



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	346625	Eagle Zinc Zenith Plus
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	27/10/2020	
<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 . Eagle Zinc Zenith Plus**

Product Type	Single Medicine Product	Effective Date	22/02/2021
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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 aging individuals
- Maintain/support general health and wellbeing in breastfeeding women
- 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
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in active individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body In older males
- Maintain/support (state vitamin/mineral/nutrient) levels in the body In older females
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adults
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegans
- Maintain/support (state vitamin/mineral) within normal range in vegetarians
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support (state vitamin/mineral) within normal range in active individuals
- 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 aging individuals
- Maintain/support (state vitamin/mineral) within normal range in breastfeeding women
- Maintain/support (state vitamin/mineral) within normal range in adults
- Maintain/support (state vitamin/mineral) within normal range in vegans

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Aid/assist/helps synthesis of neurotransmitters  
 Maintain/support reproductive system health  
 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 serious immunological diseases.  
 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.  
 Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.  
 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**

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.  
 If symptoms persist, seek the advice of a healthcare professional.  
 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).  
 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.  
 For practitioner dispensing only.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

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

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Equivalent: ascorbic acid	64.2 mg
Equivalent: zinc	12 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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