Public Summary

Summary for ARTG Entry:	316213	Essential C+ Immune
ARTG entry for	Medicine Listed	
Sponsor	Melrose Laboratories Pty Ltd	
Postal Address	16-18 Lionel Rd, Mt Waverley, VIC, 3149 Australia	
ARTG Start Date	5/04/2019	
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.

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 . Essential C+ Immune

Product Type	Single Medicine Product	**Effective Date**	25/06/2019

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Helps maintain/support body's natural channels of elimination

Maintain/support general health and wellbeing

Maintain/support immune system health

Maintain/support healthy immune system function

Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Decrease/reduce/relieve common cold duration

Helps decrease/reduce/relieve the severity of symptoms of common colds and flu

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to drugs/alcohol.

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.

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

Product presentation must only refer to detoxification in relation to natural body processes.

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients

ascorbic acid	**450 mg/g**
calcium ascorbate dihydrate	**109.575 mg/g**
Equivalent: ascorbic acid	90 mg/g
colecalciferol	**.0062 mg/g**
Olea europaea leaf Extract dry concentrate	**50 mg/g**
Equivalent: Olea europaea (Dry)	500 mg/g
Saccharomyces cerevisiae	**220 mg/g**
Terminalia ferdinandiana fruit flesh Powder	**10 mg/g**
zinc citrate	**16.13 mg/g**
Equivalent: zinc	5 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica
dl-alpha-tocopherol
Flavour
glucose monohydrate
hydrogenated soya oil
hydrolysed gelatin
maize starch
silicon dioxide
sucrose
thaumatin

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