



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	235616	Orthoplex NeuroEnhance
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.

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.

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 NeuroEnhance

Product Type	Single Medicine Product	Effective Date	5/03/2020
---------------------	-------------------------	-----------------------	-----------

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 Russian herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support blood capillary health
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Aid/assist thyroid hormone production
- Maintain/support bile production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Helps decrease/reduce homocysteine levels in healthy individuals
- Aid/assist/helps protein synthesis in the body
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Traditionally used in Russian herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Support healthy stress response in the body
Traditionally used in Russian herbal medicine to support healthy stress response in the body
Help maintain/support emotional wellbeing
Decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Western herbal medicine to maintain/support general mental wellbeing
Traditionally used in Russian herbal medicine to maintain/support general mental wellbeing
Traditionally used in Russian herbal medicine to brain tonic/Enhance brain health
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Support healthy emotional/mood balance
Traditionally used in Western herbal medicine to support healthy emotional/mood balance
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones
Maintain/support sperm production
Maintain/support skin health
Maintain/support skin integrity/structure
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 hormone imbalances.
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 any thyroid related diseases.
Label statement: 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.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
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 chronic fatigue syndrome.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must only refer to mild anxiety.
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 imply or refer to infertility.
Product presentation must not imply or refer to drugs/alcohol.
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.
If product is indicated for supplementation, Label statement: 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).
Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.
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



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	35 mg
Crocus sativus	7.334 mg
Equivalent: Crocus sativus	25.67 mg
Hypericum perforatum	250 mg
Equivalent: Hypericum perforatum	1.5 g
Equivalent: hypericins calculated as hypericin (of Hypericum perforatum)	750 microgram
Equivalent: hyperforin (of Hypericum perforatum)	7.5 mg
pyridoxal 5-phosphate	5 mg
Equivalent: pyridoxine	3.42 mg
pyridoxine hydrochloride	11 mg
Equivalent: pyridoxine	9.05 mg
Rhodiola rosea	81.25 mg
Equivalent: Rhodiola rosea	650 mg
Equivalent: rosavin (of Rhodiola rosea)	2.44 mg
Equivalent: Salidroside (of Rhodiola rosea)	812.5 microgram
Withania somnifera	160 mg
Equivalent: withanolides (of Withania somnifera)	8 mg
Equivalent: Withania somnifera	2 g
zinc citrate	26.15 mg
Equivalent: zinc	8.5 mg

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>.