



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	316883	Heme Synergy
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	26/04/2019	
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 . Heme Synergy

Product Type	Single Medicine Product	Effective Date	29/04/2019
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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 natural liver cleansing/detoxification processes
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support eye health
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Aid/assist/helps in the maintenance of blood levels of oxygen
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support immune system health
- Maintain/support healthy immune system function

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Maintain/support muscle function
 Aid/assist/helps glucose/sugar/carbohydrate metabolism
 Helps decrease/reduce homocysteine levels in healthy individuals
 Aid/assist/helps protein synthesis in the body
 Maintain/support (state vitamin/mineral/nutrient) levels in the body
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
 Support healthy stress response in the body
 Maintain/support nerve conduction
 Aid/assist/helps synthesis of neurotransmitters
 Maintain/support nervous system health
 Maintain/support nervous system function
 Maintain/support skin health
 Maintain/support wound healing in healthy individuals
 Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to heart disease.

Product presentation must only refer to detoxification in relation to natural body processes.
 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 serious cardiovascular conditions.
 Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
 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).
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 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 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 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

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.
 Not for the treatment of iron deficiency conditions (or words to that effect).
 The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.
 If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Child resistant closure	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	100 microgram
calcium ascorbate dihydrate	121.73 mg
Equivalent: ascorbic acid	100 mg
calcium folinate	110 microgram
Equivalent: folic acid	100 microgram
calcium pantothenate	10 mg
Equivalent: pantothenic acid	9.16 mg
hydroxocobalamin	200 microgram
iron (II) glycinate	106.19 mg
Equivalent: iron	24 mg
levomefolate calcium	108.69 microgram
Equivalent: levomefolic acid	100 microgram
mecobalamin (co-methylcobalamin)	200 microgram
nicotinamide	20 mg
pyridoxal 5-phosphate monohydrate	5 mg
Equivalent: pyridoxine	3.19 mg
retinol palmitate	1.375 mg
Equivalent: vitamin A	750 RE
riboflavin sodium phosphate	10 mg
Equivalent: riboflavin	7.6 mg
thiamine hydrochloride	5 mg

Other Ingredients (Excipients)

butylated hydroxytoluene
citric acid
colloidal anhydrous silica
disodium edetate
dl-alpha-tocopherol
gellan gum
glycine
hypromellose
leucine
maize starch
maltodextrin
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide
sucrose

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