



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

## Public Summary

<b>Summary for ARTG Entry:</b>	324484	Bio Curcumin 5400
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	8/10/2019	
<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 . Bio Curcumin 5400

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/07/2021
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Ayurvedic medicine to anti-inflammatory/relieve inflammation
- Anti-inflammatory/relieve inflammation
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
  - Linked indication - Anti-inflammatory/relieve inflammation
  - Linked indication - Helps enhance/improve/promote joint mobility
  - Linked indication - Decrease/reduce/relieve mild joint pain/soreness
  - Linked indication - Decrease/reduce/relieve mild joint stiffness
- Maintain/support joint health
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve mild joint inflammation/swelling

### Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild joint symptoms.
- Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

### 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

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**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Curcuma longa rhizome Extract dry concentrate standardised</b>	<b>100 mg</b>
Equivalent: Curcuma longa (Fresh)	16500 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
crospovidone  
hypromellose  
lecithin  
macrogol 400  
magnesium stearate  
microcrystalline cellulose

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