



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	344476	METAGENICS PRIME 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	25/09/2020	
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 PRIME ESSENTIALS MULTIVITAMIN AND MINERAL

Product Type	Single Medicine Product	Effective Date	25/09/2020
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support energy production
Maintain/support healthy blood circulation
Maintain/support cardiovascular system health
Maintain/support cognitive function/mental function
Maintain/support brain function
Maintain/support nervous system function
Support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to serious cardiovascular conditions.
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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not to be taken by children under 2 years old (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.



Australian Government
Department of Health
 Therapeutic Goods Administration

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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	100 mg
betacarotene	6 mg
Biotin	50 microgram
borax	26.46 mg
Equivalent: boron	3 mg
calcium folinate	432.67 microgram
Equivalent: folinic acid	400 microgram
calcium pantothenate	50 mg
Camellia sinensis leaf Extract dry concentrate standardised	120 mg
Equivalent: Camellia sinensis (Dry)	3.6 g
chromic chloride hexahydrate	768.84 microgram
Equivalent: chromium	150 microgram
colecalfiferol	.025 mg
d-alpha-tocopheryl acid succinate	123.1 mg
manganese amino acid chelate	15.63 mg
Equivalent: manganese	2.5 mg
mecobalamin (co-methylcobalamin)	400 microgram
mixed (low-alpha type) tocopherols concentrate	12.3 mg
molybdenum trioxide	187.55 microgram
Equivalent: molybdenum	125 microgram
nicotinamide	100 mg
potassium iodide	130.8 microgram
Equivalent: iodine	100 microgram
pyridoxal 5-phosphate	5 mg
Equivalent: pyridoxine	3.19 mg
pyridoxine hydrochloride	30 mg
Equivalent: pyridoxine	24.7 mg
riboflavin	20 mg
selenomethionine	187.5 microgram
Equivalent: selenium	75 microgram
thiamine hydrochloride	50 mg
Vitis vinifera seed Extract dry concentrate standardised	157.89 mg
Equivalent: Vitis vinifera (Fresh)	18.95 g
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

Acacia

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary