	Synergesic
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	6/08/2020	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Synergesic

Product Type	Single Medicine Product	Effective Date	6/08/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation in healthy individuals
- Decrease/reduce/relieve mild joint aches and pains
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint aches and pains
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild rheumatic aches and pains
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint pain/soreness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Helps maintain/support bile secretion/flow
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to support healthy stress response in the body
- Traditionally used in Ayurvedic medicine to support healthy stress response in the body
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
 - Linked indication - Maintain/support physical endurance/capacity/stamina
 - Linked indication - Support healthy emotional/mood balance
 - Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall
- Traditionally used in Ayurvedic medicine to maintain/support general mental wellbeing
- Traditionally used in Ayurvedic medicine to nervine/support nervous system

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Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness
 Traditionally used in Ayurvedic medicine to maintain/support healthy sleeping patterns

Indication Requirements

Product presentation must only refer to mild joint symptoms.
 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 only refer to mild rheumatic aches/pains.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

Boswellia serrata sap resin Extract dry concentrate standardised	276.92 mg
Equivalent: Boswellia serrata (Dry)	5.538 g
Curcuma longa rhizome Extract dry concentrate standardised	125 mg
Equivalent: Curcuma longa (Dry)	3.906 g
Piscidia piscipula stem bark Extract dry concentrate	250 mg
Equivalent: Piscidia piscipula (Dry)	1000 mg
Withania somnifera root Extract dry concentrate	100 mg
Equivalent: Withania somnifera (Dry)	2.5 g
Zingiber officinale rhizome Extract dry concentrate	90.91 mg
Equivalent: Zingiber officinale (Dry)	1000 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
 colloidal anhydrous silica
 croscarmellose sodium
 crospovidone
 hypromellose
 macrogol 400
 magnesium stearate
 maltodextrin
 microcrystalline cellulose
 povidone
 silicon dioxide

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