



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	217882	UltraClean OmegaFactors for Juniors
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	29/11/2013	
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 OmegaFactors for Juniors

Product Type	Single Medicine Product	Effective Date	15/11/2025
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Permitted Indications

Helps maintain/support healthy eye development in children

Maintain/support healthy growth and development in children

Maintain/support general health and wellbeing in children

Aids/assists teeth development in children

Maintain/support bone health

Aids/assists healthy bone development/growth/building in children

Maintain/support healthy immune system function in children

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Maintain/support cognitive development in children

Maintain/support cognitive function/mental function in children

Maintain/support brain function in children

Maintain/support brain/central nervous system development in children

Indication Requirements

Product presentation must not imply or refer to neurological conditions or developmental delays.

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 the table in Part 2 of Schedule 1 to this instrument are also used.

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

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).

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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



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Specific Indications

No Specific Indications included on Record

Warnings

Contains fish OR Contains fish products

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

colecalciferol	5 microgram
concentrated fish Omega-3 triglycerides	526 mg
Equivalent: docosahexaenoic acid	126 mg
Equivalent: eicosapentaenoic acid	189 mg
potassium iodide	40 microgram
Equivalent: iodine	30.58 microgram
retinol palmitate	112.2 microgram
Equivalent: vitamin A	61.2 microgram

Other Ingredients (Excipients)

citric acid
dl-alpha-tocopherol
Flavour
Gelatin
glycerol
hydrogenated vegetable oil
hypromellose
lecithin
mixed (low-alpha type) tocopherols concentrate
purified water
sorbitol solution (70 per cent) (non-crystallising)
Soya Oil
Stevia rebaudiana
Theobroma Oil
titanium dioxide
Vaccinium myrtillus
vegetable oil
white beeswax
xylitol

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