



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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
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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 females
- Maintain/support preconception health in healthy males
- 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

- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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 mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to hormone imbalances.
- 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.
- Product presentation must not imply or refer to infertility.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

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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