



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	391341	Eagle Clinical Zinc Protect
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	27/06/2022	
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 . Eagle Clinical Zinc Protect

Product Type	Single Medicine Product	Effective Date	27/06/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support general health and wellbeing
Maintain/support general health and wellbeing in breastfeeding women
Maintain/support general health and wellbeing in aging individuals
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegetarians
Maintain/support (state vitamin/mineral/nutrient) levels in the body In older females
Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegans
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
Maintain/support (state vitamin/mineral/nutrient) levels in the body in active individuals
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body In older males
Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals
Maintain/support (state vitamin/mineral) within normal range in vegetarians
Maintain/support (state vitamin/mineral) within normal range in vegans
Maintain/support (state vitamin/mineral) within normal range in breastfeeding women
Maintain/support (state vitamin/mineral) within normal range In older males
Maintain/support (state vitamin/mineral) within normal range In older females
Maintain/support (state vitamin/mineral) within normal range in active individuals
Maintain/support (state vitamin/mineral) within normal range
Maintain/support (state vitamin/mineral) within normal range in aging individuals
Aid/assist/helps synthesis of neurotransmitters
Maintain/support reproductive system health

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Maintain/support sperm health
Maintain/support sperm motility
Maintain/support sperm production
Maintain/support skin health
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration

Indication Requirements

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 infertility.
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 immunological diseases.
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

For practitioner dispensing only.
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.
If symptoms persist, seek the advice of a healthcare professional.
WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
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.
WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	50 mg
d-alpha-tocopheryl acid succinate	41.3184 mg
Dunaliella salina cell Extract soft concentrate standardised	26.67 mg
Equivalent: Dunaliella salina (Fresh)	50.0062 mg
manganese amino acid chelate	10 mg
Equivalent: manganese	2 mg
pyridoxine hydrochloride	40 mg
Equivalent: pyridoxine	32.9 mg
selenomethionine	65 microgram
Equivalent: selenium	26 microgram
zinc amino acid chelate	90 mg
Equivalent: zinc	18 mg
zinc ascorbate monohydrate	79.5 mg
Equivalent: zinc	

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Equivalent: ascorbic acid

12 mg

64.2 mg

Other Ingredients (Excipients)

ascorbyl palmitate
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
crospovidone
Gelatin
hypromellose
hypromellose
lecithin
macrogol 3000
magnesium stearate
microcrystalline cellulose
mixed (low-alpha type) tocopherols concentrate
polyvinyl alcohol
potable water
purified talc
silicon dioxide
Soya Oil
sucrose
titanium dioxide

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Public Summary