



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	235616	Orthoplex NeuroEnhance
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio Concepts Pty Ltd	
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
<b>ARTG Start Date</b>	30/03/2015	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 NeuroEnhance**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	26/11/2020
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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 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 smell sensation
- Maintain/support taste sensation
- 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 Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Russian herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Russian herbal medicine to support healthy stress response in the body
- Support healthy stress response in the body

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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**

Label statement: If symptoms persist, talk to your health professional.  
If product is indicated for supplementation, 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 disease in any body organ, in particular the kidney or liver.  
Product presentation must not imply or refer to any thyroid related diseases.  
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 only refer to mild anxiety.  
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.  
Product presentation must not imply or refer to serious immunological diseases.  
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 infertility.  
Product presentation must not imply or refer to drugs/alcohol.  
Product presentation must not imply or refer to serious cardiovascular conditions.  
Product presentation must not imply or refer to chronic fatigue syndrome.  
Product presentation must not imply or refer to hormone imbalances.

**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.  
St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.  
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**

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**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>35 mg</b>
<b>Crocus sativus stigma Extract dry concentrate</b>	<b>7.334 mg</b>
Equivalent: Crocus sativus (Dry)	25.67 mg
<b>Hypericum perforatum herb top flowering Extract dry concentrate</b>	<b>250 mg</b>
Equivalent: Hypericum perforatum (Dry)	1.5 g
<b>pyridoxal 5-phosphate</b>	<b>5 mg</b>
Equivalent: pyridoxine	3.42 mg
<b>pyridoxine hydrochloride</b>	<b>11 mg</b>
Equivalent: pyridoxine	9.05 mg
<b>Rhodiola rosea root Extract dry concentrate standardised</b>	<b>81.25 mg</b>
Equivalent: Rhodiola rosea (Dry)	650 mg
<b>Withania somnifera root Extract dry concentrate standardised</b>	<b>160 mg</b>
Equivalent: Withania somnifera (Dry)	2 g
<b>zinc citrate</b>	<b>26.15 mg</b>
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

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