



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	409315	Tri-Zinc Supreme
ARTG entry for	Medicine Listed	
Sponsor	Designs For Health Pty Ltd	
Postal Address	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
ARTG Start Date	22/05/2023	
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 . Tri-Zinc Supreme

Product Type	Single Medicine Product	Effective Date	22/05/2023
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Permitted Indications

- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Maintain/support bone health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support testosterone level
- Maintain/support skin health
- Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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 consult your healthcare practitioner (or words to that effect).

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

polaprezinc	23.26 mg
Equivalent: zinc	5 mg
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg
zinc citrate dihydrate	31.15 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

hypromellose

magnesium stearate

malic acid

methionine

microcrystalline cellulose

purified water

silicon dioxide

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