



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

## Public Summary

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

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/08/2022
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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.
- 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.
- 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.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious cardiovascular conditions.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings



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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.

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
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**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Biotin</b>	<b>300 microgram</b>
<b>calcium folinate</b>	<b>508.4 microgram</b>
Equivalent: folic acid	400 microgram
<b>calcium pantothenate</b>	<b>49.12 mg</b>
Equivalent: pantothenic acid	45 mg
<b>colecalfiferol</b>	<b>.025 mg</b>
<b>cyanocobalamin</b>	<b>400 microgram</b>
<b>d-alpha-tocopheryl acetate</b>	<b>18.38 mg</b>
<b>nicotinamide</b>	<b>90 mg</b>
<b>nicotinic acid</b>	<b>10 mg</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>15.67 mg</b>
Equivalent: pyridoxine	10 mg
<b>pyridoxine hydrochloride</b>	<b>48.62 mg</b>
Equivalent: pyridoxine	40 mg
<b>retinol palmitate</b>	<b>824.67 microgram</b>
Equivalent: vitamin A	449.82 microgram
<b>riboflavin sodium phosphate</b>	<b>63.53 mg</b>
Equivalent: riboflavin	50 mg
<b>thiamine nitrate</b>	<b>61.68 mg</b>
Equivalent: thiamine	50 mg
<b>ubidecarenone</b>	<b>30 mg</b>

**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
- yellow beeswax

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