



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370650	B-Supreme
ARTG entry for	Medicine Listed	
Sponsor	Designs For Health Pty Ltd	
Postal Address	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
ARTG Start Date	6/07/2021	
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.

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 . B-Supreme

Product Type	Single Medicine Product	Effective Date	6/07/2021
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Permitted Indications

Maintain/support energy levels
Maintain/support energy production
Maintain/support general health and wellbeing
Maintain/support hair health
Maintain/support nail health/strength/thickness
Maintain/support healthy body tissues
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Helps maintain/support haemoglobin formation/synthesis
Maintain/support cardiovascular system health
Maintain/support healthy liver function
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Aid/assist/helps protein synthesis in the body
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Support healthy stress response in the body
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support skin health

Indication Requirements

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

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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



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

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

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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.

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	2 mg
calcium pantothenate	109.17 mg
Equivalent: pantothenic acid	100 mg
Equivalent: calcium	9.16 mg
choline bitartrate	100 mg
Equivalent: choline	41.13 mg
dimethylglycine hydrochloride	135.39 mg
levomefolate glucosamine	901.7 microgram
Equivalent: levomefolic acid	500 microgram
mecobalamin (co-methylcobalamin)	250 microgram
nicotinamide	50 mg
pyridoxal 5-phosphate monohydrate	78.37 mg
Equivalent: pyridoxine	50 mg
riboflavin sodium phosphate	68.49 mg
Equivalent: riboflavin	50 mg
thiamine hydrochloride	112.15 mg
Equivalent: thiamine	100 mg
ubidecarenone	50 mg

Other Ingredients (Excipients)

- colloidal anhydrous silica
- hypromellose
- magnesium stearate
- purified water
- silicon dioxide

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