



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	325843	Theracurmin BioActive
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	1/11/2019	
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 . Theracurmin BioActive

Product Type	Single Medicine Product	Effective Date	27/08/2024
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Anti-inflammatory/relieve inflammation
Decrease/reduce/relieve mild joint aches and pains
Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
 Linked indication - Decrease/reduce/relieve mild joint aches and pains
Decrease/reduce/relieve mild joint inflammation/swelling
Maintain/support gallbladder function

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
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 only refer to mild joint symptoms.
Product presentation must not imply or refer to disease in any body organ.

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.
(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

curcumin 30 mg

Other Ingredients (Excipients)

citric acid

croscarmellose sodium

Ghatti Gum

hypromellose

magnesium stearate

maltodextrin

maltose

microcrystalline cellulose

silicon dioxide

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