



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

**Public Summary**

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

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**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

Public Summary



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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 not imply or refer to mental illnesses, disorders or conditions.  
 Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
 Product presentation must only refer to mild joint symptoms.

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 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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

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