

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: Curcumin Biocomplex 397870

ARTG entry for Medicine Listed

Sponsor Ora Health Pty Ltd

Postal Address 24/10-18 Orchard Road, Brookvale, NSW, 2100

17/10/2022 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

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. Curcumin Biocomplex

Product Type Effective Date 17/10/2022 Single Medicine Product

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support collagen formation

Maintain/support natural liver cleansing/detoxification processes

Maintain/support energy production

Maintain/support eye health

Maintain/support general health and wellbeing

Maintain/support healthy teeth

Traditionally used in Ayurvedic medicine to anti-inflammatory/relieve inflammation in healthy individuals

Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation in healthy individuals

Maintain/support connective tissue health

Aid/assist/helps connective tissue production/formation

Maintain/support bone health

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint aches and pains

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis

Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis

Helps maintain/support joint cartilage health

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

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

Traditionally used in Western herbal medicine to maintain/support joint mobility/flexibility

Maintain/support joint mobility/flexibility

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support blood capillary health

Maintain/support blood vessel health

Maintain/support healthy thyroid gland function

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Maintain/support healthy thyroid hormones

Aid/assist thyroid hormone production

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to maintain/support digestive system health

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to maintain/support gallbladder function

Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic

Maintain/support bile production

Traditionally used in Western herbal medicine to maintain/support healthy liver function

Traditionally used in Western herbal medicine to maintain/support liver health

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Aid/assist/helps protein synthesis in the body

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Support healthy stress response in the body

Aid/assist/helps synthesis of neurotransmitters

Maintain/support nervous system function

Maintain/support skin health

Maintain/support skin integrity/structure

Maintain/support wound healing in healthy individuals

Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must only refer to mild joint symptoms.

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

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to any thyroid related diseases.

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 disease in any body organ.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Ora

Visual Identification

Active Ingredients

Boswellia serrata gum Extract dry concentrate	50 mg
Equivalent: Boswellia serrata (Dry)	700 mg
Curcuma longa rhizome Extract dry concentrate	200 mg
Equivalent: Curcuma longa (Dry)	2.6 g
Curcuma longa rhizome Extract dry concentrate standardised	50 mg
Equivalent: Curcuma longa (Dry)	1.25 g
magnesium ascorbate monohydrate	112.08 mg
Equivalent: ascorbic acid	100 mg
Punica granatum fruit peel Extract dry concentrate	20 mg
Equivalent: Punica granatum (Dry)	1 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

microcrystalline cellulose

potable water

potassium acetate

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