



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

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	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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