



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

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

Product Type	Single Medicine Product	Effective Date	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

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

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

exceeded.

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.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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

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

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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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Public Summary