



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	285687	MediHerb Zinc-C Powder
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	14/02/2017	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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-C Powder

Product Type	Effective Date
Single Medicine Product	2/10/2019

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support collagen health
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Aid/assist/helps connective tissue production/formation
- 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
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support (state vitamin/mineral) within normal range in breastfeeding women
- Maintain/support (state vitamin/mineral) within normal range in elderly individuals
- Maintain/support (state vitamin/mineral) within normal range in active individuals
- Maintain/support (state vitamin/mineral) within normal range in vegans
- Maintain/support (state vitamin/mineral) within normal range in vegetarians
- Support healthy stress response in the body

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Maintain/support brain function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support brain/central nervous system development
Maintain/support reproductive system health
Maintain/support sperm health
Maintain/support sperm motility
Maintain/support sperm production
Decrease/reduce/relieve common cold duration
Decrease/reduce/relieve symptoms of common colds and flu
Decrease/reduce/relieve mild upper respiratory tract congestion
Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
 Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 Linked indication - Decrease/reduce/relieve sneezing
 Linked indication - Decrease/reduce/relieve cough
 Linked indication - Relieve runny/dripping nose
Decrease/reduce/relieve sneezing
Relieve symptoms of mild upper respiratory tract infections
Decrease/reduce/relieve cough
Relieve runny/dripping nose
Relieve symptoms of sore throat/pharyngitis
Maintain/support skin health
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Respiratory tract infections must be qualified by 'mild'.
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).
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Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to infertility.
Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Product presentation must not imply or refer to neurological conditions or developmental delays.
Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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.
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.
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].
Adults only. OR Not to be used in children under two years of age without medical advice (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 Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	200 mg/g
betacarotene	.4 mg/g
lysine hydrochloride	249.88 mg/g
Equivalent: lysine	200 mg/g
manganese amino acid chelate	10 mg/g
Equivalent: manganese	1 mg/g
pyridoxal 5-phosphate monohydrate	7.84 mg/g
Equivalent: pyridoxine	5 mg/g
quercetin dihydrate	20 mg/g
selenomethionine	37.26 microgram/g
Equivalent: selenium	15 microgram/g
zinc citrate dihydrate	15.58 mg/g
Equivalent: zinc	5 mg/g

Other Ingredients (Excipients)

Acacia
beetroot
citric acid
colloidal anhydrous silica
Flavour
glycine
maltodextrin
Pea Starch
purified water
sodium alginate
Stevia rebaudiana
thaumatin

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