



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	395855	Clean Omega D
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Ora Health Pty Ltd	
<b>Postal Address</b>	24/10-18 Orchard Road, Brookvale, NSW, 2100 Australia	
<b>ARTG Start Date</b>	12/09/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 serious cardiovascular conditions.  
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.



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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.

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).

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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.

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

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 immunological diseases.

#### 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

Public Summary

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