



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

## Public Summary

<b>Summary for ARTG Entry:</b>	337390	UltraClean EPA/DHA Plus
<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>	3/06/2020	
<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.

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 . UltraClean EPA/DHA Plus

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/06/2020
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Anti-inflammatory/relieve inflammation  
Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis  
    Linked indication - Helps enhance/promote healthy joint function  
    Linked indication - Decrease/reduce/relieve mild joint pain/soreness  
Helps in the maintenance of healthy blood lipids/blood fats  
Maintain/support cardiovascular system health  
Maintain/support heart health  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Maintain/support cognitive function/mental function  
Maintain/support brain function  
Support healthy emotional/mood balance  
Maintains/support healthy foetal development  
Maintain/support skin health when dietary intake is inadequate

#### Indication Requirements

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must only refer to mild joint symptoms.

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



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

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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

**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**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule soft enteric

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>concentrated fish Omega-3 triglycerides</b>	<b>1000 mg</b>
Equivalent: docosahexaenoic acid	210 mg
Equivalent: eicosapentaenoic acid	320 mg
<b>d-alpha-tocopherol</b>	<b>16.8 mg</b>

**Other Ingredients (Excipients)**

ethyl vanillin

Gelatin

glycerol

mixed (low-alpha type) tocopherols concentrate

pectin

purified water

sorbitol

Sunflower Oil

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