



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	272314	Ethical Nutrients Pain Relief Triple Strength
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	4/03/2016	
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 Triple Strength

Product Type	Single Medicine Product	Effective Date	31/07/2020
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Permitted Indications

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

Indication Requirements

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.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Product presentation must only refer to mild rheumatic aches/pains.
Label statement: If symptoms persist, talk to your health professional.

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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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Boswellia serrata gum oleoresin Extract dry concentrate	450 mg
Equivalent: Boswellia serrata (Dry)	4.5 g
Curcuma longa rhizome Extract dry concentrate	500 mg
Equivalent: Curcuma longa (Dry)	12.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
carmellose
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose

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