

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	264390	Thompson's B Complex		
ARTG entry for	Medicine Listed			
Sponsor	Integria Healthca	are Australia Pty Ltd		
Postal Address	PO Box 4854, El Australia	IGHT MILE PLAINS, QLD, 4113	3	
ARTG Start Date	25/11/2015			
Product Category	Medicine			
Status	Active			
Approval Area	Listed Medicines	\$		
Conditions				

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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 Product Type Effective Date 21/09/2022 Single Medicine Product **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 in adolescents Maintain/support (state vitamin/mineral/nutrient) levels in the body Maintain/support (state vitamin/mineral) within normal range in adolescents Maintain/support (state vitamin/mineral) within normal range in teenagers Maintain/support (state vitamin/mineral) within normal range Support healthy stress response in the body in teenagers Support healthy stress response in the body in adolescents Support healthy stress response in the body Aid/assist/helps synthesis of neurotransmitters

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 mental illnesses, disorders or conditions.

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

Page 1 of 2

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Produced at 05.01.2023 at 04:12:51 AEDT

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Therapeutic Goods Administration

Product presentation must not imply or refer to serious cardiovascular conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet. If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information				
Pack Size		Poison Schedule		
Components				
1. Formulation 1				
Dosage Form Ta	ablet, film coated			
Route of Administration O	ral			
Visual Identification				
Active Ingredients				
Biotin			20 microgram	
calcium pantothenate			7.5 mg	
Equivalent: pantothenic acid			6.9 mg	
choline bitartrate			25 mg	
cyanocobalamin			5 microgram	
folic acid			90 microgram	
inositol			25 mg	
nicotinamide			25 mg	
pyridoxine hydrochloride			5 mg	
Equivalent: pyridoxine			4.1 mg	
riboflavin			5 mg	
thiamine hydrochloride			5 mg	
Other Ingredients (Excipients)			
calcium hydrogen phosphate	dihydrate			
citric acid monohydrate				
croscarmellose sodium				
hypromellose				
magnesium stearate				
maltodextrin				
microcrystalline cellulose potable water				
polable water				

Public Summarv

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Page 2 of 2

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