



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	275536	Orthoplex PreDop Lift
<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>	18/05/2016	
<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.

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 PreDop Lift**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/05/2020
---------------------	-------------------------	-----------------------	-----------

**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support natural body cleansing/detoxification processes
- Traditionally used in Russian herbal medicine to maintain/support physical endurance/capacity/stamina
- Traditionally used in Russian herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support eye health
- Maintain/support general health and wellbeing
- 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 healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Aid/assist thyroid hormone production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Helps decrease/reduce homocysteine levels
- Aid/assist/helps protein synthesis in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Public Summary



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

Traditionally used in Russian herbal medicine to adaptogen/Help body adapt to stress  
Traditionally used in Russian herbal medicine to aids/assists the body to cope with environmental stress  
Traditionally used in Russian herbal medicine to support healthy body stress recovery  
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  
Traditionally used in Russian herbal medicine to soothe/calm nerves  
Traditionally used in Russian herbal medicine to decrease/reduce/relieve symptoms of stress  
Traditionally used in Russian herbal medicine to maintain/support mental concentration/focus/clarity  
Traditionally used in Russian herbal medicine to maintain/support mental endurance/stamina  
Traditionally used in Russian herbal medicine to maintain/support cognitive function/mental function  
Traditionally used in Russian herbal medicine to maintain/support learning and information processing  
Traditionally used in Russian herbal medicine to maintain/support memory/mental recall  
Traditionally used in Russian herbal medicine to maintain/support general mental wellbeing  
Traditionally used in Russian herbal medicine to brain tonic/Enhance brain health  
Traditionally used in Russian herbal medicine to nerve tonic  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Traditionally used in Russian herbal medicine to calmative/nervous system relaxant  
Traditionally used in Russian herbal medicine to nervine/support nervous system  
Maintain/support nervous system function  
Support healthy emotional/mood balance  
Traditionally used in Russian herbal medicine to support healthy emotional/mood balance  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones in healthy males  
Maintain/support sperm production

**Indication Requirements**

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.

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.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to drugs/alcohol.  
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 serious immunological diseases.  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to hormone imbalances.  
Product presentation must not imply or refer to infertility.  
Product presentation must not imply or refer to chronic fatigue syndrome.  
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

The recommended dose of this medicine provides small amounts of caffeine  
If symptoms persist consult your healthcare practitioner (or words to that effect).  
Phenylketonurics are warned that this product contains phenylalanine (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.  
This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

**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**

<b>Eleutherococcus senticosus</b>	<b>133.33 mg</b>
Equivalent: Eleutherococcus senticosus	2 g
<b>Glycyrrhiza glabra</b>	<b>38.46 mg</b>
Equivalent: glycyrrhizinic acid	2.92 mg
Equivalent: Glycyrrhiza glabra	500 mg
<b>phenylalanine</b>	<b>100 mg</b>
<b>pyridoxal 5-phosphate</b>	<b>3.5 mg</b>
Equivalent: pyridoxine	2.4 mg
<b>Rhodiola rosea</b>	<b>93.75 mg</b>
Equivalent: Rhodiola rosea	750 mg
Equivalent: rosavin (of Rhodiola rosea)	2.81 mg
Equivalent: Salidroside (of Rhodiola rosea)	.94 mg
<b>selenomethionine</b>	<b>75 microgram</b>
Equivalent: selenium	30 microgram
<b>Theobroma cacao</b>	<b>66.67 mg</b>
Equivalent: caffeine	2 mg
Equivalent: Theobroma cacao	2 g
<b>tyrosine</b>	<b>400 mg</b>

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
edetic acid  
gellan gum  
glucose monohydrate  
hypromellose  
maltodextrin  
microcrystalline cellulose  
potable water  
potassium acetate  
sucrose

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>.