



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	225464	MediHerb EFA Essentials
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	8/07/2014	
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 . MediHerb EFA Essentials

Product Type	Single Medicine Product	Effective Date	5/11/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Helps maintain/support healthy eye development
- Helps maintain/support healthy vision development
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in children over 12 years of age
- Maintain/support general health and wellbeing in adolescents
- Maintain/support general health and wellbeing in breastfeeding women
- Anti-inflammatory/relieve inflammation
- Helps in the maintenance of healthy blood lipids/blood fats
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in children over 12 years of age
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
- Maintain/support cognitive function/mental function
- Maintain/support brain function
- Maintain/support brain health
- Maintain/support brain/central nervous system development
- Maintain/support skin health
- Maintain/support skin hydration
- Maintain/support skin integrity/structure

Indication Requirements

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Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to serious cardiovascular conditions.

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 mental illnesses, disorders or conditions.

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

Product presentation must not imply or refer to neurological conditions or developmental delays.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains fish OR Contains fish products.

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

If symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

d-alpha-tocopherol	38.46 mg
Evening Primrose Oil	500 mg
natural fish oil	500 mg
Equivalent: docosahexaenoic acid	60 mg
Equivalent: eicosapentaenoic acid	90 mg

Other Ingredients (Excipients)

Gelatin

glycerol

purified water

Soya Oil

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