



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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 mental illnesses, disorders or conditions.

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

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 chronic fatigue syndrome.

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

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

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