



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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

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
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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

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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.



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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

Phenylketonurics are warned that this product contains phenylalanine (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.

(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].

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).

Do not use if pregnant or likely to become pregnant (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

Route of Administration Oral

Visual Identification

Active Ingredients

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

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

Other Ingredients (Excipients)

Acacia

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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

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