



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	363828	Eagle Clinical DHA + Choline
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	30/04/2021	
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 . Eagle Clinical DHA + Choline

Product Type	Single Medicine Product	Effective Date	5/11/2021
--------------	-------------------------	----------------	-----------

Permitted Indications

- Maintain/support healthy growth and development in breast fed healthy infants
- Maintain/support general health and wellbeing in breastfeeding women
- Maintain/support general health and wellbeing
- Aids/assists teeth development
- Maintain/support healthy teeth
- Maintain/support teeth mineralisation
- Anti-inflammatory/relieve inflammation
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support (state mineral) absorption in bones
- Help maintain/support bone mineralisation
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Helps in the maintenance of healthy blood lipids/blood fats
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
- Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
- Maintain/support (state vitamin/mineral) within normal range in breastfeeding women
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support cognitive function/mental function
- Maintain/support brain function
- Maintain/support brain health



Australian Government
Department of Health
Therapeutic Goods Administration

Maintain/support brain/central nervous system development in breast fed healthy infants

Indication Requirements

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

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).

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 cardiovascular conditions.

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).

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

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

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

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).

Contains fish OR Contains fish products.

For practitioner dispensing only.

If symptoms persist, seek the advice of a healthcare professional.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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

choline bitartrate	348.89 mg
Equivalent: choline	143.5 mg
colecalfiferol	6.25 microgram
concentrated fish Omega-3 triglycerides	978.26 mg
Equivalent: eicosapentaenoic acid	97.83 mg
Equivalent: docosahexaenoic acid	450 mg

Other Ingredients (Excipients)

dl-alpha-tocopherol

Gelatin

glycerol

iron oxide black

lecithin

Lemon Oil

mixed (low-alpha type) tocopherols concentrate

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

purified water

Rice bran oil

silicon dioxide

vegetable oil

white beeswax

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary