



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	264390	Thompson's B Complex
<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 Australia	
<b>ARTG Start Date</b>	25/11/2015	
<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 B Complex**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/09/2021
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**Permitted Indications**

- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing in teenagers
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in adolescents
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in teenagers
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
- Maintain/support (state vitamin/mineral) within normal range in teenagers
- Maintain/support (state vitamin/mineral) within normal range in adolescents
- Maintain/support (state vitamin/mineral) within normal range
- Support healthy stress response in the body in adolescents
- Support healthy stress response in the body
- Support healthy stress response in the body in teenagers
- 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 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 serious cardiovascular conditions.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

If symptoms persist consult your healthcare practitioner (or words to that effect).

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**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Biotin</b>	<b>20 microgram</b>
<b>calcium pantothenate</b>	<b>7.5 mg</b>
Equivalent: pantothenic acid	6.9 mg
<b>choline bitartrate</b>	<b>25 mg</b>
<b>cyanocobalamin</b>	<b>5 microgram</b>
<b>folic acid</b>	<b>90 microgram</b>
<b>inositol</b>	<b>25 mg</b>
<b>nicotinamide</b>	<b>25 mg</b>
<b>pyridoxine hydrochloride</b>	<b>5 mg</b>
Equivalent: pyridoxine	4.1 mg
<b>riboflavin</b>	<b>5 mg</b>
<b>thiamine hydrochloride</b>	<b>5 mg</b>

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
citric acid monohydrate  
croscarmellose sodium  
hypromellose  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
potable water  
sodium citrate dihydrate

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