



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	326832	Copper Plus
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	28/11/2019	
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 . Copper Plus

Product Type	Single Medicine Product	Effective Date	28/11/2019
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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 collagen formation
- Maintain/support collagen health
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy body tissues
- Maintain/support bone health
- Aid/assist healthy red blood cell production

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Maintain/support red blood cell health
 Helps maintain/support haemoglobin formation/synthesis
 Maintain/support blood vessel health
 Maintain/support healthy immune system function
 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)
 Maintain/support nerve conduction
 Maintain/support nervous system health
 Maintain/support nervous system function
 Maintain/support skin health

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 immunological diseases.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
 Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
 Product presentation must not imply or refer to serious cardiovascular 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

copper (II) glycinate	6.67 mg
Equivalent: copper	2 mg
riboflavin	500 microgram

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate
Carnauba Wax
citric acid
colloidal anhydrous silica
croscarmellose sodium



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glycerol
Guar Gum
lecithin
magnesium stearate
maize starch
maltodextrin
microcrystalline cellulose
purified water

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