



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|-------------------|
| Summary for ARTG Entry: | 226346 | Ener-C Lemon Lime |
| ARTG entry for | Medicine Listed | |
| Sponsor | Pauling Labs Australia Pty Ltd | |
| Postal Address | 7 Rocklea Drive, Port Melbourne, VIC, 3207 Australia | |
| ARTG Start Date | 29/07/2014 | |
| 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 . Ener-C Lemon Lime

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 12/03/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support collagen formation
Helps convert (state food) into energy
Maintain/support energy production
Aids/assists eye adaption to variations in light intensity/night vision
Maintain/support healthy eyesight/vision
Maintain/support body electrolyte balance
Maintain/support general health and wellbeing
Maintain/support gum health
Maintain/support healthy teeth
Maintain/support connective tissue health
Maintain/support bone health
Helps maintain/support joint cartilage health
Maintain/support healthy thyroid gland function
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support (state vitamin/mineral) within normal range
Decrease/reduce/relieve common cold duration
Decrease/reduce/relieve the severity of common cold symptoms
Maintain/support skin health
Maintain/support wound healing

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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).

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

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

If product is indicated for supplementation, 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.

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

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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).

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.

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

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| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|------------------------------|--------------------|
| ascorbic acid | 105.43 mg/g |
| aspartic acid | 736.84 microgram/g |
| calcium carbonate | 11.7 mg/g |
| Equivalent: calcium | 4.68 mg/g |
| calcium pantothenate | 263.16 microgram/g |
| Equivalent: calcium | 22.1 microgram/g |
| Equivalent: pantothenic acid | 241.05 microgram/g |
| chromium picolinate | 10.16 microgram/g |
| Equivalent: chromium | 1.26 microgram/g |
| cyanocobalamin | 2.63 microgram/g |
| cysteine hydrochloride | 368.42 microgram/g |
| d-alpha-tocopheryl acetate | 2.26 mg/g |
| folic acid | 4.21 microgram/g |
| magnesium carbonate hydrate | 12.88 mg/g |
| Equivalent: magnesium | 3.1 mg/g |



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| manganese gluconate | 478.9 microgram/g |
| Equivalent: manganese | 52.63 microgram/g |
| monobasic calcium phosphate | 3.65 mg/g |
| Equivalent: calcium | 580 microgram/g |
| Equivalent: phosphorus | 580 microgram/g |
| monobasic potassium phosphate | 10.16 mg/g |
| Equivalent: phosphorus | 2.31 mg/g |
| Equivalent: potassium | 2.92 mg/g |
| nicotinamide | 526.31 microgram/g |
| potassium iodide | 20.9 microgram/g |
| Equivalent: iodine | 15.78 microgram/g |
| pyridoxine hydrochloride | 210.52 microgram/g |
| Equivalent: pyridoxine | 172 microgram/g |
| quercetin dihydrate | 2.1 mg/g |
| retinol acetate | 90.5 microgram/g |
| Equivalent: vitamin A | 78.9 RE/g |
| zinc ascorbate | 526.31 microgram/g |
| Equivalent: zinc | 82.63 microgram/g |

Other Ingredients (Excipients)

citric acid
Flavour
fructose
glycine
Lemon
magnesium hydroxide
malic acid
maltodextrin
monobasic sodium phosphate
potassium bicarbonate
potassium carbonate
silicon dioxide
sodium bicarbonate
tartaric acid

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