Public Summary

Summary for ARTG Entry:	328687	Activated Bs plus Ubiquinol
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	16/01/2020	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Activated Bs plus Ubiquinol

Product Type	Single Medicine Product	**Effective Date**	16/01/2020

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support energy levels
Helps convert (state food) into energy
Maintain/support energy production
Maintain/support physical endurance/capacity/stamina during exercise
Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
Aid/assist healthy red blood cell production
Helps maintain/support haemoglobin formation/synthesis
Maintain/support healthy liver function
Maintain/support healthy immune system function
Support healthy stress response in the body
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system function
Maintains/support healthy foetal development

Indication Requirements

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.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

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

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Biotin	**300 microgram**
calcium pantothenate	**50 mg**
Equivalent: pantothenic acid	45.8 mg
choline bitartrate	**208.99 mg**
inositol	**50 mg**
levomefolate calcium	**433 microgram**
Equivalent: levomefolic acid	400 microgram
mecobalamin (co-methylcobalamin)	**400 microgram**
nicotinamide	**50 mg**
pyridoxal 5-phosphate monohydrate	**31.35 mg**
Equivalent: pyridoxine	20 mg
riboflavin sodium phosphate	**46.5 mg**
Equivalent: riboflavin	36.6 mg
thiamine hydrochloride	**50 mg**
Equivalent: thiamine	44.6 mg
ubiquinol-10	**25 mg**

Other Ingredients (Excipients)

Acacia
ascorbic acid
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
dextrin
disodium edetate
gellan gum
hypromellose
lecithin
magnesium stearate

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microcrystalline cellulose

potable water

potassium acetate

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