



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	310442	NUTRA-LIFE BILBERRY 10,000 PLUS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Vitaco Health Australia Pty Ltd	
<b>Postal Address</b>	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia	
<b>ARTG Start Date</b>	17/10/2018	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . NUTRA-LIFE BILBERRY 10,000 PLUS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	17/10/2018
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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 healthy eye function  
Maintain/support eye health  
Helps maintain/support eye macula health  
Helps maintain/support eye retina health  
Maintain/support healthy eyesight/vision  
Maintain/support general health and wellbeing  
Maintain/support red blood cell health  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support blood capillary health  
Maintain/support blood vessel health  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

### Indication Requirements

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



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

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

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).

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

ascorbic acid	262.5 mg
betacarotene	3 mg
chromic chloride hexahydrate	256.6 microgram
Equivalent: chromium	50 microgram
Citrus bioflavonoids extract	50 mg
d-alpha-tocopheryl acid succinate	62.6 mg
glutamine	25 mg
lutein	6 mg
nicotinamide	10 mg
riboflavin	25 mg
rutoside	50 mg
taurine	50 mg
Vaccinium myrtillus fruit Extract dry concentrate standardised	100 mg
Equivalent: Vaccinium myrtillus (Fresh)	10 g
Vitis vinifera seed Extract dry concentrate	25 mg
Equivalent: Vitis vinifera (Dry)	3 g
zinc amino acid chelate	75 mg
Equivalent: zinc	15 mg

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate
- crospovidone
- dl-alpha-tocopherol
- hypromellose
- iron oxide black
- iron oxide red
- iron oxide yellow
- liquid glucose
- macrogol 3350

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magnesium stearate  
maize starch  
microcrystalline cellulose  
polyvinyl alcohol  
povidone  
purified talc  
purified water  
silicon dioxide  
sodium ascorbate  
starch sodium octenyl succinate  
sucrose

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