



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	359718	MultiFactors For Juniors
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
ARTG Start Date	5/04/2021 11:00:00 PM	
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 . MultiFactors For Juniors

Product Type	Single Medicine Product	Effective Date	6/04/2021
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Permitted Indications

- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support eye health
- Maintain/support healthy growth and development
- Aids/assists teeth development
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support healthy immune system function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support cognitive development
- Maintain/support cognitive function/mental function
- Maintain/support nervous system function

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or 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).
- Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
- 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 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 neurological conditions or developmental delays.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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
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Components

1 . Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	50 mg
Biotin	.0375 mg
calcium citrate tetrahydrate	166.03 mg
Equivalent: calcium	35 mg
calcium pantothenate	10.92 mg
Equivalent: pantothenic acid	10 mg
chromium picolinate	.1006 mg
Equivalent: chromium	.0125 mg
colecalfiferol	.005 mg
copper gluconate	.0893 mg
Equivalent: copper	.0125 mg
cyanocobalamin	.01 mg
d-alpha-tocopheryl acid succinate	10.33 mg
Equivalent: d-alpha-tocopherol	12.5 IU
folic acid	.1 mg
iron amino acid chelate	9.52 mg
Equivalent: iron	2 mg
lysine hydrochloride	3.75 mg
Equivalent: lysine	3 mg
magnesium phosphate pentahydrate	72.6 mg
Equivalent: magnesium	15 mg
manganese (II) glycinate	2.19 mg
Equivalent: manganese	.5 mg
nicotinamide	4.995 mg
phytomenadione	.025 mg
potassium iodide	.059 mg
Equivalent: iodine	.045 mg
pyridoxal 5-phosphate monohydrate	3.92 mg
Equivalent: pyridoxine	2.5 mg
retinol acetate	.2291 mg
Equivalent: vitamin A	200 RE/microgram
riboflavin sodium phosphate	6.58 mg

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Equivalent: riboflavin	5 mg
selenomethionine	.0312 mg
Equivalent: selenium	.0125 mg
thiamine nitrate	6.1638 mg
zinc glycinate	7.5 mg
Equivalent: zinc	1.5 mg

Other Ingredients (Excipients)

Acacia
butylated hydroxytoluene
citric acid
colloidal anhydrous silica
dl-alpha-tocopherol
Flavour
glycine
hypromellose
magnesium stearate
maize starch
maltodextrin
mannitol
medium chain triglycerides
modified food starch
mono- and di- glycerides
povidone
rice starch
silicon dioxide
Siraitia grosvenorii
sodium bicarbonate
sucrose
thaumatin
xylitol

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