



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346630	Mediherb 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	27/10/2020	
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 . Mediherb Zinc Protect

Product Type	Single Medicine Product	Effective Date	21/04/2022
---------------------	-------------------------	-----------------------	------------

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 in aging individuals
- Maintain/support general health and wellbeing
- 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 older females
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegetarians
- Maintain/support (state vitamin/mineral/nutrient) levels in the body In older males
- 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 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 older females
- Maintain/support (state vitamin/mineral) within normal range In older males
- Maintain/support (state vitamin/mineral) within normal range in breastfeeding women
- Maintain/support (state vitamin/mineral) within normal range in vegans
- Maintain/support (state vitamin/mineral) within normal range in vegetarians
- Maintain/support (state vitamin/mineral) within normal range in active individuals
- Maintain/support (state vitamin/mineral) within normal range in aging individuals
- Maintain/support (state vitamin/mineral) within normal range
- 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 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

If symptoms persist, seek the advice of a healthcare professional.

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.

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. For practitioner dispensing only.

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**

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: ascorbic acid	

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Equivalent: zinc 64.2 mg
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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary