



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

## Public Summary

<b>Summary for ARTG Entry:</b>	338194	Pharma Mag Forte
<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>	22/06/2020	
<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.

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 . Pharma Mag Forte

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/06/2020
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### Permitted Indications

- Maintain/support energy production
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Helps maintain/support vasodilator/ blood vessel dilation
- Maintain/support blood vessel health
- Maintain/support healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support muscle relaxation
- Helps maintain/support cellular uptake of (state vitamin/mineral/nutrient)
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support nerve conduction
- Maintain/support nervous system function

### Indication Requirements

- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- 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 circulatory disorders/diseases/conditions e.g. thrombosis.



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**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**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**

<b>calcium hydrogen phosphate dihydrate</b>	<b>146 mg</b>
Equivalent: calcium	34 mg
<b>calcium orotate</b>	<b>80.6 mg</b>
Equivalent: calcium	10 mg
<b>magnesium aspartate</b>	<b>250 mg</b>
Equivalent: magnesium	21 mg
<b>magnesium orotate dihydrate</b>	<b>457 mg</b>
Equivalent: magnesium	30 mg
<b>potassium aspartate monohydrate</b>	<b>242 mg</b>
Equivalent: potassium	50 mg

**Other Ingredients (Excipients)**

**Carnauba Wax**  
**chlorophyllin-copper complex**  
**colloidal anhydrous silica**  
**croscarmellose sodium**  
**hypromellose**  
**macrogol 3350**  
**magnesium stearate**  
**microcrystalline cellulose**  
**purified talc**

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