



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	308361	Ultra Muscleze Energy
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	20/08/2018	
Product Category	Medicine	
Status	Active	
Approval Area	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 chronic fatigue syndrome.
- 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 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.

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

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

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].

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

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

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

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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

Other Ingredients (Excipients)

Flavour
inulin
malic acid
Steviol glycosides

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Public Summary