



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	249052	ETHICAL NUTRIENTS PAIN RELIEF
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	20/07/2015	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . ETHICAL NUTRIENTS PAIN RELIEF

Product Type	Single Medicine Product	Effective Date	10/07/2020
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Permitted Indications

- Traditionally used in Ayurvedic medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Chinese medicine to anti-inflammatory/relieve inflammation
- Anti-inflammatory/relieve inflammation
- Traditionally used in Ayurvedic medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of soft tissue trauma
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of soft tissue trauma
- Decrease/reduce/relieve mild rheumatic aches and pains
- 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
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Traditionally used in Ayurvedic medicine to maintain/support joint health
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve mild joint inflammation/swelling
- Traditionally used in Chinese medicine to decrease/reduce/relieve mild joint inflammation/swelling
- Traditionally used in Chinese medicine to decrease/reduce/relieve mild joint pain/soreness
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve mild joint pain/soreness
- Maintain/support healthy liver function
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Chinese medicine to decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Ayurvedic medicine to maintain/support tendon health
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea

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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.

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

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

Product presentation must only refer to mild joint symptoms.

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

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

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Boswellia serrata gum oleoresin Extract dry concentrate 150 mg

Equivalent: Boswellia serrata (Dry) 1.5 g

Curcuma longa rhizome Extract dry concentrate 167 mg

Equivalent: Curcuma longa (Dry) 4.175 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

chlorophyllin-copper complex

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

microcrystalline cellulose

potassium acetate

purified water

sorbitan monolaurate

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