### **Australian Government**

### Department of Health, Disability and Ageing

Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: 324484 Bio Curcumin 5400

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020

Australia

ARTG Start Date 8/10/2019
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. Bio Curcumin 5400

Product Type Single Medicine Product Effective Date 29/08/2025

# 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 - Decrease/reduce/relieve mild joint stiffness Linked indication - Decrease/reduce/relieve mild joint pain/soreness Linked indication - Helps enhance/improve/promote joint mobility

Maintain/support joint health

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve mild joint inflammation/swelling

### Indication Requirements

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 the table in Part 2 of Schedule 1 to this instrument are also used.

Product presentation must only refer to mild joint symptoms.

Label statement: If symptoms persist, talk to your health professional.

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

In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.

# Additional Product information

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# Department of Health, Disability and Ageing

Therapeutic Goods Administration

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** 

Curcuma longa rhizome Extract dry concentrate standardised

100 mg

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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