Public Summary

Summary for ARTG Entry:	337390 UltraClean EPA/DHA Plus
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia
ARTG Start Date	3/06/2020
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.

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

Product Type	Single Medicine Product	**Effective Date**	3/06/2020

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

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.

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.

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

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

concentrated fish Omega-3 triglycerides	**1000 mg**
Equivalent: docosahexaenoic acid	210 mg
Equivalent: eicosapentaenoic acid	320 mg
d-alpha-tocopherol	**16.8 mg**

Other Ingredients (Excipients)

ethyl vanillin
Gelatin
glycerol
mixed (low-alpha type) tocopherols concentrate
pectin
purified water
sorbitol
Sunflower Oil

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