



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

**Public Summary**

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

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**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 - Helps enhance/improve/promote joint mobility
  - Linked indication - Decrease/reduce/relieve mild joint pain/soreness
  - Linked indication - Decrease/reduce/relieve mild joint stiffness
- 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**

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild joint symptoms.
- 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.
- Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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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**

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