



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

## Public Summary

<b>Summary for ARTG Entry:</b>	356117	Alpha EFA
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	3/03/2021	
<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.

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 . Alpha EFA

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/05/2021
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support general health and wellbeing  
Anti-inflammatory/relieve inflammation  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Maintain/support skin health

#### Indication Requirements

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

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).

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, soft

**Route of Administration**



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Oral

**Visual Identification**

**Active Ingredients**

<b>d-alpha-tocopherol</b>	<b>750 microgram</b>
<b>Hippophae rhamnoides seed Extract liquid concentrate</b>	<b>175 mg</b>
Equivalent: Hippophae rhamnoides (Dry)	1.75 g
<b>Hippophae rhamnoides fruit Extract liquid concentrate</b>	<b>325 mg</b>
Equivalent: Hippophae rhamnoides (Dry)	1.625 g

**Other Ingredients (Excipients)**

betacarotene  
carrageenan  
dibasic sodium phosphate  
glycerol  
hydroxypropyl starch  
lecithin  
medium chain triglycerides  
Olive Oil  
purified water  
Rosmarinus officinalis  
Soya Oil  
Sunflower Oil  
vegetable oil

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