



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	325793	Oriental Botanicals Kids' Nutrient Ninja
ARTG entry for	Medicine Listed	
Sponsor	Global Therapeutics Pty Ltd	
Postal Address	PO Box 1999, BYRON BAY, NSW, 2481 Australia	
ARTG Start Date	31/10/2019	
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 . Oriental Botanicals Kids' Nutrient Ninja

Product Type	Single Medicine Product	Effective Date	31/10/2019
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Permitted Indications

- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify/invigorate spleen
- Maintain/support energy production
- Maintain/support healthy growth and development in children up to 12 years of age
- Maintain/support healthy growth and development
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Aids/assists teeth development
- Maintain/support healthy teeth
- Maintain/support teeth mineralisation
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Traditionally used in Chinese medicine to decrease/reduce/relieve loss of appetite
- Maintain/support healthy appetite when dietary intake is inadequate
- Traditionally used in Chinese medicine to calms the mind
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit
- Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest
- Maintain/support cognitive development
- Aid/assist/helps synthesis of neurotransmitters

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Maintain/support brain/central nervous system development

Indication Requirements

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

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

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to neurological conditions or developmental delays.

Product presentation must not imply or refer to disease in any body organ.

Product presentation must not imply or refer to eating disorders.

Product presentation must not imply or refer to serious cardiovascular conditions.

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	30 mg
betacarotene	.3 mg
Biotin	25 microgram
calcium citrate tetrahydrate	23.98 mg
Equivalent: calcium	5 mg
calcium pantothenate	1.64 mg
Equivalent: calcium	140 microgram
Equivalent: pantothenic acid	1.5 mg
choline bitartrate	151.96 mg
Equivalent: choline	62.5 mg
chromium picolinate	40 microgram
Equivalent: chromium	5 microgram
Citrus bioflavonoids extract	500 microgram
colecalfiferol	.0025 mg
d-alpha-tocopheryl acid succinate	4 mg
Equivalent: d-alpha-tocopherol	4.84 IU
ferrous fumarate	7.61 mg
Equivalent: iron	2.5 mg

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folic acid	100 microgram
magnesium glycinate	111.11 mg
Equivalent: magnesium	15 mg
manganese (II) glycinate	2.84 mg
Equivalent: manganese	650 microgram
mecobalamin (co-methylcobalamin)	2.4 microgram
menaquinone 7	10 microgram
nicotinamide	2.997 mg
potassium iodide	59 microgram
Equivalent: iodine	45 microgram
pyridoxal 5-phosphate monohydrate	784 microgram
Equivalent: pyridoxine	500 microgram
pyridoxine hydrochloride	.999 mg
retinol acetate	.2357 mg
riboflavin sodium phosphate	1.32 mg
Equivalent: riboflavin	1 mg
selenomethionine	18.8 microgram
Equivalent: selenium	7.5 microgram
Tagetes erecta	5 mg
Equivalent: Tagetes erecta	200 mg
thiamine nitrate	1.998 mg
zinc glycinate monohydrate	5.32 mg
Equivalent: zinc	1.5 mg
Ziziphus jujuba	217 mg
Equivalent: Ziziphus jujuba	3.255 g

Other Ingredients (Excipients)

Acacia
beetroot
citric acid
colloidal anhydrous silica
d-alpha-tocopherol
dl-alpha-tocopherol
Flavour
hypromellose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
mono- and di- glycerides
Pea Starch
purified water
rice starch
silicon dioxide
Siraitia grosvenorii
sodium alginate
sodium ascorbate
sodium bicarbonate
thaumatin
xylitol

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