



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

## Public Summary

<b>Summary for ARTG Entry:</b>	396782	BN Chews Vanilla & Lime
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Pracmed Healthcare	
<b>Postal Address</b>	Unit 21 / 43 Lang Parade, Milton, QLD, 4064 Australia	
<b>ARTG Start Date</b>	30/09/2022	
<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 . BN Chews Vanilla & Lime

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/12/2022
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support energy levels  
Maintain/support body metabolism/metabolic rate  
Maintain/support energy production  
Helps maintain/support healthy eye development  
Maintain/support healthy eye function  
Maintain/support eye health  
Maintain/support healthy eyesight/vision  
Maintain/support body electrolyte balance  
Maintain/support healthy growth and development  
Maintain/support general health and wellbeing  
Maintain/support hair health  
Maintain/support nail health/strength/thickness  
Aid/assist in the healing of minor body tissue injuries  
Maintain/support bone health  
Aids/assists healthy bone development/growth/building  
Maintain/support (state mineral) absorption in bones  
Aid/assist healthy red blood cell production  
Maintain/support red blood cell health  
Helps maintain/support healthy blood sugar/glucose  
Helps maintain/support transport of oxygen in the body  
Helps maintain/support haemoglobin formation/synthesis  
Maintain/support cardiovascular system health  
Helps maintain/support healthy heart function  
Maintain/support healthy cardiovascular system function  
Maintain/support blood capillary health  
Maintain/support blood vessel health

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Maintain/support healthy thyroid gland function  
Aid/assist thyroid hormone production  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support muscle function  
Aid/assist/helps glucose/sugar/carbohydrate metabolism  
Aid/assist/helps protein synthesis in the body  
Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Decrease/reduce/relieve symptoms of stress  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Maintain/support nervous system function  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones  
Maintain/support skin health  
Maintain/support wound healing

**Indication Requirements**

Product presentation must not imply or refer to chronic fatigue syndrome.  
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 serious cardiovascular conditions.  
  
Product presentation must not imply or refer to infertility.  
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.  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to heart disease.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
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.  
Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.  
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.  
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 any thyroid related 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 hormone imbalances.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.  
Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.  
Not for the treatment of iron deficiency conditions (or words to that effect).  
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.  
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.

**Additional Product information**

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**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Child resistant closure	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, chewable

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>60 mg</b>
<b>betacarotene</b>	<b>2.2995 mg</b>
<b>Biotin</b>	<b>150 microgram</b>
<b>calcium carbonate</b>	<b>625 mg</b>
Equivalent: calcium	250 mg
<b>calcium citrate tetrahydrate</b>	<b>236.97 mg</b>
Equivalent: calcium	50 mg
<b>calcium pantothenate</b>	<b>5 mg</b>
Equivalent: pantothenic acid	4.58 mg
Equivalent: calcium	420 microgram
<b>choline bitartrate</b>	<b>2.5 mg</b>
Equivalent: choline	1.03 mg
<b>chromic chloride hexahydrate</b>	<b>179.4 microgram</b>
Equivalent: chromium	35 microgram
<b>chromium picolinate</b>	<b>201.1 microgram</b>
Equivalent: chromium	25 microgram
<b>colecalfiferol</b>	<b>.0125 mg</b>
<b>cupric citrate hemipentahydrate</b>	<b>1.06 mg</b>
Equivalent: copper	375 microgram
<b>cyanocobalamin</b>	<b>125 microgram</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>12.4 mg</b>
Equivalent: d-alpha-tocopheryl acid succinate	15 IU
<b>ferrous fumarate</b>	<b>28.82 mg</b>
Equivalent: iron	9 mg
<b>folic acid</b>	<b>250 microgram</b>
<b>heavy magnesium oxide</b>	<b>90.69 mg</b>
Equivalent: magnesium	52.5 mg
<b>inositol</b>	<b>10 mg</b>
<b>manganese amino acid chelate</b>	<b>10 mg</b>
Equivalent: manganese	1 mg
<b>mecobalamin</b>	<b>125 microgram</b>
<b>molybdenum trioxide</b>	<b>56.3 microgram</b>
Equivalent: molybdenum	37.5 microgram
<b>nicotinamide</b>	<b>25 mg</b>
<b>potassium iodide</b>	<b>98.1 microgram</b>
Equivalent: potassium	23.1 microgram
Equivalent: iodine	75 microgram
<b>pyridoxine hydrochloride</b>	<b>.79 mg</b>

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Equivalent: pyridoxine	.65 mg
<b>retinol acetate</b>	<b>.4312 mg</b>
Equivalent: vitamin A	.375 mg
<b>riboflavin</b>	<b>5 mg</b>
<b>selenomethionine</b>	<b>37.3 microgram</b>
Equivalent: selenium	15 microgram
<b>thiamine nitrate</b>	<b>5 mg</b>
Equivalent: thiamine	4.05 mg
<b>zinc amino acid chelate</b>	<b>37.5 mg</b>
Equivalent: zinc	7.5 mg

**Other Ingredients (Excipients)**

Acacia  
butylated hydroxytoluene  
carmellose sodium  
citric acid  
colloidal anhydrous silica  
dl-alpha-tocopherol  
ethylcellulose  
Flavour  
Gelatin  
hypromellose  
hypromellose  
iron oxide red  
iron oxide yellow  
isomalt  
magnesium stearate  
maize starch  
mannitol  
medium chain triglycerides  
purified water  
silicon dioxide  
starch sodium octenyl succinate  
sucralose  
sucrose  
xylitol

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