



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	307114	Brauer Baby & Kids Ultra Pure Cod Liver Oil with DHA
ARTG entry for	Medicine Listed	
Sponsor	BNutrition Pty Ltd	
Postal Address	PO Box 234, Tanunda, SA, 5352 Australia	
ARTG Start Date	17/07/2018	
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.

Products

1 . Brauer Baby & Kids Ultra Pure Cod Liver Oil with DHA

Product Type	Single Medicine Product	Effective Date	21/03/2019
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Permitted Indications

Maintain/support healthy eye function
Maintain/support eye health
Maintain/support healthy eyesight/vision
Maintain/support body mucous membrane health
Maintain/support general health and wellbeing
Maintain/support bone health
Aids/assists healthy bone development/growth/building in children
Aids/assists healthy bone development/growth/building
Aids/assists healthy bone development/growth/building in healthy infants over 6 months of age
Maintain/support bone strength
Help maintain/support bone mineralisation
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate



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Maintain/support skin health

Maintain/support skin integrity/structure

Indication Requirements

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

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 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 not imply or refer to serious musculoskeletal or neurological conditions.

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

Cod-liver oil	500 mg
Equivalent: docosahexaenoic acid	50 mg
Equivalent: colexaliferol	2.1875 microgram
Equivalent: eicosapentaenoic acid	35 mg
Equivalent: vitamin A	262.76 RE

Other Ingredients (Excipients)

Gelatin

glycerol

Lemon Oil

purified water

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