



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	233598	UltraClean 85 Liquid
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	10/02/2015	
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.

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 85 Liquid

Product Type	Single Medicine Product	Effective Date	11/11/2020
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Permitted Indications

- Helps maintain/support healthy eye development in healthy infants
- Helps maintain/support healthy eye development in children
- Anti-inflammatory/relieve inflammation
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Helps enhance/promote healthy joint function
- 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 blood vessel health
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
- Maintain/support cognitive function/mental function
- Maintain/support brain function
- Maintain/support brain/central nervous system development in children
- Maintain/support brain/central nervous system development in healthy infants
- Support healthy emotional/mood balance
- Helps maintains/support healthy foetal CNS/brain development
- Maintains/support healthy foetal development in breastfeeding women

Indication Requirements

- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must only refer to mild joint symptoms.
- 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.
- Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- Label statement: If symptoms persist, talk to your health professional.

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Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

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

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

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

concentrated fish Omega-3 triglycerides	905 mg/mL
Equivalent: docosahexaenoic acid	188.24 mg/mL
Equivalent: eicosapentaenoic acid	497.75 mg/mL

Other Ingredients (Excipients)

Lemon Oil

mixed (low-alpha type) tocopherols concentrate

Soya Oil

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