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 Single Medicine Product **Effective Date** 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 serious cardiovascular conditions.

Product presentation must not imply or refer to serious immunological diseases.

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 circulatory disorders/diseases/conditions e.g. thrombosis.

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).

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

Public Summary

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