

## **Department of Health and Aged Care**

Therapeutic Goods Administration

**Public Summary** 

,				
Summary for ARTG Entry:	377217	Henry Blooms Her Multi		
ARTG entry for	Medicine Listed	I		
Sponsor	Phytologic Holdings Pty Limited			
Postal Address	16-20 Baker Sti Australia	reet, Banksmeadow, NSW, 2019		
ARTG Start Date	1/11/2021			
Product Category	Medicine			
Status	Active			
Approval Area	Listed Medicine	S		
O an dition a				

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. Henry Blooms Her Multi Product Type Effective Date 9/01/2023 Single Medicine Product **Permitted Indications** Antioxidant/Reduce free radicals formed in the body Helps reduce/decrease free radical damage to body cells Helps enhance/promote collagen formation Maintain/support collagen formation Maintain/support collagen health Aids/assists natural body cleansing/detoxification processes Enhance/promote energy levels Maintain/support energy levels Helps convert (state food) into energy Maintain/support body metabolism/metabolic rate Maintain/support vitality Maintain/support eye health Helps enhance/promote general health and wellbeing Maintain/support hair health Maintain/support teeth mineralisation Maintain/support nail health/strength/thickness Aid/assist/helps connective tissue production/formation Maintain/support healthy body tissues Maintain/support body tissue repair/regeneration 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 Helps maintain/supports healthy joint cartilage growth/development/production Aid/assist healthy red blood cell production Helps enhance/promote red blood cell health Helps maintain/support healthy blood sugar/glucose Produced at 17.01.2023 at 04:09:16 AEDT Page 1 of 4

This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information



### **Department of Health and Aged Care**

Therapeutic Goods Administration

Aid/assist/helps in the maintenance of blood levels of oxygen

Helps maintain/support transport of oxygen in the body

Maintain/support cardiovascular system health

Maintain/support heart health

Maintain/support blood capillary health

Maintain/support healthy thyroid hormones in females

Maintain/support thyroid gland health in females

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support muscle health

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Support healthy stress response in the body

Helps enhance/promote healthy nerve conduction/transmission/neurotransmission

Maintain/support nervous system health

Maintain/support female reproductive system health

Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract

Maintain/support skin health

Maintain/support skin repair/healing/regeneration

Maintain/support urinary tract health

#### Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.

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.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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

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

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.

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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 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 heart disease.

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

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

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).

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.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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

#### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

Warnings

Page 2 of 4

This is not an ARTG Certificate document.

Produced at 17.01.2023 at 04:09:16 AEDT

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information



**Department of Health and Aged Care** 

Therapeutic Goods Administration

Do not take while on warfarin therapy without medical advice.

Not recommended for use during pregnancy or lactation

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.

Adults only.

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. Contains magnesium, which may have a laxative effect or cause diarrhoea (or words to that effect).

## 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		
betacarotene	4.2 mg	
Biotin	150 microgram	r
borax	4.41 mg	
Equivalent: boron	500 microgram	
calcium ascorbate dihydrate	54.47 mg	
Equivalent: ascorbic acid	45 mg	
Equivalent: calcium	4.97 mg	
calcium hydrogen phosphate	305.49 mg	
Equivalent: calcium	90 mg	_
calcium pantothenate	25.56 mg	5
Equivalent: calcium	2.15 mg	
Equivalent: pantothenic acid	23.41 mg	
chromium nicotinate	250 microgram	y manual
Equivalent: chromium	25 microgram	
Citrus bioflavonoids extract	12.5 mg	
colecalciferol	.025 mg	
colloidal anhydrous silica	19.25 mg	
Equivalent: silicon	9 mg	9
copper gluconate	8.57 mg	
Equivalent: copper	1.2 mg	
cyanocobalamin	10 microgram	
d-alpha-tocopheryl acid succinate	7 mg	
ferrous fumarate	36.47 mg	
Equivalent: iron	12 mg	
folic acid	400 microgram	
heavy magnesium oxide	99.47 mg	
Equivalent: magnesium	60 mg	
manganese sulfate monohydrate	15.38 mg	
Equivalent: manganese	5 mg	
molybdenum trioxide	67.5 microgram	
Equivalent: molybdenum	45 microgram	
nicotinamide	50 mg	
phytomenadione	.06 mg	

Page 3 of 4

This is not an ARTG Certificate document.

Produced at 17.01.2023 at 04:09:16 AEDT

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information



# Department of Health and Aged Care Therapeutic Goods Administration

Equivalent: iodine150 microgramEquivalent: potassium46.2 microgrampyridoxine hydrochloride30.39 mgEquivalent: pyridoxine25 mgriboflavin15 mgselenomethionine149 microgramEquivalent: selenium60 microgramthiamine nitrate18.5 mgEquivalent: thiamine15 mgubidecarenone5 mgVaccinium macrocarpon fruit Extract dry concentrate10 mgEquivalent: Vaccinium macrocarpon (Fresh)500 mgzinc oxide9.96 mg		
Equivalent: potassium46.2 microgrampyridoxine hydrochloride30.39 mgEquivalent: pyridoxine25 mgriboflavin15 mgselenomethionine149 microgramEquivalent: selenium60 microgramthiamine nitrate18.5 mgEquivalent: thiamine15 mgubidecarenone5 mgVaccinium macrocarpon fruit Extract dry concentrate10 mgEquivalent: Vaccinium macrocarpon (Fresh)500 mgzinc oxide9.96 mg	potassium iodide	196.2 microgram
pyridoxine hydrochloride30.39 mgEquivalent: pyridoxine25 mgriboflavin15 mgselenomethionine149 microgramEquivalent: selenium60 microgramthiamine nitrate18.5 mgEquivalent: thiamine15 mgubidecarenone5 mgVaccinium macrocarpon fruit Extract dry concentrate10 mgEquivalent: Vaccinium macrocarpon (Fresh)500 mgzinc oxide9.96 mg	Equivalent: iodine	150 microgram
Equivalent: pyridoxine25 mgriboflavin15 mgselenomethionine149 microgramEquivalent: selenium60 microgramthiamine nitrate18.5 mgEquivalent: thiamine15 mgubidecarenone5 mgVaccinium macrocarpon fruit Extract dry concentrate10 mgEquivalent: Vaccinium macrocarpon (Fresh)500 mgzinc oxide9.96 mg	Equivalent: potassium	46.2 microgram
riboflavin 15 mg selenomethionine 149 microgram Equivalent: selenium 60 microgram thiamine nitrate 18.5 mg Equivalent: thiamine 15 mg ubidecarenone 5 mg Vaccinium macrocarpon fruit Extract dry concentrate 10 mg Equivalent: Vaccinium macrocarpon (Fresh) 500 mg zinc oxide 9.96 mg	pyridoxine hydrochloride	30.39 mg
selenomethionine 149 microgram   Equivalent: selenium 60 microgram   thiamine nitrate 18.5 mg   Equivalent: thiamine 15 mg   ubidecarenone 5 mg   Vaccinium macrocarpon fruit Extract dry concentrate 10 mg   Equivalent: Vaccinium macrocarpon (Fresh) 500 mg   zinc oxide 9.96 mg	Equivalent: pyridoxine	25 mg
Equivalent: selenium60 microgramthiamine nitrate18.5 mgEquivalent: thiamine15 mgubidecarenone5 mgVaccinium macrocarpon fruit Extract dry concentrate10 mgEquivalent: Vaccinium macrocarpon (Fresh)500 mgzinc oxide9.96 mg	riboflavin	15 mg
thiamine nitrate18.5 mgEquivalent: thiamine15 mgubidecarenone5 mgVaccinium macrocarpon fruit Extract dry concentrate10 mgEquivalent: Vaccinium macrocarpon (Fresh)500 mgzinc oxide9.96 mg	selenomethionine	149 microgram
Equivalent: thiamine15 mgubidecarenone5 mgVaccinium macrocarpon fruit Extract dry concentrate10 mgEquivalent: Vaccinium macrocarpon (Fresh)500 mgzinc oxide9.96 mg	Equivalent: selenium	60 microgram
ubidecarenone 5 mg   Vaccinium macrocarpon fruit Extract dry concentrate 10 mg   Equivalent: Vaccinium macrocarpon (Fresh) 500 mg   zinc oxide 9.96 mg	thiamine nitrate	18.5 mg
Vaccinium macrocarpon fruit Extract dry concentrate 10 mg   Equivalent: Vaccinium macrocarpon (Fresh) 500 mg   zinc oxide 9.96 mg	Equivalent: thiamine	15 mg
Equivalent: Vaccinium macrocarpon (Fresh) 500 mg   zinc oxide 9.96 mg	ubidecarenone	5 mg
zinc oxide 9.96 mg	Vaccinium macrocarpon fruit Extract dry concentrate	10 mg
	Equivalent: Vaccinium macrocarpon (Fresh)	500 mg
Equivalent: zinc 8 mg	zinc oxide	9.96 mg
	Equivalent: zinc	8 mg

### **Other Ingredients (Excipients)**

Acacia

calcium hydrogen phosphate dihydrate calcium hydrogen phosphate colloidal anhydrous silica croscarmellose sodium crospovidone d-alpha-tocopherol dl-alpha-tocopherol fractionated coconut oil hypromellose iron oxide yellow liquid glucose macrogol 400 magnesium stearate maize starch mannitol microcrystalline cellulose povidone silicon dioxide sodium ascorbate soluble maize starch sucrose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information