# Australian Government

# Department of Health, Disability and Ageing

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 288806 Vitamin B5 500mg

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 11/05/2017

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 . Vitamin B5 500mg

Product Type Single Medicine Product Effective Date 14/10/2025

# Permitted Indications

Helps convert (state food) into energy

Maintain/support energy production

Maintain/support general health and wellbeing

Aid/assist digestion of glucose/sugar/carbohydrates

Maintain/support (state vitamin/mineral/nutrient) levels 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 skin health

### **Indication Requirements**

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

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 mental illnesses, disorders or conditions.

#### **Standard Indications**

No Standard Indications included on Record

# **Specific Indications**

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

### **Additional Product information**

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# **Australian Government**

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Therapeutic Goods Administration

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 pantothenate555 mgEquivalent: pantothenic acid500 mg

Other Ingredients (Excipients)

hypromellose

magnesium stearate

microcrystalline cellulose

purified water

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