Public Summary

Summary for ARTG Entry:	308310 Ultra Muscleze 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	17/08/2018
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 . Ultra Muscleze Night

Product Type	Single Medicine Product	**Effective Date**	3/12/2018

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Aids/assists healthy bone development/growth/building

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 healthy muscle contraction function

Maintain/support muscle relaxation

Decrease/reduce/relieve restlessness/excess nervous energy when dietary intake is inadequate

Decrease/reduce/relieve symptoms of stress

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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

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.

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

Contains milk/milk products.

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)

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	**9.375 mg/g**
calcium hydrogen phosphate dihydrate	**75.139 mg/g**
Equivalent: calcium	17.5 mg/g
choline bitartrate	**79.798 mg/g**
Equivalent: choline	32.797 mg/g
d-alpha-tocopheryl acid succinate	**8.522 mg/g**
dibasic sodium phosphate	**501 microgram/g**
Equivalent: sodium	162 microgram/g
glycine	**31.25 mg/g**
inositol	**125 mg/g**
magnesium amino acid chelate	**265.2 mg/g**
Equivalent: magnesium	30.5 mg/g
Prunus cerasus fruit flesh Juice concentrate	**3 mg/g**
Equivalent: Prunus cerasus (Fresh)	75 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica
Flavour
inulin
malic acid
maltodextrin
silicon dioxide
Steviol glycosides

Public Summary