Australian Government

Department of Health, Disability and Ageing

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 Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020

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** 20/08/2025

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.

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

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.

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).

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

Page 1 of 2



Department of Health, Disability and Ageing

Therapeutic Goods Administration

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.

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

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 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

Other Ingredients (Excipients)

citric acid hypromellose magnesium stearate microcrystalline cellulose purified water

silicon dioxide

Equivalent: thiamine

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