



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	226358	Ener-C Orange
<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>	29/07/2014	
<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 Orange**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/07/2014
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**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

- #Multivitamin/ multi-mineral supplement assist in the maintenance of health and general wellbeing.
- #Vitamin C help the body to metabolise fat, and protein, helps in the development and maintenance of cartilage and gums, wound healing, the development and maintenance of teeth, and bones. #High strength vitamin C. Antioxidant. May help protect cells from free radicals.
- #Vitamin C may help reduce duration and severity of the common cold
- #Vitamin C Helps absorption of dietary iron.
- #Vitamin C may help in connective tissue formation. May help in wound repair via its role in collagen production.
- #Chromium is required to help metabolise fats, and carbohydrates.
- #Manganese is required to help metabolise fats, proteins, and carbohydrates, and helps in the development and maintenance of bones.
- #Zinc is required to help metabolise fats, proteins, and carbohydrates, and helps to maintain healthy skin and immune function.
- #Magnesium is required to help metabolise fats, proteins, and carbohydrates, and helps in tissue formation, and maintain proper muscle function.
- #Phosphorous is required to help metabolise fats, proteins, and carbohydrates, and helps in the development and maintenance of teeth and bones.
- #Vitamin B12 is required to help metabolise fats, proteins, and carbohydrates.
- #Vitamin B6 is required to help metabolise fats, proteins, and carbohydrates, and helps in tissue formation.
- #Thiamine is required to help metabolise fats, carbohydrates, and proteins. Helps normal growth.
- #Folate helps to metabolise proteins.
- #Niacinamide helps to metabolise proteins and carbohydrates, helps normal growth.
- #Calcium helps in the development and maintenance of teeth and bones.

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#Vitamin A helps to maintain eyesight, skin, membranes, and immune function. Antioxidant.  
 #Vitamin A Helps in the development and maintenance of night vision.  
 #Vitamin A Helps in the development and maintenance of bones.  
 #Vitamin A Helps in the development and maintenance of teeth.  
 #Iodine helps in the function of the thyroid gland. For iodine supplementation.  
 #Vitamin E is an antioxidant.  
 #Boost of Energy  
 #Immune Support  
 #Electrolytes  
 #Antioxidants  
 #A, E, & B Vitamins  
 #Wellbeing support  
 #Maintain your wellbeing

**Warnings**

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.  
 Adults only (or words to that effect).

**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>ascorbic acid</b>	<b>116.27 mg/g</b>
<b>aspartic acid</b>	<b>813.95 microgram/g</b>
<b>calcium carbonate</b>	<b>12.93 mg/g</b>
Equivalent: calcium	5.17 mg/g
<b>calcium pantothenate</b>	<b>290.69 microgram/g</b>
Equivalent: calcium	23.26 microgram/g
Equivalent: pantothenic acid	266.27 microgram/g
<b>chromium picolinate</b>	<b>11.23 microgram/g</b>
Equivalent: chromium	1.4 microgram/g
<b>cyanocobalamin</b>	<b>2.9 microgram/g</b>
<b>cysteine hydrochloride</b>	<b>406.98 microgram/g</b>
<b>d-alpha-tocopheryl acetate</b>	<b>2.49 mg/g</b>
<b>folic acid</b>	<b>4.65 microgram/g</b>
<b>magnesium carbonate hydrate</b>	<b>14.23 mg/g</b>
Equivalent: magnesium	3.43 mg/g
<b>manganese gluconate</b>	<b>529.06 microgram/g</b>
Equivalent: manganese	58.2 microgram/g
<b>monobasic calcium phosphate</b>	<b>4.03 mg/g</b>
Equivalent: calcium	693.16 microgram/g
Equivalent: phosphorus	745.55 microgram/g
<b>monobasic potassium phosphate</b>	<b>11.22 mg/g</b>
Equivalent: potassium	3.22 mg/g
Equivalent: phosphorus	2.56 mg/g
<b>nicotinamide</b>	<b>581.4 microgram/g</b>
<b>potassium iodide</b>	<b>22.84 microgram/g</b>
Equivalent: iodine	17.44 microgram/g
<b>pyridoxine hydrochloride</b>	<b>232.56 microgram/g</b>

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Equivalent: pyridoxine	191.33 microgram/g
<b>quercetin dihydrate</b>	<b>406.98 microgram/g</b>
<b>retinol acetate</b>	<b>100 microgram/g</b>
Equivalent: vitamin A	87.2 RE/g
<b>zinc ascorbate</b>	<b>581.4 microgram/g</b>
Equivalent: zinc	91.27 microgram/g

**Other Ingredients (Excipients)**

ascorbic acid  
betacarotene  
citric acid  
dl-alpha-tocopherol  
Flavour  
fructose  
glycine  
magnesium hydroxide  
Maize Oil  
maize starch  
malic acid  
maltodextrin  
monobasic sodium phosphate  
Orange  
potassium bicarbonate  
potassium carbonate  
silicon dioxide  
Siraitia grosvenorii  
sodium bicarbonate  
starch sodium octenyl succinate  
tartaric acid

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