



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	118309	Orthoplex Selenium Drops
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	12/04/2005	
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 Selenium Drops

Product Type	Single Medicine Product	Effective Date	1/11/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body in children
- Helps reduce/decrease free radical damage to body cells in children
- Aids/assists natural body cleansing/detoxification processes
- Aids/assists natural body cleansing/detoxification processes in children
- Maintain/support natural body cleansing/detoxification processes in children
- Maintain/support natural body cleansing/detoxification processes
- Maintain/support eye health
- Maintain/support general health and wellbeing
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid gland function in children
- Maintain/support healthy thyroid hormones in children
- Maintain/support thyroid gland health
- Maintain/support thyroid gland health in children
- Aid/assist thyroid hormone production in healthy individuals
- Aid/assist thyroid hormone production in children
- Maintain/support immune system health in children
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy immune system function in children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support reproductive system health
- Maintain/support healthy reproductive hormones in healthy males
- Maintain/support sperm production

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Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.
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 immunological diseases.
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 any thyroid related 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).
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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

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.
Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

selenomethionine	496.7 microgram/mL
Equivalent: selenium	200 microgram/mL

Other Ingredients (Excipients)

ethanol
purified water

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