



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	275536	Orthoplex PreDop Lift
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	18/05/2016	
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 PreDop Lift

Product Type	Single Medicine Product	Effective Date	2/11/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- 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)
- 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
- Support healthy stress response in the body
- Traditionally used in Russian herbal medicine to support healthy stress response in the body

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Help maintain/support emotional wellbeing
 Traditionally used in Russian herbal medicine to decrease/reduce/relieve symptoms of stress
 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 general mental wellbeing
 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 not imply or refer to drugs/alcohol.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Label statement: If symptoms persist, talk to your health professional.

Product presentation must only refer to detoxification in relation to natural body processes.
 Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 Product presentation must not imply or refer to any thyroid related diseases.
 Product presentation must not imply or refer to serious immunological diseases.

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 disease in any body organ, in particular the kidney or liver.
 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 hormone imbalances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Phenylketonurics are warned that this product contains phenylalanine (or words to that effect).
 This medicine 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.
 If symptoms persist consult your healthcare practitioner (or words to that effect).
 The recommended dose of this medicine provides small amounts of caffeine
 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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

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Eleutherococcus senticosus root Extract dry concentrate	133.33 mg
Equivalent: Eleutherococcus senticosus (Dry)	2 g
Glycyrrhiza glabra root Extract dry concentrate standardised	38.46 mg
Equivalent: Glycyrrhiza glabra (Dry)	500 mg
phenylalanine	100 mg
pyridoxal 5-phosphate	3.5 mg
Equivalent: pyridoxine	2.4 mg
Rhodiola rosea root Extract dry concentrate standardised	93.75 mg
Equivalent: Rhodiola rosea (Dry)	750 mg
selenomethionine	75 microgram
Equivalent: selenium	30 microgram
Theobroma cacao seed Extract dry concentrate standardised	66.67 mg
Equivalent: Theobroma cacao (Dry)	2 g
tyrosine	400 mg
Other Ingredients (Excipients)	
colloidal anhydrous silica	
edetic acid	
gellan gum	
glucose monohydrate	
hypromellose	
maltodextrin	
microcrystalline cellulose	
potable water	
potassium acetate	
sucrose	

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