



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	292760	Vitality Formula Male
ARTG entry for	Medicine Listed	
Sponsor	Mygen Health Pty Ltd	
Postal Address	PO Box 4006, LANE COVE, NSW, 1595 Australia	
ARTG Start Date	14/08/2017	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Vitality Formula Male

Product Type	Composite Pack	Effective Date	30/05/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps protein synthesis in the body
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in elderly individuals
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

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Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
 Aids/assists the body to cope with environmental stress
 Support healthy stress response in the body
 Maintain/support nerve conduction
 Aid/assist/helps synthesis of neurotransmitters
 Maintain/support nervous system health
 Maintain/support nervous system function
 Maintain/support preconception health in healthy males
 Maintain/support reproductive system health in males
 Maintain/support healthy reproductive hormones
 Maintain/support sperm health in healthy males
 Maintain/support sperm motility in healthy males
 Maintain/support sperm production in healthy males
 Maintain/support testosterone level

Indication Requirements

Product presentation must not imply or refer to infertility.

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 serious cardiovascular conditions.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must not imply or refer to serious immunological diseases.

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).

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Product presentation must not imply or refer to chronic fatigue syndrome.

If directed to women, 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 serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (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
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	500 mg
calcium pantothenate	150 mg

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Equivalent: pantothenic acid	135 mg
levomefolate calcium	542 microgram
Equivalent: levomefolic acid	500 microgram
manganese amino acid chelate	50 mg
Equivalent: manganese	5 mg
mecobalamin (co-methylcobalamin)	500 microgram
nicotinamide	50 mg
potassium iodide	104.6 microgram
Equivalent: iodine	80 microgram
pyridoxal 5-phosphate	30.77 mg
Equivalent: pyridoxine	20 mg
riboflavin	30 mg
selenomethionine	250 microgram
Equivalent: selenium	100 microgram
thiamine hydrochloride	50 mg
zinc citrate dihydrate	94.02 mg
Equivalent: zinc	30 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- hypromellose
- iron oxide black
- iron oxide red
- iron oxide yellow
- macrogol 400
- macrogol 8000
- magnesium stearate
- microcrystalline cellulose
- povidone
- titanium dioxide

2 . Formulation 2

Dosage Form Capsule, soft
Route of Administration Oral

Visual Identification

Active Ingredients

betacarotene	3 mg
colecalfiferol	.025 mg
d-alpha-tocopherol	134.24 mg
lycopene	3 mg
ubidecarenone	100 mg

Other Ingredients (Excipients)

- Colour
- dl-alpha-tocopherol**
- Gelatin
- glycerol
- hydrogenated vegetable oil
- lecithin
- Maize Oil

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purified water

Soya Oil

vegetable oil

yellow beeswax

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