



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373903	Zn Sentinel
ARTG entry for	Medicine Listed	
Sponsor	Greal Labs Pty Ltd	
Postal Address	PO Box 193, Fitzroy, VIC, 3065 Australia	
ARTG Start Date	31/08/2021	
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 . Zn Sentinel

Product Type	Single Medicine Product	Effective Date	31/08/2021
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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 healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support oral health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support reproductive system health
- Maintain/support sperm health
- Maintain/support sperm motility
- Maintain/support sperm production
- Maintain/support testosterone level in healthy males
- Maintain/support skin health
- Maintain/support wound healing

Indication Requirements

- 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.
- 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).
- Label statement: If symptoms persist, talk to your health professional.
- Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR

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[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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

zinc citrate dihydrate	31.15 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

Acacia

carmellose sodium

citric acid

colloidal anhydrous silica

Flavour

magnesium stearate

microcrystalline cellulose

Siraitia grosvenorii

xylitol

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