



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	395855	Clean Omega D
ARTG entry for	Medicine Listed	
Sponsor	Ora Health Pty Ltd	
Postal Address	24/10-18 Orchard Road, Brookvale, NSW, 2100 Australia	
ARTG Start Date	12/09/2022	
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 . Clean Omega D

Product Type	Single Medicine Product	Effective Date	20/05/2023
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Permitted Indications

Helps maintain/support healthy eye development in infants
Maintain/support healthy growth and development
Maintain/support general health and wellbeing
Maintain/support healthy teeth
Maintain/support bone health
Aids/assists healthy bone development/growth/building
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
Maintain/support cardiovascular system health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle health
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
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
Maintain/support cognitive function/mental function
Maintain/support nervous system health
Maintain/support brain/central nervous system development in infants
Maintain/support nervous system function

Indication Requirements

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.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose



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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: [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 cardiovascular conditions.

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 immunological diseases.

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).

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 serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

colecalfiferol	12.5 microgram
DHA/EPA rich Schizochytrium algal oil	962.7 mg
Equivalent: docosahexaenoic acid	300 mg
Equivalent: eicosapentaenoic acid	150 mg

Other Ingredients (Excipients)

ascorbyl palmitate
carrageenan
d-alpha-tocopherol
glycerol
hydroxypropyl starch
medium chain triglycerides
mixed (low-alpha type) tocopherols concentrate
purified water
Rosemary Oil
sodium carbonate
Sunflower Oil