



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	316197	Essential C+ Energy
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+ Energy

Product Type	Single Medicine Product	Effective Date	25/06/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Enhance/promote energy levels
- Maintain/support energy levels
- Enhance/promote/physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Enhance/improve/promote/increase cognitive performance
- Enhance/improve/promote/increase mental alertness/wakefulness

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to chronic fatigue syndrome.

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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 mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.

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	450 mg/g
caffeine	25 mg/g
calcium ascorbate dihydrate	109.575 mg/g
Equivalent: ascorbic acid	90 mg/g
calcium pantothenate	10 mg/g
levocarnitine tartrate	125 mg/g
nicotinamide	10 mg/g
pyridoxine hydrochloride	10 mg/g
Equivalent: pyridoxine	8.23 mg/g
riboflavin	10 mg/g
Terminalia ferdinandiana fruit flesh Powder	10 mg/g
thiamine hydrochloride	10 mg/g

Other Ingredients (Excipients)

- citric acid
- colloidal anhydrous silica
- Flavour
- glucose monohydrate
- thaumatin

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