



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299666	ETHICAL NUTRIENTS EXTRA C
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	15/02/2018	
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 EXTRA C

Product Type	Single Medicine Product	Effective Date	15/09/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Helps enhance/promote teeth health
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Helps enhance/promote bone health
- Decrease/reduce/relieve symptoms of hayfever
- Helps decrease/reduce/relieve symptoms of mild allergies
- Maintain/support healthy immune system function
- Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
- Decrease/reduce/relieve the severity of common cold symptoms
- Relieve symptoms of mild upper respiratory tract infections
- Decrease/reduce/relieve symptoms of common cold
- Helps enhance/promote skin health
- Maintain/support wound healing
- Maintain/support skin repair/healing/regeneration

Indication Requirements

- 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 serious allergic conditions such as anaphylaxis.
- Label statement: If symptoms persist, talk to your health professional.



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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.

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 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.

Respiratory tract infections must be qualified by 'mild'.

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).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

calcium ascorbate dihydrate	779.8 mg
Equivalent: ascorbic acid	640 mg
cysteine hydrochloride	9.7 mg
hesperidin	17.91 mg
magnesium ascorbate	54.63 mg
Equivalent: ascorbic acid	49 mg
nicotinamide ascorbate	255.5 mg
Equivalent: ascorbic acid	151 mg
Equivalent: nicotinamide	104.5 mg
potassium ascorbate	24.15 mg
Equivalent: potassium	3.77 mg
Equivalent: ascorbic acid	17 mg
sodium ascorbate	139.14 mg
Equivalent: ascorbic acid	123 mg

Other Ingredients (Excipients)

- carrageenan**
- Citrus bioflavonoids extract**
- croscarmellose sodium**
- hypromellose**
- macrogol 8000**
- microcrystalline cellulose**
- powdered cellulose**
- silicon dioxide**

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stearic acid

tartaric acid

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