



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|--|
| Summary for ARTG Entry: | 299075 | ETHICAL NUTRIENTS MEGA ZINC 40MG WITH VITAMIN C ORANGE |
| ARTG entry for | Medicine Listed | |
| Sponsor | Metagenics (Aust) Pty Ltd | |
| Postal Address | PO Box 675, VIRGINIA BC, QLD, 4014 Australia | |
| ARTG Start Date | 29/01/2018 | |
| 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 . ETHICAL NUTRIENTS MEGA ZINC 40MG WITH VITAMIN C ORANGE

| Product Type | Single Medicine Product | Effective Date | 28/08/2020 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

Permitted Indications

- Maintain/support general health and wellbeing in boys up to 12 years of age
- Maintain/support general health and wellbeing in males
- Maintain/support general health and wellbeing in adolescent males
- Maintain/support healthy immune system function in children over 5 years of age
- Maintain/support healthy immune system function in teenagers
- Maintain/support healthy immune system function in adults
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in teenagers
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adults
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in children over 5 years of age
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in adults
- Maintain/support nervous system function in children over 5 years of age
- Maintain/support reproductive system health in males
- Maintain/support reproductive system health in adolescent males
- Decrease/reduce/relieve common cold duration in teenagers
- Decrease/reduce/relieve common cold duration in adults
- Decrease/reduce/relieve the severity of common cold symptoms in adults
- Relieve symptoms of acne in teenagers
- Soothe/relieve skin inflammation in teenagers
- Maintain/support skin health in adults
- Maintain/support skin health in teenagers
- Maintain/support skin health in children over 5 years of age
- Maintain/support wound healing in children over 5 years of age
- Maintain/support wound healing in adults



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Maintain/support wound healing in teenagers
 Maintain/support skin repair/healing/regeneration in teenagers
 Maintain/support skin repair/healing/regeneration in children over 5 years of age
 Maintain/support skin repair/healing/regeneration in adults

Indication Requirements

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

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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to infertility.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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

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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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.

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 Powder
Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|------------------------------------|--------------------|
| betacarotene | 1.052 mg/g |
| calcium ascorbate dihydrate | 318.52 mg/g |
| Equivalent: ascorbic acid | 263.16 mg/g |
| pyridoxine hydrochloride | 2.63 mg/g |
| Equivalent: pyridoxine | 2.16 mg/g |
| zinc amino acid chelate | 52.63 mg/g |
| Equivalent: zinc | 10.52 mg/g |

Other Ingredients (Excipients)

citric acid
 colloidal anhydrous silica
 dl-alpha-tocopherol
 Flavour
 hypromellose
 liquid glucose
 maize starch

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maltodextrin
potassium citrate
sodium ascorbate
starch sodium octenyl succinate
Steviol glycosides
tartaric acid

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