



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

## Public Summary

<b>Summary for ARTG Entry:</b>	315129	Mediherb Curcuma Active
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	6/03/2019	
<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 . Mediherb Curcuma Active

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/02/2021
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Anti-inflammatory/relieve inflammation
- Decrease/reduce/relieve mild rheumatic aches and pains
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
  - Linked indication - Decrease/reduce/relieve mild joint aches and pains
  - Linked indication - Decrease/reduce/relieve mild joint inflammation/swelling
  - Linked indication - Decrease/reduce/relieve mild joint pain/soreness
  - Linked indication - Decrease/reduce/relieve mild joint stiffness
- Maintain/support joint health
- Maintain/support joint mobility/flexibility

#### 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 Table 2 of this instrument are also used.

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

Product presentation must only refer to mild rheumatic aches/pains.

Product presentation must only refer to mild joint symptoms.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

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

For practitioner dispensing only.

#### Additional Product information



**Australian Government**  
**Department of Health**  
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**

<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  
croscarmellose sodium  
crospovidone  
hypromellose  
lecithin  
magnesium stearate  
microcrystalline cellulose  
sodium starch glycollate

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