



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	304902	Ener-C Sport Electrolyte Drink Mix
ARTG entry for	Medicine Listed	
Sponsor	Pauling Labs Australia Pty Ltd	
Postal Address	7 Rocklea Drive, Port Melbourne, VIC, 3207 Australia	
ARTG Start Date	21/06/2018	
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 Sport Electrolyte Drink Mix

Product Type	Single Medicine Product	Effective Date	12/03/2021
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Permitted Indications

Helps enhance/promote body energy reserves
Decrease/reduce/relieve symptoms of dehydration
Maintain/support body electrolyte balance
Helps restore body electrolyte balance
Maintain/support muscle function
Aid/assist/helps post exercise recovery
Helps enhance/improve/promote/increase physical/exercise performance
Maintain/support (state vitamin/mineral/nutrient) levels in the body

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.
Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(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].
Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children.
This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.
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.

Additional Product information

Public Summary



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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

calcium ascorbate	81.605 mg/g
Equivalent: ascorbic acid	66.1001 mg/g
Equivalent: calcium	7.5077 mg/g
calcium citrate	34.1565 mg/g
Equivalent: calcium	7.0704 mg/g
chromium picolinate	291.5622 microgram/g
Equivalent: chromium	5.8312 microgram/g
citric acid monohydrate	169.1061 mg/g
glucose monohydrate	233.2498 mg/g
magnesium citrate	99.1078 mg/g
Equivalent: magnesium	14.5781 mg/g
potassium chloride	61.7954 mg/g
Equivalent: potassium	32.0718 mg/g
Equivalent: chloride	29.7236 mg/g
sodium chloride	93.6897 mg/g
Equivalent: chloride	57.2444 mg/g
Equivalent: sodium	36.4453 mg/g
sodium selenite	7.3619 microgram/g
Equivalent: selenium	1.4578 microgram/g
zinc ascorbate	9.7186 mg/g
Equivalent: zinc	1.4578 mg/g
Equivalent: ascorbic acid	7.2891 mg/g

Other Ingredients (Excipients)

Acacia senegal
beetroot
Coconut
maltodextrin
Raspberry
Stevia rebaudiana
triacetin

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