



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	345614	METAGENICS MALE ESSENTIALS MULTIVITAMIN and MINERAL
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	9/10/2020	
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.

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

Product Type	Single Medicine Product	Effective Date	9/10/2020
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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 liver disease, such as cirrhosis, hepatitis.
- Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
- 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 mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to drugs/alcohol.

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Product presentation must not imply or refer to serious immunological 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 only refer to detoxification in relation to natural body processes.

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

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 hormone imbalances.

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

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).

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	50 mg
betacarotene	4 mg
Biotin	50 microgram
borax	26.54 mg
Equivalent: boron	3.01 mg
calcium amino acid chelate	50 mg
Equivalent: calcium	10 mg
calcium citrate tetrahydrate	142.32 mg
Equivalent: calcium	30 mg
calcium hydrogen phosphate dihydrate	257.62 mg
Equivalent: calcium	60 mg
calcium pantothenate	50 mg
chromic chloride hexahydrate	768.84 microgram
Equivalent: chromium	150 microgram
colecalfiferol	.0125 mg
d-alpha-tocopheryl acid succinate	25 mg
Equivalent: d-alpha-tocopherol	20.26 mg
dibasic potassium phosphate	77.95 mg
Equivalent: potassium	35 mg
folic acid	400.06 microgram
magnesium amino acid chelate	100 mg

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

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