



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	330888	METAGENICS MINERAL ESSENTIALS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	6/03/2020	
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 MINERAL ESSENTIALS

Product Type	Single Medicine Product	Effective Date	6/03/2020
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Permitted Indications

Maintain/support energy levels
Maintain/support energy levels in children
Aids/assists healthy bone development/growth/building
Aids/assists healthy bone development/growth/building in children
Maintain/support cardiovascular system health
Aid/assist thyroid hormone production
Maintain/support immune system health
Maintain/support immune system health in children
Maintain/support healthy neuromuscular system/function
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support nervous system health
Maintain/support healthy pregnancy
Maintain/support healthy reproductive hormones

Indication Requirements

Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Product presentation must not imply or refer to serious immunological diseases.

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 serious cardiovascular conditions.

Product presentation must not imply or refer to hormone imbalances.



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

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

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 mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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.

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

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.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

borax	1.45 mg/g
Equivalent: boron	163.93 microgram/g
calcium hydrogen phosphate dihydrate	228.75 mg/g
Equivalent: calcium	53.28 mg/g
Equivalent: phosphorus	41.18 mg/g
chromium nicotinate	81.97 microgram/g
Equivalent: chromium	8.2 microgram/g
iron amino acid chelate	8.2 mg/g
Equivalent: iron	1.64 mg/g
magnesium amino acid chelate	245.9 mg/g
Equivalent: magnesium	24.59 mg/g
manganese amino acid chelate	5.12 mg/g
Equivalent: manganese	819.67 microgram/g
molybdenum trioxide	29.51 microgram/g
Equivalent: molybdenum	19.67 microgram/g
potassium citrate	164.12 mg/g
Equivalent: potassium	59.34 mg/g
potassium iodide	32.13 microgram/g
Equivalent: iodine	24.56 microgram/g
selenomethionine	40.98 microgram/g
Equivalent: selenium	16.39 microgram/g
silicon dioxide	8.2 mg/g
zinc amino acid chelate	8.2 mg/g
Equivalent: zinc	1.64 mg/g

Other Ingredients (Excipients)

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Apple cider vinegar
calcium hydrogen phosphate
citric acid
Flavour
maltodextrin
Steviol glycosides

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