



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	376651	METAGENICS FIBROPLEX MAGACTIVE TABLET
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	21/10/2021	
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.

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 MAGACTIVE TABLET

Product Type	Single Medicine Product	Effective Date	5/08/2022
--------------	-------------------------	----------------	-----------

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

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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 chronic fatigue syndrome.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- Label statement: If symptoms persist, talk to your health professional.

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.



Australian Government
Department of Health
Therapeutic Goods Administration

[Contains vitamin B6].

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.

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

chromic chloride hexahydrate	1.03 mg
Equivalent: chromium	199.89 microgram
magnesium amino acid chelate	500 mg
Equivalent: magnesium	100 mg
magnesium glycinate dihydrate	1 g
Equivalent: magnesium	100 mg
pyridoxal 5-phosphate monohydrate	15 mg
Equivalent: pyridoxine	9.57 mg
zinc amino acid chelate	40 mg
Equivalent: zinc	8 mg

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
crospovidone
glycerol
hydrolysed rice
hypromellose
hypromellose
magnesium stearate
microcrystalline cellulose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary