



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311269	METAGENICS FIBROPLEX MAGACTIVE FOR KIDS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	7/11/2018	
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 FOR KIDS

Product Type	Single Medicine Product	Effective Date	7/02/2024
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Permitted Indications

- Maintain/support energy levels in children
- Maintain/support muscle function in children
- Maintain/support muscle relaxation in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
- Support healthy stress response in the body in children
- Maintain/support nervous system health in children
- Support healthy emotional/mood balance in children

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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 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



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Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

acetyl levocarnitine hydrochloride	16.79 mg/g
ascorbic acid	42.86 mg/g
chromium nicotinate	35.71 microgram/g
Equivalent: chromium	3.57 microgram/g
glutamine	71.43 mg/g
magnesium glycinate dihydrate	428.57 mg/g
Equivalent: magnesium	42.86 mg/g
mecobalamin	21.43 microgram/g
nicotinamide	7.14 mg/g
pyridoxal 5-phosphate monohydrate	7.14 mg/g
Equivalent: pyridoxine	4.56 mg/g
riboflavin sodium phosphate	371.95 microgram/g
Equivalent: riboflavin	271.52 microgram/g
selenomethionine	8.93 microgram/g
Equivalent: selenium	3.57 microgram/g
taurine	85.71 mg/g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
citric acid
colloidal anhydrous silica
Colour
Flavour
malic acid
monobasic potassium phosphate
Steviol glycosides

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