



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.  
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 mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to serious cardiovascular conditions.  
If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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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**

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

**Other Ingredients (Excipients)**

citric acid  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
purified water  
silicon dioxide

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