



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	304902	Ener-C Sport Electrolyte Drink Mix
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Pauling Labs Australia Pty Ltd	
<b>Postal Address</b>	7 Rocklea Drive, Port Melbourne, VIC, 3207 Australia	
<b>ARTG Start Date</b>	21/06/2018	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Ener-C Sport Electrolyte Drink Mix

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	13/02/2019
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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

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.



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This product 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.

(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].

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**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

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

Public Summary

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