



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	359718	MultiFactors For Juniors
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
<b>ARTG Start Date</b>	5/04/2021 11:00:00 PM	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 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.
- 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 neurological conditions or developmental delays.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
- 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**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, chewable

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

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

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Equivalent: riboflavin	5 mg
<b>selenomethionine</b>	<b>.0312 mg</b>
Equivalent: selenium	.0125 mg
<b>thiamine nitrate</b>	<b>6.1638 mg</b>
<b>zinc glycinate</b>	<b>7.5 mg</b>
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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