



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

## Public Summary

<b>Summary for ARTG Entry:</b>	329751	ETHICAL NUTRIENTS EXTRA C ZINGLES ORANGE
<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>	11/02/2020	
<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.

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 . ETHICAL NUTRIENTS EXTRA C ZINGLES ORANGE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	11/02/2020
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### Permitted Indications

- Maintain/support immune system health in children
- Maintain/support immune system health
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve common cold duration in children
- Decrease/reduce/relieve symptoms of common colds and flu
- Decrease/reduce/relieve symptoms of common colds and flu in children
- Decrease/reduce/relieve the severity of common cold symptoms
- Decrease/reduce/relieve the severity of common cold symptoms in children

### Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- 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: 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.
- Product presentation must not imply or refer to serious immunological diseases.
- If product is indicated for supplementation, Label statement: 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.



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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**

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).

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

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

1 . Formulation 1

**Dosage Form**                      Tablet, chewable

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>500 mg</b>
<b>calcium ascorbate dihydrate</b>	<b>302.6 mg</b>
Equivalent: ascorbic acid	250 mg
<b>sodium ascorbate</b>	<b>281.2 mg</b>
Equivalent: ascorbic acid	250 mg
<b>zinc sulfate monohydrate</b>	<b>27.44 mg</b>
Equivalent: zinc	10 mg

**Other Ingredients (Excipients)**

- Acacia
- betacarotene
- colloidal anhydrous silica
- dl-alpha-tocopherol
- Flavour
- hypromellose
- magnesium stearate
- maize starch
- maltodextrin
- medium chain triglycerides
- microcrystalline cellulose
- Pineapple
- potassium citrate
- silicon dioxide
- sodium ascorbate
- sodium bicarbonate
- sucralose
- sucrose
- tartaric acid

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