



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	308361	Ultra Muscleze Energy
<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>	20/08/2018	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

**Conditions**

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 . Ultra Muscleze Energy**

Product Type	Single Medicine Product	Effective Date	20/08/2018
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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 physical endurance/capacity/stamina when dietary intake is inadequate
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support body electrolyte balance
- Maintain/support bone health
- Maintain/support healthy cardiovascular system function
- Maintain/support healthy immune system function
- Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
- Helps reduce occurrence of muscle cramp when dietary intake is inadequate
- Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate
- Maintain/support muscle function
- Helps enhance/improve/promote/increase physical/exercise performance
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps protein synthesis in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system function

**Indication Requirements**

- Product presentation must not imply or refer to serious immunological diseases.
- 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 cardiovascular conditions.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- 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.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to chronic fatigue syndrome.

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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.

Do not take while on warfarin therapy without medical advice.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [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** Powder

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium ascorbate dihydrate</b>	<b>15.216 mg/g</b>
Equivalent: ascorbic acid	12.5 mg/g
Equivalent: calcium	1.43 mg/g
<b>calcium folinate</b>	<b>20.4 microgram/g</b>
Equivalent: folinic acid	18.8 microgram/g
<b>calcium hydrogen phosphate dihydrate</b>	<b>21.459 mg/g</b>
Equivalent: calcium	5 mg/g
<b>calcium hydrogen phosphate dihydrate</b>	<b>587 microgram/g</b>
Equivalent: calcium	173 microgram/g
<b>calcium pantothenate</b>	<b>10.917 mg/g</b>
Equivalent: pantothenic acid	10 mg/g
Equivalent: calcium	917 microgram/g
<b>chromium picolinate</b>	<b>25.1 microgram/g</b>
Equivalent: chromium	3.1 microgram/g
<b>glutamine</b>	<b>62.5 mg/g</b>
<b>hydroxocobalamin</b>	<b>12.5 microgram/g</b>
<b>levocarnitine tartrate</b>	<b>36.656 mg/g</b>
Equivalent: levocarnitine	25 mg/g
<b>magnesium amino acid chelate</b>	<b>400 mg/g</b>
Equivalent: magnesium	40 mg/g
<b>nicotinamide</b>	<b>6.25 mg/g</b>
<b>potassium aspartate</b>	<b>6.658 mg/g</b>
Equivalent: potassium	1.375 mg/g
<b>pyridoxal 5-phosphate monohydrate</b>	<b>4.565 mg/g</b>
Equivalent: pyridoxine	3.125 mg/g
<b>pyridoxine hydrochloride</b>	<b>3.8 mg/g</b>
Equivalent: pyridoxine	3.125 mg/g

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<b>riboflavin</b>	<b>3.125 mg/g</b>
<b>riboflavin sodium phosphate</b>	<b>4.273 mg/g</b>
Equivalent: riboflavin	3.125 mg/g
<b>ribose</b>	<b>25 mg/g</b>
<b>selenomethionine</b>	<b>7.8 microgram/g</b>
Equivalent: selenium	3.1 microgram/g
<b>taurine</b>	<b>62.5 mg/g</b>
<b>thiamine hydrochloride</b>	<b>3.75 mg/g</b>
<b>ubidecarenone</b>	<b>9.375 mg/g</b>
<b>zinc amino acid chelate</b>	<b>3.125 mg/g</b>
Equivalent: zinc	625 microgram/g

**Other Ingredients (Excipients)**

**Flavour**  
**inulin**  
**malic acid**  
**Steviol glycosides**

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