



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	330206	Ultra Muscleze P5P
<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>	20/02/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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
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### 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

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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 cardiovascular conditions.  
 If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.  
 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 chronic fatigue syndrome.  
 Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.  
 Product presentation must not imply or refer to mental illnesses, disorders or 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.

**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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>magnesium glycinate</b>	<b>477 mg</b>
Equivalent: magnesium	67.2 mg
<b>magnesium oxide</b>	<b>137 mg</b>
Equivalent: magnesium	82.8 mg
<b>pyridoxal 5-phosphate monohydrate</b>	<b>53.7 mg</b>
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

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