



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

## Public Summary

|                                |                                                                        |                               |
|--------------------------------|------------------------------------------------------------------------|-------------------------------|
| <b>Summary for ARTG Entry:</b> | 305454                                                                 | Ultra Muscleze Forest Berries |
| <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<br>Australia |                               |
| <b>ARTG Start Date</b>         | 27/06/2018                                                             |                               |
| <b>Product Category</b>        | Medicine                                                               |                               |
| <b>Status</b>                  | Active                                                                 |                               |
| <b>Approval Area</b>           | Listed Medicines                                                       |                               |

### Conditions

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 Muscleze Forest Berries

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 27/06/2018 |
|---------------------|-------------------------|-----------------------|------------|

### Permitted Indications

Maintain/support energy levels  
Relieve weariness/tiredness/fatigue/feeling of weakness  
Maintain/support body electrolyte balance  
Maintain/support bone health  
Aids/assists healthy bone development/growth/building  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
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  
Helps enhance/promote healthy muscle function  
Maintain/support muscle function  
Maintain/support muscle relaxation  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate  
Support healthy stress response in the body  
Maintain/support nerve conduction  
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

### Indication Requirements

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

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 chronic fatigue syndrome.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR



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[Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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 serious musculoskeletal or neurological conditions.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.  
[Contains vitamin B6].

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

#### 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

|                                             |                        |
|---------------------------------------------|------------------------|
| <b>calcium hydrogen phosphate dihydrate</b> | <b>4.938 mg/g</b>      |
| Equivalent: calcium                         | 1.15 mg/g              |
| <b>calcium hydrogen phosphate dihydrate</b> | <b>.783 mg/g</b>       |
| Equivalent: calcium                         | .231 mg/g              |
| <b>calcium pantothenate</b>                 | <b>4.549 mg/g</b>      |
| Equivalent: pantothenic acid                | 4.167 mg/g             |
| Equivalent: calcium                         | 382 microgram/g        |
| <b>cyanocobalamin</b>                       | <b>3 microgram/g</b>   |
| <b>d-alpha-tocopheryl acid succinate</b>    | <b>11.017 mg/g</b>     |
| <b>dibasic sodium phosphate</b>             | <b>669 microgram/g</b> |
| Equivalent: sodium                          | 217 microgram/g        |
| <b>folic acid</b>                           | <b>25 microgram/g</b>  |
| <b>glutamine</b>                            | <b>83.333 mg/g</b>     |
| <b>heavy magnesium oxide</b>                | <b>10.006 mg/g</b>     |
| Equivalent: magnesium                       | 6.033 mg/g             |
| <b>levocarnitine tartrate</b>               | <b>12.5 mg/g</b>       |
| Equivalent: levocarnitine                   | 8.525 mg/g             |
| <b>magnesium amino acid chelate</b>         | <b>353.623 mg/g</b>    |
| Equivalent: magnesium                       | 40.667 mg/g            |
| <b>molybdenum trioxide</b>                  | <b>15 microgram/g</b>  |
| Equivalent: molybdenum                      | 10 microgram/g         |
| <b>nicotinamide</b>                         | <b>3.333 mg/g</b>      |
| <b>potassium aspartate</b>                  | <b>8.333 mg/g</b>      |
| Equivalent: potassium                       | 1.75 mg/g              |

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|                                 |                        |
|---------------------------------|------------------------|
| <b>pyridoxine hydrochloride</b> | <b>8.333 mg/g</b>      |
| Equivalent: pyridoxine          | 6.85 mg/g              |
| <b>riboflavin</b>               | <b>833 microgram/g</b> |
| <b>selenomethionine</b>         | <b>10 microgram/g</b>  |
| Equivalent: selenium            | 4 microgram/g          |
| <b>taurine</b>                  | <b>83.333 mg/g</b>     |
| <b>thiamine hydrochloride</b>   | <b>4.167 mg/g</b>      |

**Other Ingredients (Excipients)**

**beet red**  
**colloidal anhydrous silica**  
**Flavour**  
**inulin**  
**malic acid**  
**Steviol glycosides**

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