



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	357135	METAGENICS C-ULTRASCORB
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	22/03/2021	
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.

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

Product Type	Single Medicine Product	Effective Date	22/03/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support energy production
- Maintain/support healthy teeth
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve the severity of common cold symptoms
- Maintain/support skin health
- Maintain/support wound healing
- Maintain/support skin repair/healing/regeneration

Indication Requirements

- Product presentation must not imply or refer to serious immunological diseases.
- If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- 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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- 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.
- Label statement: If symptoms persist, talk to your health professional.

Standard Indications

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No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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. Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect). 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 Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	151 mg
calcium ascorbate dihydrate	798.85 mg
Equivalent: ascorbic acid	660 mg
cysteine hydrochloride monohydrate	10.81 mg
hesperidin	17.91 mg
magnesium ascorbate monohydrate	54.61 mg
Equivalent: ascorbic acid	49 mg
nicotinamide	25 mg
potassium ascorbate	22.42 mg
Equivalent: ascorbic acid	17 mg
Equivalent: potassium	3.77 mg
sodium ascorbate	138.36 mg
Equivalent: ascorbic acid	122.99 mg

Other Ingredients (Excipients)

croscarmellose sodium
glycerol
hypromellose
magnesium stearate
maize starch
maltodextrin
microcrystalline cellulose
silicon dioxide
tartaric acid

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