



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	295237	Multi Vitamin & Mineral Excel - Oriental Botanicals Tablets
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	18/10/2017	
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 . Multi Vitamin & Mineral Excel - Oriental Botanicals Tablets

Product Type	Single Medicine Product	Effective Date	3/03/2020
--------------	-------------------------	----------------	-----------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support healthy eyesight/vision
- Maintain/support hair health
- Maintain/support healthy teeth
- Maintain/support bone health
- Maintain/support healthy cardiovascular system function
- Maintain/support artery health
- Maintain/support healthy immune system function
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Support healthy stress response in the body
- Maintain/support cognitive function/mental function
- Maintain/support brain function
- Maintain/support brain health
- Maintain/support skin health
- Maintain/support skin integrity/structure

Indication Requirements

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 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



Australian Government
Department of Health
 Therapeutic Goods Administration

used.

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.

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 serious immunological diseases.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

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

betacarotene	3 mg
Biotin	100 microgram
borax	4.41 mg
Equivalent: boron	500 microgram
calcium ascorbate dihydrate	110 mg
Equivalent: ascorbic acid	90.87 mg
Equivalent: calcium	10.34 mg
calcium citrate tetrahydrate	84 mg
Equivalent: calcium	17.71 mg
calcium pantothenate	100 mg
Equivalent: pantothenic acid	91.61 mg
Equivalent: calcium	8.39 mg
choline bitartrate	25 mg
chromium nicotinate	500 microgram
Equivalent: chromium	50 microgram
Citrus bioflavonoids extract	50 mg
colecalfiferol	.005 mg
colloidal anhydrous silica	32.09 mg
Equivalent: silicon	15 mg

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

cupric sulfate pentahydrate	196.5 microgram
Equivalent: copper	50 microgram
cyanocobalamin	100 microgram
d-alpha-tocopheryl acid succinate	82.64 mg
dibasic potassium phosphate	50 mg
Equivalent: potassium	22.45 mg
folic acid	400 microgram
glutamine	50 mg
inositol	25 mg
lycopene	2 mg
lysine hydrochloride	50 mg
magnesium amino acid chelate	90 mg
Equivalent: magnesium	18 mg
manganese amino acid chelate	20 mg
Equivalent: manganese	2 mg
molybdenum trioxide	50 microgram
Equivalent: molybdenum	33.33 microgram
nicotinamide	100 mg
nicotinic acid	5 mg
phytomenadione	.05 mg
potassium iodide	50 microgram
Equivalent: potassium	11.8 microgram
Equivalent: iodine	38.2 microgram
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.14 mg
retinol palmitate	1.1 mg
riboflavine	20 mg
rutoside	15 mg
selenomethionine	124.2 microgram
Equivalent: selenium	50 microgram
Tagetes erecta	20 mg
taurine	100 mg
thiamine hydrochloride	30 mg
zinc amino acid chelate	75 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

Acacia
aluminium sodium silicate
aluminium starch octenylsuccinate
ascorbyl palmitate
butylated hydroxytoluene
calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
dl-alpha-tocopherol
dl-alpha-tocopheryl acetate
ethylcellulose
Gelatin
hydrogenated soya oil
hydrolysed gelatin



Australian Government

Department of Health
Therapeutic Goods Administration

hypromellose
liquid glucose
macrogol 400
magnesium stearate
maize starch
microcrystalline cellulose
mixed (low-alpha type) tocopherols concentrate
potable water
povidone
silicon dioxide
sodium ascorbate
soluble maize starch
Soya Oil
sucrose
tartaric acid

© 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