



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|----------|
| Summary for ARTG Entry: | 338074 | MolyZinc |
| ARTG entry for | Medicine Listed | |
| Sponsor | Interclinical Laboratories Pty Ltd | |
| Postal Address | PO Box 6474, ALEXANDRIA, NSW, 2015 Australia | |
| ARTG Start Date | 18/06/2020 | |
| 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.

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.

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 . MolyZinc

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 18/06/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support energy levels
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support healthy teeth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Aid/assist healthy red blood cell production
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support blood capillary health
- Maintain/support blood vessel health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps protein synthesis in the body
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

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- Maintain/support cognitive function/mental function in healthy adults
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support female reproductive system health
- Maintain/support preconception health in healthy males
- Maintain/support preconception health in healthy females
- Maintain/support reproductive system health in males
- Maintain/support healthy reproductive hormones
- Maintain/support sperm health in healthy males
- Maintain/support sperm production in healthy males
- Maintain/support testosterone level
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support skin regeneration
- Maintain/support wound healing

Indication Requirements

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 serious cardiovascular conditions.

Label statement: If symptoms persist, talk to your health professional.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

Product presentation must not imply or refer to hormone imbalances.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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.

Product presentation must not imply or refer to chronic fatigue syndrome.

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.

Additional Product information

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

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|--------------------------------|---------------|
| Dosage Form | Capsule, hard |
| Route of Administration | Oral |

Visual Identification

Active Ingredients

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|------------------------|---------------|
| ascorbic acid | 30 mg |
| molybdenum trioxide | 150 microgram |
| Equivalent: molybdenum | 100 microgram |



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|--|----------------|
| pyridoxal 5-phosphate monohydrate | 1.61 mg |
| Equivalent: pyridoxine | 1.03 mg |
| zinc glycinate monohydrate | 17.7 mg |
| Equivalent: zinc | 5 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

magnesium stearate

microcrystalline cellulose

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