



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346628	B Complex Excel
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	27/10/2020	
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 . B Complex Excel

Product Type	Single Medicine Product	Effective Date	27/10/2020
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Permitted Indications

- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support vitality
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Helps maintain/support haemoglobin formation/synthesis
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Support healthy stress response in the body
- Maintain/support cognitive function/mental function
- Maintain/support brain function
- Maintain/support brain health
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system function
- Support healthy emotional/mood balance

Indication Requirements

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

Standard Indications



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No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral 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

Biotin	150 microgram
calcium pantothenate	110 mg
Equivalent: pantothenic acid	100.8 mg
Camellia sinensis	113.75 mg
choline bitartrate	137.5 mg
cyanocobalamin	150 microgram
folic acid	150 microgram
inositol	100 mg
nicotinamide	150 mg
pyridoxine hydrochloride	75 mg
Equivalent: pyridoxine	61.7 mg
riboflavine	50 mg
thiamine nitrate	100 mg
Equivalent: thiamine	81.06 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

hypromellose

macrogol 400

magnesium stearate

microcrystalline cellulose

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