



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	329196	ElementAll Diet Tropical
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Factors Group Australia Pty Ltd	
<b>Postal Address</b>	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
<b>ARTG Start Date</b>	28/01/2020	
<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 . ElementAll Diet Tropical**

Product Type	Single Medicine Product	Effective Date	28/01/2020
--------------	-------------------------	----------------	------------

**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support natural cleansing/detoxification processes of the gastrointestinal system/gut
- Maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support body electrolyte balance
- Maintain/support healthy growth and development
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Aid/assist/helps connective tissue production/formation
- Maintain/support body tissue repair/regeneration
- Helps enhance/promote body tissue repair/regeneration
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Helps maintain/supports healthy joint cartilage growth/development/production
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Helps maintain/support healthy blood sugar/glucose

Public Summary



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

Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Aid/assist thyroid hormone production  
Maintain/support healthy appetite  
Enhance/improve/promote/increase bowel regularity  
Maintain/support healthy bowel/colon function  
Decrease/reduce/relieve flatulence/carminative  
Maintain/support small intestine health  
Maintain/support healthy small intestine function  
Maintain/support healthy digestive system function  
Maintain/support healthy digestion  
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid  
Aid/assist digestion of glucose/sugar/carbohydrates  
Aid/assist/helps digestion of (state nutrient)  
Helps restore good/beneficial/friendly intestinal/gut/bowel flora  
Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth  
Maintain/support gastrointestinal system health  
Aids/assists repair of gastrointestinal/gut wall lining  
Helps reduce occurrence of abdominal bloating  
Decrease/reduce/relieve symptoms of indigestion/dyspepsia  
Relieve digestive discomfort  
Decrease/reduce/relieve symptoms of nervous indigestion  
Maintain/support immune system health  
Helps stimulate a healthy immune system response  
Maintain/support muscle function  
Aid/assist/helps glucose/sugar/carbohydrate metabolism  
Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral) within normal range  
Maintain/support cognitive function/mental function  
Maintain/support reproductive system health

**Indication Requirements**

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

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to serious immunological diseases.  
Product presentation must only refer to detoxification in relation to natural body processes.  
Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.  
Product presentation must not imply or refer to gastro oesophageal reflux disease.

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 infertility.  
Product presentation must not imply or refer to drugs/alcohol.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.  
Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.  
Product presentation must not imply or refer to serious cardiovascular conditions.

Label statement: Drink plenty of water (or words to that effect).  
Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).  
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.



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

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

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 refer to or imply weight loss.

**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].

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.

Do not use if pregnant or likely to become pregnant (or words to that effect)

Phenylketonurics are warned that this product contains phenylalanine (or words to that effect).

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

**Components**

**1 . Formulation 1**

**Dosage Form** Powder

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>alanine</b>	<b>.788 mg/g</b>
<b>aspartic acid</b>	<b>3.153 mg/g</b>
<b>Biotin</b>	<b>.0014 mg/g</b>
<b>borax</b>	<b>.0626 mg/g</b>
Equivalent: boron	7.1 microgram/g
<b>calcium glycerophosphate</b>	<b>11.157 mg/g</b>
Equivalent: calcium	2.131 mg/g
<b>calcium pantothenate</b>	<b>.1008 mg/g</b>
Equivalent: pantothenic acid	.0923 mg/g
<b>calcium phosphate</b>	<b>1.779 mg/g</b>
Equivalent: calcium	.71 mg/g
<b>choline bitartrate</b>	<b>2.298 mg/g</b>
Equivalent: choline	.945 mg/g
<b>chromium picolinate</b>	<b>.003 mg/g</b>
Equivalent: chromium	.37 microgram/g
<b>colecalfiferol</b>	<b>0 mg/g</b>
<b>cupric sulfate pentahydrate</b>	<b>.0186 mg/g</b>
Equivalent: copper	4.74 microgram/g
<b>cyanocobalamin</b>	<b>.057 microgram/g</b>
<b>cysteine hydrochloride</b>	<b>5.137 mg/g</b>
Equivalent: cysteine	3.949 mg/g

Public Summary



Australian Government  
Department of Health  
Therapeutic Goods Administration

<b>dl-alpha-tocopheryl acetate</b>	<b>.298 mg/g</b>
<b>ferrous fumarate</b>	<b>.131 mg/g</b>
Equivalent: iron	.043 mg/g
<b>folic acid</b>	<b>.888 microgram/g</b>
<b>glucose monohydrate</b>	<b>355.114 mg/g</b>
<b>glutamine</b>	<b>63.132 mg/g</b>
<b>glycine</b>	<b>.788 mg/g</b>
<b>histidine hydrochloride</b>	<b>5.262 mg/g</b>
<b>isoleucine</b>	<b>12.784 mg/g</b>
<b>lecithin</b>	<b>7.102 mg/g</b>
<b>leucine</b>	<b>47.351 mg/g</b>
<b>levocarnitine tartrate</b>	<b>.312 mg/g</b>
Equivalent: levocarnitine	.213 mg/g
<b>levomefolate glucosamine</b>	<b>.237 microgram/g</b>
Equivalent: levomefolic acid	.128 microgram/g
<b>lysine hydrochloride</b>	<b>12.814 mg/g</b>
Equivalent: lysine	10.256 mg/g
<b>magnesium citrate</b>	<b>4.735 mg/g</b>
Equivalent: magnesium	.767 mg/g
<b>magnesium glycerophosphate</b>	<b>1.424 mg/g</b>
Equivalent: magnesium	.178 mg/g
<b>manganese sulfate monohydrate</b>	<b>.0288 mg/g</b>
Equivalent: manganese	9.375 microgram/g
<b>methionine</b>	<b>3.409 mg/g</b>
<b>molybdenum trioxide</b>	<b>.3 microgram/g</b>
Equivalent: molybdenum	.2 microgram/g
<b>nicotinamide</b>	<b>.092 mg/g</b>
<b>phenylalanine</b>	<b>5.682 mg/g</b>
<b>phytomenadione</b>	<b>.28 microgram/g</b>
<b>potassium citrate</b>	<b>11.439 mg/g</b>
Equivalent: potassium	4.141 mg/g
<b>potassium iodide</b>	<b>.628 microgram/g</b>
Equivalent: iodine	.48 microgram/g
<b>proline</b>	<b>3.153 mg/g</b>
<b>pyridoxine hydrochloride</b>	<b>.0219 mg/g</b>
<b>retinol palmitate</b>	<b>13.1249 microgram/g</b>
<b>riboflavine</b>	<b>.0142 mg/g</b>
<b>selenomethionine</b>	<b>.8122 microgram/g</b>
Equivalent: selenium	.327 microgram/g
<b>serine</b>	<b>.788 mg/g</b>
<b>sodium ascorbate</b>	<b>.639 mg/g</b>
Equivalent: ascorbic acid	.568 mg/g
<b>taurine</b>	<b>.313 mg/g</b>
<b>thiamine nitrate</b>	<b>.0175 mg/g</b>
<b>threonine</b>	<b>5.682 mg/g</b>
<b>tyrosine</b>	<b>3.196 mg/g</b>
<b>valine</b>	<b>12.784 mg/g</b>
<b>zinc sulfate monohydrate</b>	<b>.162 mg/g</b>
Equivalent: zinc	.059 mg/g

**Other Ingredients (Excipients)**

Acacia

Public Summary



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

aluminium sodium silicate  
aluminium starch octenylsuccinate  
butylated hydroxytoluene  
calcium hydrogen phosphate dihydrate  
calcium hydrogen phosphate  
calcium silicate  
citric acid  
colloidal anhydrous silica  
dl-alpha-tocopherol  
Flavour  
Gelatin  
maize starch  
maltodextrin  
medium chain triglycerides  
microcrystalline cellulose  
mono- and di- glycerides  
potable water  
purified water  
rice starch  
silicon dioxide  
sodium ascorbate  
sodium citrate dihydrate  
starch sodium octenyl succinate  
sucrose  
tricalcium phosphate

---

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary