



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	260780	Orthoplex BioEnhanced Methyl-B
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	9/10/2015	
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 BioEnhanced Methyl-B

Product Type	Single Medicine Product	Effective Date	31/07/2018
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- 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 blood capillary health
- Maintain/support immune system health
- Maintain/support healthy immune system function

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

Maintain/support muscle function
 Aid/assist/helps glucose/sugar/carbohydrate metabolism
 Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals
 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 mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must not imply or refer to serious cardiovascular 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: [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.
 Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.
 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
------------------	------------------------

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	300 mg
Biotin	500 microgram
calcium folinate	108.04 microgram
Equivalent: folic acid	100 microgram
calcium pantothenate	50 mg
Equivalent: calcium	4.2 mg
Equivalent: pantothenic acid	45.8 mg
hydroxocobalamin	100 microgram

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

levomefolate calcium	433.6 microgram
Equivalent: levomefolic acid	400 microgram
mecobalamin (co-methylcobalamin)	400 microgram
nicotinamide	100 mg
pyridoxal 5-phosphate	25 mg
Equivalent: pyridoxine	17.11 mg
riboflavin sodium phosphate	30 mg
Equivalent: riboflavin	21.9 mg
thiamine hydrochloride	100 mg
Equivalent: thiamine	89.19 mg
ubidecarenone	30 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
microcrystalline cellulose
potable water
potassium acetate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary