



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

## Public Summary

<b>Summary for ARTG Entry:</b>	327961	xEO Mega
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	doTERRA Australia Pty Ltd	
<b>Postal Address</b>	Ground Floor, 350 Wellington Road, MULGRAVE, VIC, 3170 Australia	
<b>ARTG Start Date</b>	20/12/2019	
<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 . xEO Mega

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	4/03/2021
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support eye health
- Helps maintain/support eye retina health
- Maintain/support healthy eyesight/vision
- Maintain/support general health and wellbeing
- Maintain/support bone health
- Maintain/support bone strength
- 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 healthy cardiovascular system function
- Maintain/support heart health
- 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
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in elderly individuals
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support brain function
- Maintain/support wound healing

### 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



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

[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.

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.

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.

Product presentation must not imply or refer to mental illnesses, disorders or 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**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>astaxanthin esters extracted from Haematococcus pluvialis</b>	<b>2 mg</b>
Equivalent: Astaxanthin (of Haematococcus pluvialis)	250 microgram
<b>betacarotene</b>	<b>1.0009 mg</b>
<b>Borago officinalis seed Oil fixed</b>	<b>50 mg</b>
<b>Caraway Oil</b>	<b>2.286 mg</b>
<b>Chamomile Oil German</b>	<b>285 microgram</b>
<b>colecalfiferol</b>	<b>5 microgram</b>
<b>concentrated fish Omega-3 triglycerides</b>	<b>81 mg</b>
Equivalent: eicosapentaenoic acid	8.1 mg
Equivalent: docosahexaenoic acid	40.5 mg
<b>concentrated fish Omega-3 triglycerides</b>	<b>179.028 mg</b>
Equivalent: eicosapentaenoic acid	72 mg
Equivalent: docosahexaenoic acid	36 mg
<b>Cumin Oil</b>	<b>3.429 mg</b>
<b>d-alpha-tocopherol</b>	<b>10.1 mg</b>
<b>Ginger Oil</b>	<b>2.856 mg</b>
<b>lutein</b>	<b>.75 mg</b>
<b>lycopene</b>	<b>.25 mg</b>
<b>Olibanum Oil</b>	<b>4.572 mg</b>
<b>Orange Oil</b>	<b>3.429 mg</b>
<b>Peppermint Oil</b>	<b>3.429 mg</b>
<b>Punica granatum seed Oil fixed</b>	<b>12.5 mg</b>

Public Summary



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Syzygium aromaticum whole plant Oil essential	5.715 mg
Thyme Oil	3.999 mg
zeaxanthin	.2504 mg

**Other Ingredients (Excipients)**

d-alpha-tocopherol  
dl-alpha-tocopherol  
glycerol  
lecithin  
Maize Oil  
mixed (low-alpha type) tocopherols concentrate  
modified food starch  
Olive Oil  
purified water  
Rosmarinus officinalis  
Safflower Oil  
Sunflower Oil  
vegetable oil

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