



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	261257	ETHICAL NUTRIENTS HIGH STRENGTH OMEGA-3 FRESH MINT
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	15/10/2015	
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.

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 HIGH STRENGTH OMEGA-3 FRESH MINT

Product Type	Single Medicine Product	Effective Date	16/03/2021
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Permitted Indications

Helps maintain/support healthy eye development in children
Maintain/support eye health
Maintain/support general health and wellbeing
Anti-inflammatory/relieve inflammation
Traditionally used in Naturopathic medicine to decrease/reduce/relieve mild rheumatic aches and pains
Helps in the maintenance of healthy blood lipids/blood fats
Maintain/support cardiovascular system health
Maintain/support heart health
Maintain/support cognitive function/mental function
Maintain/support brain/central nervous system development in children
Maintain/support nervous system function

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must only refer to mild rheumatic aches/pains.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to neurological conditions or developmental delays.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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 Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

concentrated fish Omega-3 triglycerides	927 mg/mL
Equivalent: docosahexaenoic acid	185.4 mg/mL
Equivalent: eicosapentaenoic acid	370.8 mg/mL

Other Ingredients (Excipients)

Flavour

Steviol glycosides

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