



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	408553	Nature's Way High Strength Adult Vita Gummies Mega B Complex
ARTG entry for	Medicine Listed	
Sponsor	Pharmacare Laboratories Pty Ltd	
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia	
ARTG Start Date	5/05/2023	
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 High Strength Adult Vita Gummies Mega B Complex

Product Type	Single Medicine Product	Effective Date	26/05/2023
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Permitted Indications

- Maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support hair health when dietary intake is inadequate
- Maintain/support nail health/strength/thickness
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps decrease/reduce homocysteine levels
- Aid/assist/helps protein synthesis in the body
- Support healthy stress response in the body
- Maintain/support brain function
- Maintain/support brain health
- Maintain/support nervous system health
- Maintain/support brain/central nervous system development
- Maintain/support nervous system function

Indication Requirements

- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to neurological conditions or developmental delays.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased



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physical activity.

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

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

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

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

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].

If symptoms persist consult your healthcare practitioner (or words to that effect).

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
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Components

1 . Formulation 1

Dosage Form Pastille

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	10 microgram
cyanocobalamin	75 microgram
nicotinamide	10 mg
pyridoxine hydrochloride	.975 mg
Equivalent: pyridoxine	.8 mg
riboflavin	1.2 mg
thiamine hydrochloride	1 mg
Equivalent: thiamine	747.4 microgram

Other Ingredients (Excipients)

- Carnauba Wax**
- citric acid**
- Colour**
- Flavour**
- Gelatin**
- maltitol solution**
- mannitol**
- potable water**
- sucralose**
- vegetable oil**

Public Summary

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