



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

## Public Summary

<b>Summary for ARTG Entry:</b>	377750	Henry Blooms Herbal Anti-Hangover
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Phytologic Holdings Pty Limited	
<b>Postal Address</b>	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
<b>ARTG Start Date</b>	11/11/2021	
<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 . Henry Blooms Herbal Anti-Hangover

Product Type	Single Medicine Product	Effective Date	11/11/2021
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support blood health
- Maintain/support cardiovascular system health
- Maintain/support heart health
- Maintain/support blood capillary health
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of occasional hangovers
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms

### Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
- 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 disease in any body organ, in particular the kidney or liver.
- Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.



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

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).

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

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.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Adults only.

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Oral Liquid
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>19.98 mg/mL</b>
<b>Biotin</b>	<b>1.1 microgram/mL</b>
<b>calcium pantothenate</b>	<b>145.4 microgram/mL</b>
Equivalent: pantothenic acid	130 microgram/mL
<b>cyanocobalamin</b>	<b>11.1 microgram/mL</b>
<b>cysteine hydrochloride monohydrate</b>	<b>9.99 mg/mL</b>
Equivalent: cysteine	6.89 mg/mL
<b>Hovenia dulcis fruit Extract dry concentrate</b>	<b>11.322 mg/mL</b>
Equivalent: Hovenia dulcis (Dry)	113.22 mg/mL
<b>magnesium citrate</b>	<b>4.31 mg/mL</b>
Equivalent: magnesium	.666 mg/mL
<b>Malus domestica fruiting body Extract dry concentrate</b>	<b>4.673 mg/mL</b>
Equivalent: Malus domestica (Dry)	443.935 mg/mL
<b>nicotinamide</b>	<b>.3552 mg/mL</b>
<b>Panax ginseng root Extract dry concentrate</b>	<b>1.11 mg/mL</b>
Equivalent: Panax ginseng (Dry)	11.1 mg/mL
<b>potassium chloride</b>	<b>8.47 mg/mL</b>
Equivalent: potassium	4.44 mg/mL
<b>Pueraria lobata root Extract dry concentrate</b>	<b>6.66 mg/mL</b>
Equivalent: Pueraria lobata (Dry)	66.6 mg/mL
<b>pyridoxine hydrochloride</b>	<b>81 microgram/mL</b>
Equivalent: pyridoxine	66.6 microgram/mL
<b>riboflavin sodium phosphate</b>	<b>87.6 microgram/mL</b>
Equivalent: riboflavin	66.6 microgram/mL

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<b>thiamine nitrate</b>	<b>1.37 mg/mL</b>
Equivalent: thiamine	1.11 mg/mL

**Other Ingredients (Excipients)**

**Flavour**

**glycerol**

**lecithin**

**maltodextrin**

**potassium sorbate**

**purified water**

**sorbitol**

**sucralose**

**xanthan gum**

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