



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	407077	Nature's Way Kids Smart High Strength Vita Gummies Triple Immune Support
ARTG entry for	Medicine Listed	
Sponsor	Pharmacare Laboratories Pty Ltd	
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia	
ARTG Start Date	30/03/2023	
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.

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 Triple Immune Support

Product Type	Single Medicine Product	Effective Date	30/03/2023
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support healthy growth and development
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet. 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



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Active Ingredients

ascorbic acid	50 mg
Citrus bioflavonoids extract	10 mg
colecalfiferol	.005 mg
Sambucus nigra fruit Juice dry	15.8 mg
Equivalent: Sambucus nigra (Juice fresh)	553 mg
zinc sulfate monohydrate	8.236 mg
Equivalent: zinc	3 mg

Other Ingredients (Excipients)

Acacia
calcium phosphate
Carnauba Wax
Colour
dl-alpha-tocopherol
Flavour
fractionated coconut oil
Gelatin
glycerol
hypromellose
maize starch
maltitol solution
maltodextrin
medium chain triglycerides
pectin
potable water
purified water
sorbitol
sucralose
sucrose
vegetable oil

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