



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	349932	Ultra B Complex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Phytologic Holdings Pty Limited	
<b>Postal Address</b>	PO Box 6193, Alexandria, NSW, 2015 Australia	
<b>ARTG Start Date</b>	27/11/2020	
<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 . Ultra B Complex**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/11/2020
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Maintain/support heart health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Support healthy stress response in the body
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support skin health

**Indication Requirements**

- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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).

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Product presentation must not imply or refer to serious immunological diseases.

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.

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

Label statement: If symptoms persist, talk to your health professional.

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).

**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>ascorbic acid</b>	<b>100 mg</b>
<b>Biotin</b>	<b>1 mg</b>
<b>calcium pantothenate</b>	<b>81.88 mg</b>
Equivalent: pantothenic acid	75 mg
<b>choline bitartrate</b>	<b>25 mg</b>
<b>cyanocobalamin</b>	<b>.1 mg</b>
<b>folic acid</b>	<b>.2 mg</b>
<b>inositol</b>	<b>25 mg</b>
<b>nicotinamide</b>	<b>100 mg</b>
<b>pyridoxine hydrochloride</b>	<b>50 mg</b>
Equivalent: pyridoxine	41.14 mg
<b>riboflavin</b>	<b>50 mg</b>
<b>thiamine nitrate</b>	<b>75 mg</b>
Equivalent: thiamine	60.8 mg

**Other Ingredients (Excipients)**

- Carnauba Wax**
- colloidal anhydrous silica**
- croscarmellose sodium**
- hypromellose**
- iron oxide yellow**
- lecithin**
- macrogol 4000**
- magnesium stearate**
- mannitol**
- microcrystalline cellulose**
- polyvinyl alcohol**

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**purified water**

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