



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

## Public Summary

<b>Summary for ARTG Entry:</b>	350478	METAGENICS FIBROPLEX PLUS ORANGE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	2/12/2020	
<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 . METAGENICS FIBROPLEX PLUS ORANGE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/11/2021
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### Permitted Indications

- Maintain/support energy levels
- Maintain/support general health and wellbeing
- Helps maintain/support healthy blood sugar/glucose
- Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support muscle relaxation
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Support healthy stress response in the body
- 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- 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).
- 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.
- Product presentation must not imply or refer to chronic fatigue syndrome.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

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

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exceeded.

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** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>acetyl levocarnitine hydrochloride</b>	<b>16.79 mg/g</b>
<b>ascorbic acid</b>	<b>42.86 mg/g</b>
<b>calcium hydrogen phosphate dihydrate</b>	<b>38.43 mg/g</b>
Equivalent: calcium	8.95 mg/g
<b>chromium nicotinate</b>	<b>35.71 microgram/g</b>
Equivalent: chromium	3.57 microgram/g
<b>glutamine</b>	<b>71.43 mg/g</b>
<b>magnesium glycinate dihydrate</b>	<b>428.57 mg/g</b>
Equivalent: magnesium	42.86 mg/g
<b>mecobalamin (co-methylcobalamin)</b>	<b>21.47 microgram/g</b>
<b>monobasic potassium phosphate</b>	<b>26 mg/g</b>
Equivalent: potassium	7.47 mg/g
<b>nicotinamide</b>	<b>7.14 mg/g</b>
<b>pyridoxine hydrochloride</b>	<b>7.15 mg/g</b>
Equivalent: pyridoxine	5.88 mg/g
<b>riboflavin</b>	<b>271.43 microgram/g</b>
<b>selenomethionine</b>	<b>8.93 microgram/g</b>
Equivalent: selenium	3.57 microgram/g
<b>taurine</b>	<b>85.71 mg/g</b>
<b>thiamine hydrochloride</b>	<b>4.29 mg/g</b>

**Other Ingredients (Excipients)**

**calcium hydrogen phosphate**  
**citric acid**  
**colloidal anhydrous silica**  
**Flavour**  
**malic acid**  
**Steviol glycosides**

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