



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

## Public Summary

<b>Summary for ARTG Entry:</b>	362762	METAGENICS MINERAL ESSENTIALS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	21/04/2021	
<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 . METAGENICS MINERAL ESSENTIALS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	31/03/2022
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### Permitted Indications

- Maintain/support energy levels
- Maintain/support energy levels in children
- Aids/assists healthy bone development/growth/building in children
- Aids/assists healthy bone development/growth/building
- Maintain/support cardiovascular system health
- Aid/assist thyroid hormone production
- Maintain/support immune system health in children
- Maintain/support immune system health
- 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

- Product presentation must not imply or refer to hormone imbalances.
- 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: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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 serious musculoskeletal or neurological conditions.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to any thyroid related diseases.

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Product presentation must not imply or refer to serious cardiovascular conditions.

**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.  
 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
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**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>borax</b>	<b>1.45 mg/g</b>
Equivalent: boron	163.93 microgram/g
<b>calcium hydrogen phosphate dihydrate</b>	<b>228.76 mg/g</b>
Equivalent: phosphorus	41.18 mg/g
Equivalent: calcium	53.28 mg/g
<b>chromium nicotinate</b>	<b>81.97 microgram/g</b>
Equivalent: chromium	8.2 microgram/g
<b>iron amino acid chelate</b>	<b>8.2 mg/g</b>
Equivalent: iron	1.64 mg/g
<b>magnesium glycinate dihydrate</b>	<b>245.9 mg/g</b>
Equivalent: magnesium	24.59 mg/g
<b>manganese amino acid chelate</b>	<b>5.12 mg/g</b>
Equivalent: manganese	819.67 microgram/g
<b>molybdenum trioxide</b>	<b>29.51 microgram/g</b>
Equivalent: molybdenum	19.67 microgram/g
<b>potassium citrate</b>	<b>68 mg/g</b>
Equivalent: potassium	24.59 mg/g
<b>potassium iodide</b>	<b>32.13 microgram/g</b>
Equivalent: iodine	24.56 microgram/g
<b>selenomethionine</b>	<b>40.98 microgram/g</b>
Equivalent: selenium	16.39 microgram/g
<b>silicon dioxide</b>	<b>8.2 mg/g</b>
<b>zinc amino acid chelate</b>	<b>8.2 mg/g</b>
Equivalent: zinc	1.64 mg/g

**Other Ingredients (Excipients)**

**Apple cider vinegar**  
**calcium hydrogen phosphate**  
**citric acid**

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**Flavour**

**maltodextrin**

**Steviol glycosides**

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