Public Summary

Summary for ARTG Entry:	330206 Ultra Muscleze P5P
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	20/02/2020
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 P5P

Product Type	Single Medicine Product	**Effective Date**	20/02/2020

Permitted Indications

Maintain/support energy production
Maintain/support physical endurance/capacity/stamina when dietary intake is inadequate in athletes
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support bone health
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
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 healthy muscle contraction function
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Maintain/support muscle relaxation
Aid/assist/helps protein synthesis in the body
Support healthy stress response in the body
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system function
Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension

Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension

Decrease/reduce/relieve symptoms of premenstrual tension

Decrease/reduce/relieve morning sickness

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.

Product presentation must not imply or refer to serious cardiovascular conditions.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Product presentation must not imply or refer to chronic fatigue syndrome.

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 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.

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].

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

magnesium glycinate	**477 mg**
Equivalent: magnesium	67.2 mg
magnesium oxide	**137 mg**
Equivalent: magnesium	82.8 mg
pyridoxal 5-phosphate monohydrate	**53.7 mg**
Equivalent: pyridoxine	34.23 mg

Other Ingredients (Excipients)

Carnauba Wax
chlorophyllin-copper complex
citric acid
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 3350
magnesium stearate
maltodextrin
microcrystalline cellulose

Public Summary

Public Summary