



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	301554	Men's Essentials
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	3/04/2018 11:00:00 PM	
<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 . Men's Essentials**

Product Type	Single Medicine Product	Effective Date	26/10/2020
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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
- Maintain/support energy production
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support bone health
- Maintain/support blood health
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support healthy liver function
- Maintain/support healthy immune system function
- Helps decrease/reduce homocysteine levels
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Helps enhance/promote/increase body utilisation of (state mineral/vitamin/nutrient)
- Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress
- Traditionally used in Eastern European herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in European herbal medicine to maintain/support mental endurance/stamina
- Traditionally used in Chinese medicine to maintain/support mental endurance/stamina
- Maintain/support cognitive function/mental function
- Maintain/support nervous system health
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Maintain/support sperm production
- Maintain/support testosterone level
- Traditionally used in Chinese medicine to kidney Tonic

**Indication Requirements**

Label statement: If symptoms persist, talk to your health professional.

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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 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 used.

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 serious immunological diseases.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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 kidney disease.

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to infertility.

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**

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

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

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

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Capsule, hard

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>50 mg</b>
<b>Biotin</b>	<b>75 microgram</b>
<b>borax</b>	<b>4.454 mg</b>
Equivalent: boron	.5 mg
<b>calcium citrate tetrahydrate</b>	<b>59.312 mg</b>
Equivalent: calcium	12.5 mg
<b>calcium folinate</b>	<b>137 microgram</b>
Equivalent: folic acid	100 microgram
<b>calcium pantothenate</b>	<b>50 mg</b>
Equivalent: pantothenic acid	45.8 mg
<b>choline bitartrate</b>	<b>50 mg</b>
<b>chromium picolinate</b>	<b>200.803 microgram</b>
Equivalent: chromium	25 microgram
<b>colecalfiferol</b>	<b>.0124 mg</b>

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<b>copper gluconate</b>	<b>715 microgram</b>
Equivalent: copper	100 microgram
<b>cyanocobalamin</b>	<b>100 microgram</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>25 IU</b>
<b>inositol</b>	<b>25 mg</b>
<b>levomefolate calcium</b>	<b>130.4 microgram</b>
Equivalent: levomefolic acid	100 microgram
<b>lycopene</b>	<b>.1 mg</b>
<b>magnesium phosphate pentahydrate</b>	<b>97.561 mg</b>
Equivalent: magnesium	20 mg
<b>manganese amino acid chelate</b>	<b>6.67 mg</b>
Equivalent: manganese	1.5 mg
<b>mecobalamin (co-methylcobalamin)</b>	<b>100 microgram</b>
<b>menaquinone 7</b>	<b>7.5 microgram</b>
<b>molybdenum trioxide</b>	<b>94 microgram</b>
Equivalent: molybdenum	62.5 microgram
<b>nicotinamide</b>	<b>50 mg</b>
<b>nicotinic acid</b>	<b>2.5 mg</b>
<b>potassium iodide</b>	<b>49.05 microgram</b>
Equivalent: potassium	11.6 microgram
Equivalent: iodine	37.5 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>4.058 mg</b>
Equivalent: pyridoxine	2.5 mg
<b>pyridoxine hydrochloride</b>	<b>30.387 mg</b>
Equivalent: pyridoxine	25 mg
<b>retinol palmitate</b>	<b>341 microgram</b>
Equivalent: vitamin A	187.5 RE
<b>Rhodiola rosea root Extract dry concentrate</b>	<b>25 mg</b>
Equivalent: Rhodiola rosea (Dry)	250 mg
<b>riboflavin</b>	<b>20 mg</b>
<b>riboflavin sodium phosphate</b>	<b>6.837 mg</b>
Equivalent: riboflavin	5 mg
<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>37.5 mg</b>
Equivalent: Schisandra chinensis (Dry)	750 mg
<b>selenomethionine</b>	<b>62.5 microgram</b>
Equivalent: selenium	25 microgram
<b>thiamine hydrochloride</b>	<b>31.78 mg</b>
Equivalent: thiamine	25 mg
<b>zinc amino acid chelate</b>	<b>44.44 mg</b>
Equivalent: zinc	10 mg

**Other Ingredients (Excipients)**

**Acacia**

**aluminium sodium silicate**

**aluminium starch octenylsuccinate**

**butylated hydroxytoluene**

**calcium hydrogen phosphate**

**Candelilla Wax**

**colloidal anhydrous silica**

**dl-alpha-tocopherol**

**ethylcellulose**



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Gelatin  
hypromellose  
magnesium stearate  
medium chain triglycerides  
microcrystalline cellulose  
Pisum sativum  
purified water  
silicon dioxide  
sodium alginate  
sodium ascorbate  
starch sodium octenyl succinate  
sucrose  
titanium dioxide  
yellow beeswax

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