



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	316206	Children's Fish-i Care
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	5/04/2019	
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 . Children's Fish-i Care

Product Type	Single Medicine Product	Effective Date	16/11/2020
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Permitted Indications

Helps maintain/support healthy eye development
Maintain/support healthy eye function in children
Maintain/support eye health in children
Maintain/support general health and wellbeing in children
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
Maintain/support cognitive function/mental function in children
Maintain/support brain function in children
Maintain/support brain health in children
Maintain/support nervous system health in children
Maintain/support brain/central nervous system development in children
Maintain/support nervous system function in children
Maintain/support skin health in children

Indication Requirements

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

No Warnings included on Record



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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

concentrated fish Omega-3 triglycerides	500 mg
Equivalent: docosahexaenoic acid	250 mg
Equivalent: eicosapentaenoic acid	50 mg
potassium iodide	65.4 microgram
Equivalent: iodine	50 microgram

Other Ingredients (Excipients)

citric acid

d-alpha-tocopheryl acetate

Flavour

Gelatin

glycerol

hypromellose

iron oxide red

purified water

sorbitol solution (70 per cent) (non-crystallising)

Soya Oil

Stevia rebaudiana

Theobroma Oil

white beeswax

xylitol

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