



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	366872	Ultra MuscZeze Night
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	24/05/2021	
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.

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 MuscZeze Night

Product Type	Single Medicine Product	Effective Date	24/05/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
- Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate
- Maintain/support muscle function
- Maintain/support muscle relaxation
- Decrease/reduce/relieve restlessness/excess nervous energy when dietary intake is inadequate
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system function
- Decrease/reduce/relieve sleeplessness when dietary intake is inadequate
- Maintain/support healthy sleeping patterns when dietary intake is inadequate

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious musculoskeletal or neurological 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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Warnings

Not suitable for use in children under the age of 12 months except on the advice of a health professional. (or words to that effect)
Contains milk/milk products.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

alpha casozepine enriched hydrolysed milk protein	9.376 mg/g
calcium hydrogen phosphate dihydrate	75.14 mg/g
Equivalent: calcium	17.5 mg/g
choline bitartrate	78.21 mg/g
Equivalent: choline	32.144 mg/g
d-alpha-tocopheryl acid succinate	8.5006 mg/g
dibasic sodium phosphate	.502 mg/g
Equivalent: sodium	.1626 mg/g
glycine	31.25 mg/g
inositol	125 mg/g
magnesium amino acid chelate	265.2 mg/g
Equivalent: magnesium	30.5 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

inulin

malic acid

silicon dioxide

Steviol glycosides

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