



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

## Public Summary

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

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . MediHerb EFA Essentials

Product Type	Effective Date
Single Medicine Product	28/06/2019

### 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 adolescents
- Maintain/support general health and wellbeing in children over 12 years of age
- 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 in children over 12 years of age
- 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 adolescents
- Maintain/support cognitive function/mental function



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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**

Product presentation must not imply or refer to serious cardiovascular conditions.  
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 mental illnesses, disorders or 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 neurological conditions or developmental delays.  
Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.  
Label statement: If symptoms persist, talk to your health professional.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Capsule, soft
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

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

**Other Ingredients (Excipients)**

**Gelatin**  
**glycerol**  
**purified water**  
**Soya Oil**

Public Summary

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