



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

## Public Summary

<b>Summary for ARTG Entry:</b>	299081	ETHICAL NUTRIENTS MEGA ZINC 40MG WITH VITAMIN C RASPBERRY
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	29/01/2018	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 RASPBERRY

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/08/2020
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### Permitted Indications

Maintain/support general health and wellbeing in adolescent males  
Maintain/support general health and wellbeing in males  
Maintain/support general health and wellbeing in boys up to 12 years of age  
Maintain/support healthy immune system function in children over 5 years of age  
Maintain/support healthy immune system function in adults  
Maintain/support healthy immune system function 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 teenagers  
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 teenagers  
Maintain/support skin health in adults  
Maintain/support skin health in children over 5 years of age  
Maintain/support wound healing in adults  
Maintain/support wound healing in children over 5 years of age



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

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

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

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.

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 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).

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

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

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).

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.

If symptoms persist consult your healthcare practitioner (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

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

##### Other Ingredients (Excipients)

**Beta vulgaris**

**citric acid**

**colloidal anhydrous silica**

**dl-alpha-tocopherol**

**Flavour**

**hypromellose**

**liquid glucose**



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

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