



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	152660	METAGENICS C-ULTRASCORB II
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	28/05/2008	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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.

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 . METAGENICS C-ULTRASCORB II

Product Type	Single Medicine Product	Effective Date	7/05/2020
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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: If symptoms persist, talk to your health professional.
- 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).
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Respiratory tract infections must be qualified by 'mild'.
- 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 allergic conditions such as anaphylaxis.
- 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

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used.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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).

Adults only. OR Not to be used in children under two years of age without medical advice (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 Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	294 mg/g
calcium ascorbate	383.7 mg/g
cysteine	5.04 mg/g
hesperidin	12.4 mg/g
magnesium ascorbate	52.6 mg/g
Equivalent: ascorbic acid	47.2 mg/g
nicotinamide	74.1 mg/g
potassium ascorbate	18.9 mg/g
Equivalent: ascorbic acid	13.3 mg/g
Equivalent: potassium	3.18 mg/g
sodium ascorbate	110 mg/g
Equivalent: ascorbic acid	97.2 mg/g

Other Ingredients (Excipients)

Flavour

hypromellose

silicon dioxide

sucralose

tetrasodium pyrophosphate

xylitol

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