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

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

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

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

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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 only refer to mild rheumatic aches/pains.

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