



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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

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

Product Type	Effective Date
Single Medicine Product	17/10/2018

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

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

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 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 serious cardiovascular conditions.

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

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

Pack Size

Poison Schedule

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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