



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	345614	METAGENICS MALE ESSENTIALS MULTIVITAMIN and MINERAL
<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>	9/10/2020	
<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 MALE ESSENTIALS MULTIVITAMIN and MINERAL**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/06/2022
---------------------	-------------------------	-----------------------	------------

**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body in males
- Maintain/support natural body cleansing/detoxification processes in males
- Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes in males
- Maintain/support body metabolism/metabolic rate in males
- Maintain/support energy production in males
- Maintain/support general health and wellbeing in aging individuals
- Maintain/support hair health in males
- Maintain/support cardiovascular system health in males
- Maintain/support heart health in males
- Hepatoprotectant/protect the liver in males
- Maintain/support healthy liver function in males
- Maintain/support liver health in males
- Maintain/support healthy immune system function in males
- Helps decrease/reduce homocysteine levels in males
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in males
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in males
- Maintain/support cognitive function/mental function in males
- Maintain/support brain function in males
- Maintain/support healthy reproductive hormones in males

**Indication Requirements**

- 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).
- 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.
- If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is

Public Summary



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

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 liver disease, such as cirrhosis, hepatitis.  
 Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.  
 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 drugs/alcohol.  
 Product presentation must not imply or refer to serious immunological diseases.  
 Product presentation must only refer to detoxification in relation to natural body processes.  
 Product presentation must not imply or refer to hormone imbalances.

**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.  
 Not to be taken by children under 2 years old (or words to that effect).  
 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.  
 WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.  
 [Contains vitamin B6].

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>50 mg</b>
<b>betacarotene</b>	<b>4 mg</b>
<b>Biotin</b>	<b>50 microgram</b>
<b>borax</b>	<b>26.54 mg</b>
Equivalent: boron	3.01 mg
<b>calcium amino acid chelate</b>	<b>50 mg</b>
Equivalent: calcium	10 mg
<b>calcium citrate tetrahydrate</b>	<b>142.32 mg</b>
Equivalent: calcium	30 mg
<b>calcium hydrogen phosphate dihydrate</b>	<b>257.62 mg</b>
Equivalent: calcium	60 mg
<b>calcium pantothenate</b>	<b>50 mg</b>
<b>chromic chloride hexahydrate</b>	<b>768.84 microgram</b>
Equivalent: chromium	150 microgram
<b>colecalfiferol</b>	<b>.0125 mg</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>25 mg</b>
Equivalent: d-alpha-tocopherol	20.26 mg
<b>dibasic potassium phosphate</b>	<b>77.95 mg</b>
Equivalent: potassium	35 mg

Public Summary



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

<b>folic acid</b>	<b>400.06 microgram</b>
<b>magnesium glycinate dihydrate</b>	<b>100 mg</b>
Equivalent: magnesium	10 mg
<b>manganese amino acid chelate</b>	<b>15.63 mg</b>
Equivalent: manganese	2.5 mg
<b>mecobalamin (co-methylcobalamin)</b>	<b>400 microgram</b>
<b>mixed (low-alpha type) tocopherols concentrate</b>	<b>2.499 mg</b>
<b>molybdenum trioxide</b>	<b>187.55 microgram</b>
Equivalent: molybdenum	125 microgram
<b>nicotinamide</b>	<b>100 mg</b>
<b>phytomenadione</b>	<b>.08 mg</b>
<b>potassium iodide</b>	<b>52.32 microgram</b>
Equivalent: iodine	40 microgram
<b>pyridoxal 5-phosphate</b>	<b>5 mg</b>
Equivalent: pyridoxine	3.19 mg
<b>pyridoxine hydrochloride</b>	<b>30 mg</b>
Equivalent: pyridoxine	24.68 mg
<b>riboflavin</b>	<b>20 mg</b>
<b>selenomethionine</b>	<b>65 microgram</b>
Equivalent: selenium	26 microgram
<b>Silybum marianum seed Extract dry concentrate standardised</b>	<b>51.19 mg</b>
Equivalent: Silybum marianum (Dry)	3.583 g
<b>thiamine hydrochloride</b>	<b>50 mg</b>
<b>zinc sulfate monohydrate</b>	<b>55 mg</b>
Equivalent: zinc	20 mg

#### Other Ingredients (Excipients)

Acacia  
calcium hydrogen phosphate dihydrate  
calcium hydrogen phosphate  
citric acid  
colloidal anhydrous silica  
croscarmellose sodium  
dl-alpha-tocopherol  
glycerol  
hypromellose  
liquid glucose  
magnesium stearate  
maize starch  
maltodextrin  
medium chain triglycerides  
microcrystalline cellulose  
potable water  
silicon dioxide  
sodium ascorbate  
Soya Oil  
starch sodium octenyl succinate  
sucrose

Public Summary