



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	407891	Nature's Way Kids Smart High Strength Vita Gummies Multi-Vitamin + Iron
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Pharmacare Laboratories Pty Ltd	
<b>Postal Address</b>	PO Box 384, MONA VALE, NSW, 1660 Australia	
<b>ARTG Start Date</b>	19/04/2023	
<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.

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 . Nature's Way Kids Smart High Strength Vita Gummies Multi-Vitamin + Iron

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/04/2023
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Help maintain/support bone mineralisation
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle health when sun exposure is inadequate
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
- Maintain/support cognitive function/mental function when dietary intake is inadequate
- Maintain/support brain health
- Maintain/support brain/central nervous system development when dietary intake is inadequate

### Indication Requirements

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

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Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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

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 neurological conditions or developmental delays.

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**

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [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** Pastille

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>60 mg</b>
<b>Biotin</b>	<b>38 microgram</b>
<b>colecalfiferol</b>	<b>.0062 mg</b>
<b>cyanocobalamin</b>	<b>3 microgram</b>
<b>dl-alpha-tocopheryl acetate</b>	<b>18 mg</b>
<b>ferrous fumarate</b>	<b>7.61 mg</b>
Equivalent: iron	2.5 mg
<b>potassium iodide</b>	<b>30.09 microgram</b>
Equivalent: iodine	23 microgram
<b>pyridoxine hydrochloride</b>	<b>1.702 mg</b>
Equivalent: pyridoxine	1.4 mg
<b>retinol palmitate</b>	<b>.3669 mg</b>
Equivalent: vitamin A	.2003 mg
<b>riboflavin</b>	<b>450 microgram</b>
<b>thiamine nitrate</b>	<b>555 microgram</b>
Equivalent: thiamine	450 microgram

**Other Ingredients (Excipients)**

- Acacia
- calcium phosphate
- Carnauba Wax
- citric acid
- Colour
- dibutyl sebacate
- dl-alpha-tocopherol
- ethylcellulose
- Flavour
- fractionated coconut oil

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Gelatin  
glycerol  
hypromellose  
maize starch  
maltitol solution  
medium chain triglycerides  
pectin  
potable water  
purified water  
silicon dioxide  
sorbitol  
starch sodium octenyl succinate  
sucralose  
sucrose  
vegetable oil

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