



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	284560	METAGENICS HIGH STRENGTH BIOESSENTIALS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	12/01/2017	
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.

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 HIGH STRENGTH BIOESSENTIALS

Product Type	Single Medicine Product	Effective Date	19/05/2020
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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 energy levels
- Maintain/support vitality
- Maintain/support general health and wellbeing
- Maintain/support bone health
- Help maintain/support bone mineralisation
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Indication Requirements

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 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.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

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. 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.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Not to be taken by children under 2 years old (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	2 mg
Biotin	50 microgram
borax	13 mg
Equivalent: boron	1.5 mg
calcium ascorbate dihydrate	153 mg
Equivalent: ascorbic acid	125 mg
calcium citrate tetrahydrate	610 mg
Equivalent: calcium	125 mg
calcium pantothenate	37.5 mg
chromic chloride hexahydrate	513 microgram
Equivalent: chromium	100 microgram
d-alpha-tocopheryl acid succinate	16 mg
Equivalent: d-alpha-tocopherol	12.5 mg
iron amino acid chelate	12.5 mg
Equivalent: iron	2.5 mg
levomefolate calcium	216 microgram
Equivalent: levomefolic acid	200 microgram
magnesium amino acid chelate	525 mg
Equivalent: magnesium	52.5 mg
manganese amino acid chelate	17 mg
Equivalent: manganese	2.75 mg
mecobalamin (co-methylcobalamin)	250 microgram
nicotinamide	25 mg
phytomenadione	8.75 microgram
potassium iodide	98 microgram
Equivalent: iodine	75 microgram
pyridoxal 5-phosphate monohydrate	25 mg
Equivalent: pyridoxine	15.95 mg
riboflavin sodium phosphate	25 mg
Equivalent: riboflavin	18.5 mg
selenomethionine	93 microgram
Equivalent: selenium	37.5 microgram
thiamine hydrochloride	25 mg
zinc amino acid chelate	50 mg

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Equivalent: zinc

10 mg

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate

calcium sulfate dihydrate

chlorophyllin-copper complex

citric acid

colloidal anhydrous silica

croscarmellose sodium

dl-alpha-tocopherol

ethylcellulose

hypromellose

hypromellose

liquid glucose

macrogol 400

magnesium stearate

maize starch

maltodextrin

microcrystalline cellulose

silicon dioxide

sodium ascorbate

starch sodium octenyl succinate

stearic acid

sucrose

tartaric acid

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