



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	341715	Mega B Q10
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	18/08/2020	
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 . Mega B Q10

Product Type	Single Medicine Product	Effective Date	18/08/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support energy levels
Helps convert (state food) into energy
Maintain/support energy production
Relieve weariness/tiredness/fatigue/feeling of weakness
Aid/assist healthy red blood cell production
Helps maintain/support haemoglobin formation/synthesis
Maintain/support healthy immune system function
Helps decrease/reduce homocysteine levels
Support healthy stress response in the body
Maintain/support nervous system function

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.

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 serious cardiovascular conditions.

Product presentation must not imply or refer to serious immunological diseases.

Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

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

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

Do not take while on warfarin therapy without medical advice.

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	300 microgram
calcium folinate	508.4 microgram
Equivalent: folic acid	400 microgram
calcium pantothenate	49.12 mg
Equivalent: pantothenic acid	45 mg
colecalfiferol	.025 mg
cyanocobalamin	400 microgram
d-alpha-tocopheryl acetate	18.38 mg
nicotinamide	90 mg
nicotinic acid	10 mg
pyridoxal 5-phosphate monohydrate	15.67 mg
Equivalent: pyridoxine	10 mg
pyridoxine hydrochloride	48.62 mg
Equivalent: pyridoxine	40 mg
retinol palmitate	824.67 microgram
riboflavin sodium phosphate	63.53 mg
Equivalent: riboflavin	50 mg
thiamine nitrate	61.68 mg
Equivalent: thiamine	50 mg
ubidecarenone	30 mg

Other Ingredients (Excipients)

- dl-alpha-tocopherol**
- Gelatin**
- glycerol**
- hydrogenated vegetable oil**
- iron oxide black**
- iron oxide red**
- lecithin**
- medium chain triglycerides**
- purified water**
- Soya Oil**
- vegetable oil**

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