



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	235632	Orthoplex AdrenoEnhance
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	30/03/2015	
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.

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 AdrenoEnhance

Product Type	Single Medicine Product	Effective Date	4/11/2020
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support energy production
- Traditionally used in Ayurvedic medicine to maintain/support physical endurance/capacity/stamina
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support eye health
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Traditionally used in Chinese medicine to hepatoprotectant/protect the liver in healthy individuals
- Traditionally used in Chinese medicine to liver tonic/Enhance liver health
- Traditionally used in Chinese medicine to maintain/support healthy liver function
- Maintain/support healthy liver function
- Maintain/support liver health
- Traditionally used in Chinese medicine to maintain/support liver health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Helps decrease/reduce homocysteine levels in healthy individuals
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
Traditionally used in Russian herbal medicine to adaptogen/Help body adapt to stress
Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
Traditionally used in Chinese medicine to aids/assists the body to cope with environmental stress
Traditionally used in Ayurvedic medicine to support healthy stress response in the body
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall
Traditionally used in Ayurvedic medicine to maintain/support general mental wellbeing
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Traditionally used in Chinese medicine to nervine/support nervous system
Traditionally used in Ayurvedic medicine to nervine/support nervous system
Maintain/support nervous system function
Traditionally used in Ayurvedic medicine to support healthy emotional/mood balance
Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Chinese medicine to maintain/support healthy sleeping patterns
Traditionally used in Ayurvedic medicine to maintain/support healthy sleeping patterns
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 liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

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).

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must only refer to detoxification in relation to natural body processes.

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

Product presentation must not imply or refer to drugs/alcohol.

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

Product presentation must not imply or refer to chronic fatigue syndrome.

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 encourage excessive or harmful consumption of alcohol or other toxic substances.

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).
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



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	30 microgram
calcium folinate	50 microgram
Equivalent: folic acid	46.28 microgram
calcium pantothenate	6 mg
Equivalent: pantothenic acid	5.5 mg
Equivalent: calcium	.5 mg
Glycyrrhiza glabra root Extract dry concentrate	25 mg
Equivalent: Glycyrrhiza glabra (Dry)	200 mg
hydroxocobalamin	2.4 microgram
nicotinamide	16 mg
Panax quinquefolius root Extract dry concentrate standardised	150 mg
Equivalent: Panax quinquefolius (Dry)	1.5 g
pyridoxal 5-phosphate	1.7 mg
Equivalent: pyridoxine	1.16 mg
Rehmannia glutinosa root Extract dry concentrate	200 mg
Equivalent: Rehmannia glutinosa (Dry)	2 g
riboflavin sodium phosphate	1.6 mg
Equivalent: riboflavin	1.22 mg
Schisandra chinensis fruit Extract dry concentrate	100 mg
Equivalent: Schisandra chinensis (Dry)	1 g
thiamine hydrochloride	1.2 mg
Equivalent: thiamine	1.07 mg
Withania somnifera root Extract dry concentrate standardised	160 mg
Equivalent: Withania somnifera (Dry)	2 g

Other Ingredients (Excipients)

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

Public Summary

© 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>.