



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	310449	Activated B Complex
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	17/10/2018	
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 . Activated B Complex

Product Type	Single Medicine Product	Effective Date	8/02/2022
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Permitted Indications

Maintain/support heat/energy production/thermogenesis
Maintain/support general health and wellbeing
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support blood health
Maintain/support cardiovascular system health
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps decrease/reduce homocysteine levels
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Support healthy stress response in the body
Help maintain/support emotional wellbeing
Maintain/support cognitive function/mental function
Maintain/support memory/mental recall
Maintain/support brain function
Maintain/support brain health
Maintain/support nervous system health
Maintain/support nervous system function
Maintains/support healthy foetal development

Indication Requirements

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: 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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).



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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

calcium pantothenate	25 mg
Equivalent: pantothenic acid	22.9 mg
levomefolate glucosamine	842 microgram
Equivalent: levomefolic acid	400 microgram
mecobalamin (co-methylcobalamin)	400 microgram
nicotinamide	25 mg
pyridoxal 5-phosphate monohydrate	25 mg
Equivalent: pyridoxine	15.95 mg
riboflavin sodium phosphate	25 mg
Equivalent: riboflavin	18.3 mg
thiamine hydrochloride	25 mg
Equivalent: thiamine	22.3 mg

Other Ingredients (Excipients)

citric acid

hypromellose

magnesium stearate

microcrystalline cellulose

purified water

silicon dioxide

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