



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	309467	UltraClean Krill Oil Concentrate
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	20/09/2018	
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.

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.

Preparations that contain the ingredient Euphasia superba oil are subject to the following condition: Must include the label warning (SFOOD) Derived from seafood OR (SHELL) Contains crustacean shellfish.

Products

1 . UltraClean Krill Oil Concentrate

Product Type	Single Medicine Product	Effective Date	10/05/2019
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Permitted Indications

Anti-inflammatory/relieve inflammation
Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
Linked indication - Decrease/reduce/relieve mild joint pain/soreness
Linked indication - Helps enhance/promote healthy joint function
Helps in the maintenance of healthy blood lipids/blood fats
Maintain/support cardiovascular system health
Maintain/support heart health
Maintain/support healthy liver function when dietary intake is inadequate
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support cognitive function/mental function
Maintain/support brain function
Aid/assist/helps synthesis of neurotransmitters
Maintains/support healthy foetal development

Indication Requirements

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 liver disease, such as cirrhosis, hepatitis.

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.

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

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains crustacea OR Contains crustacean products.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

euphausia superba oil	1000 mg
Equivalent: astaxanthin (of euphausia superba oil)	85 microgram
Equivalent: phosphatidyl choline	480 mg
Equivalent: docosahexaenoic acid	70 mg
Equivalent: eicosapentaenoic acid	150 mg

Other Ingredients (Excipients)

- d-alpha-tocopherol**
- Gelatin**
- glycerol**
- lecithin**
- medium chain triglycerides**
- purified water**
- sorbitol solution (70 per cent) (non-crystallising)**
- Soya Oil**
- vegetable oil**

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