



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	387758	CellProtect Complex
<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>	2/05/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

**Conditions**

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 . CellProtect Complex**

Product Type	Single Medicine Product	Effective Date	2/05/2022
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support natural body cleansing/detoxification processes
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy growth and development
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support healthy teeth
- Decrease/reduce nail brittleness/splitting/chipping
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Maintain/support body tissue repair/regeneration
- 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
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health

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Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Maintain/support thyroid gland health  
Aid/assist thyroid hormone production  
Maintain/support smell sensation  
Maintain/support taste sensation  
Traditionally used in Ayurvedic medicine to maintain/support digestive system health  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support muscle health  
Maintain/support muscle function  
Helps decrease/reduce homocysteine levels in healthy individuals  
Aid/assist/helps protein synthesis in the body  
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  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Maintain/support cognitive function/mental function  
Maintain/support memory/mental recall  
Traditionally used in Ayurvedic medicine to brain tonic/Enhance brain health  
Maintain/support neuromuscular function  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Maintain/support nervous system function  
Maintain/support female reproductive system health  
Maintain/support/regulate healthy menstrual cycle  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones  
Maintain/support skin health  
Maintain/support skin integrity/structure  
Maintain/support wound healing  
Maintain/support skin repair/healing/regeneration

**Indication Requirements**

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to any thyroid related diseases.

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.

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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to serious cardiovascular 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.

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

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.

Product presentation must not imply or refer to drugs/alcohol.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

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 infertility.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is



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right for you.

Product presentation must not imply or refer to hormone imbalances.

**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).

Not to be taken by children under 2 years old (or words to that effect).

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.

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Biotin</b>	<b>2.5 mg</b>
<b>borax</b>	<b>8.82 mg</b>
Equivalent: boron	1 mg
<b>Brassica oleracea var. italica sprout Powder</b>	<b>200 mg</b>
Equivalent: Brassica oleracea var. italica (Fresh)	2.4 g
<b>calcium folinate</b>	<b>238.7 microgram</b>
Equivalent: folinic acid	220 microgram
<b>colecalfiferol</b>	<b>.0125 mg</b>
<b>mecobalamin</b>	<b>100 microgram</b>
<b>Nigella sativa seed Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Nigella sativa (Dry)	1000 mg
<b>potassium iodide</b>	<b>130.9 microgram</b>
Equivalent: iodine	100 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>7.84 mg</b>
Equivalent: pyridoxine	5 mg
<b>selenomethionine</b>	<b>149 microgram</b>
Equivalent: selenium	60 microgram
<b>zinc citrate dihydrate</b>	<b>38.94 mg</b>
Equivalent: zinc	12.5 mg

**Other Ingredients (Excipients)**

- Acacia
- colloidal anhydrous silica
- d-alpha-tocopherol
- fractionated coconut oil
- hypromellose
- liquid glucose
- magnesium stearate

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microcrystalline cellulose

purified water

silicon dioxide

sodium ascorbate

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