



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	344491	Multi Essentials
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	25/09/2020	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Multi Essentials

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/09/2020
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support energy levels  
Maintain/support energy production  
Maintain/support general health and wellbeing  
Aid/assist/helps glucose/sugar/carbohydrate metabolism  
Support healthy stress response in the body  
Maintain/support cognitive function/mental function  
Maintain/support nervous system function  
Maintain/support skin health

#### 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.  
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 chronic fatigue syndrome.

#### 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.

Public Summary



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If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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

#### 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

<b>ascorbic acid</b>	<b>100 mg</b>
<b>betacarotene</b>	<b>4 mg</b>
<b>Biotin</b>	<b>100 microgram</b>
<b>borax</b>	<b>8.82 mg</b>
Equivalent: boron	1 mg
<b>calcium citrate</b>	<b>237 mg</b>
Equivalent: calcium	50 mg
<b>calcium pantothenate</b>	<b>100 mg</b>
Equivalent: calcium	8.39 mg
Equivalent: pantothenic acid	91.61 mg
<b>choline bitartrate</b>	<b>50 mg</b>
Equivalent: choline	20 mg
<b>chromium nicotinate</b>	<b>416.67 microgram</b>
Equivalent: chromium	50 microgram
<b>Citrus bioflavonoids extract</b>	<b>50 mg</b>
<b>colecalfiferol</b>	<b>.0025 mg</b>
<b>copper gluconate</b>	<b>1.43 mg</b>
Equivalent: copper	200 microgram
<b>cyanocobalamin</b>	<b>400 microgram</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>82.64 mg</b>
<b>folic acid</b>	<b>400 microgram</b>
<b>heavy magnesium oxide</b>	<b>41.459 mg</b>
Equivalent: magnesium	25 mg
<b>inositol</b>	<b>50 mg</b>
<b>manganese amino acid chelate</b>	<b>5 mg</b>
Equivalent: manganese	1 mg
<b>mixed (low-alpha type) tocopherols concentrate</b>	<b>14.7 mg</b>
<b>molybdenum trioxide</b>	<b>113 microgram</b>
Equivalent: molybdenum	75 microgram
<b>nicotinamide</b>	<b>200 mg</b>
<b>phytomenadione</b>	<b>30 microgram</b>
<b>pyridoxine hydrochloride</b>	<b>50 mg</b>
Equivalent: pyridoxine	41.14 mg

# Public Summary



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retinol acetate	.43 mg
riboflavin	50 mg
selenomethionine	64.58 microgram
Equivalent: selenium	26 microgram
thiamine hydrochloride	50 mg
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg

#### Other Ingredients (Excipients)

Acacia  
aluminium sodium silicate  
butylated hydroxytoluene  
calcium phosphate  
croscarmellose sodium  
dl-alpha-tocopherol  
Gelatin  
glycerol  
hypolose  
hypromellose  
magnesium stearate  
medium chain triglycerides  
microcrystalline cellulose  
polydextrose  
potable water  
purified water  
silicon dioxide  
sodium ascorbate  
Soya Oil  
starch sodium octenyl succinate  
stearic acid  
sucrose  
sunset yellow FCF aluminium lake  
titanium dioxide

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