



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311667	Orthoplex Activated B Complex
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	19/11/2018	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Orthoplex Activated B Complex

Product Type	Single Medicine Product	Effective Date	19/11/2018
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support eye health
Maintain/support general health and wellbeing
Maintain/support hair growth
Maintain/support hair health
Maintain/support nail health/strength/thickness
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support blood health
Helps maintain/support haemoglobin formation/synthesis
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Aid/assist/helps glucose/sugar/carbohydrate metabolism

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Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy individuals
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Support healthy stress response in the body
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support skin health
Maintain/support wound healing in healthy individuals
Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

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).
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.
If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Biotin	500 microgram
calcium folinate	521 microgram
Equivalent: folic acid	400 microgram
calcium pantothenate	163.76 mg
Equivalent: pantothenic acid	150 mg
choline bitartrate	100 mg
cyanocobalamin	500 microgram
inositol	100 mg
nicotinamide	80 mg
nicotinic acid	20 mg
pyridoxal 5-phosphate monohydrate	10 mg
Equivalent: pyridoxine	6.382 mg
pyridoxine hydrochloride	20 mg
Equivalent: pyridoxine	16.45 mg

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riboflavin sodium phosphate	20 mg
thiamine hydrochloride	50 mg
Equivalent: thiamine	44.6 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
disodium edetate
gellan gum
glycine
hypromellose
leucine
potable water
potassium acetate

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