



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

|                                |  |                             |
|--------------------------------|--|-----------------------------|
| <b>Summary for ARTG Entry:</b> | 339568   | Thompson's Vitamin B5 500mg |
| <b>ARTG entry for</b>          | Medicine Listed  |                             |
| <b>Sponsor</b>                 | Integria Healthcare Australia Pty Ltd                  |                             |
| <b>Postal Address</b>          | PO Box 4854, EIGHT MILE PLAINS, QLD, 4113<br>Australia |                             |
| <b>ARTG Start Date</b>         | 15/07/2020   |                             |
| <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 . Thompson's Vitamin B5 500mg**

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 12/10/2022 |
|---------------------|-------------------------|-----------------------|------------|

**Permitted Indications**

- Helps convert (state food) into energy
- Maintain/support general health and wellbeing in teenagers
- Maintain/support general health and wellbeing in adults
- Maintain/support general health and wellbeing in adolescents
- Maintain/support general health and wellbeing
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adults
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in teenagers
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
- Maintain/support (state vitamin/mineral) within normal range in adults
- Maintain/support (state vitamin/mineral) within normal range in teenagers
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support (state vitamin/mineral) within normal range in adolescents
- Support healthy stress response in the body in adults
- Support healthy stress response in the body
- Support healthy stress response in the body in teenagers
- Support healthy stress response in the body in adolescents
- Aid/assist/helps synthesis of neurotransmitters

**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).

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.

Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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

**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**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

|                              |               |
|------------------------------|---------------|
| <b>calcium pantothenate</b>  | <b>546 mg</b> |
| Equivalent: pantothenic acid | 500 mg        |

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

croscarmellose sodium

hypromellose

magnesium stearate

microcrystalline cellulose

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