



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	225795	METAGENICS HEMAGENICS INTENSIVE CARE
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	15/07/2014	
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 . METAGENICS HEMAGENICS INTENSIVE CARE

Product Type	Single Medicine Product	Effective Date	9/01/2020
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Permitted Indications

- Maintain/support energy production
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support healthy immune system function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support nervous system function

Indication Requirements

- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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.
- 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).
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).
 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.
 Not for the treatment of iron deficiency conditions (or words to that effect).

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

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

calcium ascorbate dihydrate	201.46 mg
Equivalent: ascorbic acid	165.2 mg
calcium citrate	125.37 mg
Equivalent: calcium	25.7 mg
cyanocobalamin	400 microgram
Dunaliella salina	66.67 mg
folic acid	400 microgram
iron amino acid chelate	100 mg
Equivalent: iron	20 mg
pyridoxine hydrochloride	4.77 mg
Equivalent: pyridoxine	3.85 mg
Stellaria media herb top Extract dry concentrate	100 mg
Equivalent: Stellaria media (Dry)	400 mg
thiamine hydrochloride	6.03 mg

Other Ingredients (Excipients)

- ascorbyl palmitate
- calcium hydrogen phosphate dihydrate
- chlorophyllin-copper complex
- citric acid
- colloidal anhydrous silica
- croscarmellose sodium
- Gelatin
- hypromellose
- macrogol 400
- maltodextrin
- microcrystalline cellulose
- mixed (low-alpha type) tocopherols concentrate
- potable water

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powdered cellulose

silicon dioxide

Soya Oil

stearic acid

sucrose

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