



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	338936	Ultra Zinc +
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	4/07/2020	
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 . Ultra Zinc +

Product Type	Single Medicine Product	Effective Date	4/07/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support healthy eye function
Maintain/support eye health
Maintain/support healthy eyesight/vision
Maintain/support connective tissue health
Maintain/support taste sensation
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Aid/assist/helps synthesis of neurotransmitters
Maintain/support reproductive system health in males
Maintain/support prostate health
Maintain/support sperm health
Maintain/support sperm motility
Maintain/support skin health
Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to infertility.

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

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

Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.



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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).

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 - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

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).

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

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

magnesium amino acid chelate	100 mg
Equivalent: magnesium	20 mg
pyridoxine hydrochloride	20.06 mg
Equivalent: pyridoxine	16.5 mg
retinol acetate	.5313 mg
zinc amino acid chelate	100 mg
Equivalent: zinc	20 mg
zinc citrate dihydrate	52.96 mg
Equivalent: zinc	17 mg
zinc gluconate	92.86 mg
Equivalent: zinc	13 mg

Other Ingredients (Excipients)

- Acacia
- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- dl-alpha-tocopherol
- hypromellose
- magnesium stearate
- maize starch
- microcrystalline cellulose
- povidone
- spray-dried glucose syrup

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