



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

## Public Summary

<b>Summary for ARTG Entry:</b>	386736	Vegan Pro
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Give Back Health Pty Ltd	
<b>Postal Address</b>	10/5 Canopus Street, Bridgeman Downs, QLD, 4035 Australia	
<b>ARTG Start Date</b>	4/04/2022 11:00:00 PM	
<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 . Vegan Pro

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/04/2022
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support natural body cleansing/detoxification processes
- Maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Aids/assists eye adaption to variations in light intensity/night vision
- Helps maintain/support healthy vision development
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support gum health
- Maintain/support healthy teeth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support bone mass/density/integrity
- Help maintain/support bone mineralisation
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health

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Helps maintain/support healthy blood sugar/glucose  
Maintain/support blood health  
Helps maintain/support haemoglobin formation/synthesis  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support artery health  
Maintain/support blood vessel health  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Aid/assist thyroid hormone production  
Aid/assist thyroid hormone production  
Maintain/support smell sensation  
Maintain/support taste sensation  
Maintain/support healthy mucous linings of the digestive system  
Maintain/support gastrointestinal mucosal membrane health  
Aids/assists repair of gastrointestinal/gut wall lining  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support muscle health  
Maintain/support muscle function  
Aid/assist/helps glucose/sugar/carbohydrate metabolism  
Helps decrease/reduce homocysteine levels  
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  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Support healthy stress response in the body  
Maintain/support cognitive development  
Maintain/support mental concentration/focus/clarity  
Maintain/support memory/mental recall  
Maintain/support brain function  
Maintain/support nerve conduction  
Maintain/support neuromuscular function  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Maintain/support brain/central nervous system development  
Maintain/support nervous system function  
Maintain/support female reproductive system health  
Maintain/support/regulate healthy menstrual cycle  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones  
Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract  
Maintain/support skin health  
Maintain/support skin integrity/structure  
Maintain/support wound healing

**Indication Requirements**

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 cardiovascular conditions.

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

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to hormone imbalances.



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Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

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.

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 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 serious immunological diseases.

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 vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must only refer to detoxification in relation to natural body processes.

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

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

Product presentation must not imply or refer to infertility.

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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.

Do not take while on warfarin therapy without medical advice.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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.

If symptoms persist consult your healthcare practitioner (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, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium citrate</b>	<b>172.92 mg/g</b>
Equivalent: calcium	41.67 mg/g
<b>calcium pantothenate</b>	<b>1.67 mg/g</b>
Equivalent: pantothenic acid	1.53 mg/g
<b>chromium picolinate</b>	<b>67 microgram/g</b>
Equivalent: chromium	8.33 microgram/g
<b>colecalfiferol</b>	<b>.0041 mg/g</b>
<b>isoleucine</b>	<b>41.67 mg/g</b>
<b>leucine</b>	<b>83.33 mg/g</b>

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<b>lysine hydrochloride</b>	<b>166.67 mg/g</b>
<b>mecobalamin (co-methylcobalamin)</b>	<b>83.3 microgram/g</b>
<b>menaquinone 7</b>	<b>15 microgram/g</b>
<b>methionine</b>	<b>83.33 mg/g</b>
<b>nicotinamide</b>	<b>4.17 mg/g</b>
<b>potassium iodide</b>	<b>16.7 microgram/g</b>
Equivalent: iodine	12.7 microgram/g
<b>pyridoxal 5-phosphate monohydrate</b>	<b>1.67 mg/g</b>
Equivalent: pyridoxine	1.067 mg/g
<b>retinol acetate</b>	<b>.1376 mg/g</b>
Equivalent: vitamin A	.1166 mg/g
<b>riboflavin sodium phosphate</b>	<b>4.17 mg/g</b>
Equivalent: riboflavin	3.17 mg/g
<b>selenomethionine</b>	<b>25 microgram/g</b>
Equivalent: selenium	10 microgram/g
<b>taurine</b>	<b>83.33 mg/g</b>
<b>thiamine hydrochloride</b>	<b>1.67 mg/g</b>
Equivalent: thiamine	1.31 mg/g
<b>ubidecarenone</b>	<b>10 mg/g</b>
<b>valine</b>	<b>41.67 mg/g</b>
<b>zinc citrate dihydrate</b>	<b>6.49 mg/g</b>
Equivalent: zinc	2.0833 mg/g

**Other Ingredients (Excipients)**

Acacia  
colloidal anhydrous silica  
d-alpha-tocopherol  
dl-alpha-tocopherol  
Flavour  
fractionated coconut oil  
glycine  
lecithin  
liquid glucose  
maize starch  
malic acid  
maltodextrin  
silicon dioxide  
sodium ascorbate  
spray-dried glucose syrup  
Stevia rebaudiana

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