



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 235718 Orthoplex OestroClear

ARTG entry for Medicine Listed
Sponsor Bio Concepts Pty Ltd
Postal Address PO Box 190, Banyo, Brisbane, QLD, 4014
 Australia
ARTG Start Date 1/04/2015
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 OestroClear

Product Type	Single Medicine Product	Effective Date	4/03/2020
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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
- Maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- 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

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Maintain/support thyroid gland health
Aid/assist thyroid hormone production
Hepatoprotectant/protect the liver
Helps maintain/support bile secretion/flow
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 (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support cognitive development
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support brain/central nervous system development
Maintain/support nervous system function
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support reproductive system health in healthy females
Maintain/support healthy reproductive hormones in healthy males
Maintain/support healthy reproductive hormones
Maintain/support sperm production
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Product presentation must only refer to detoxification in relation to natural body processes.
Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to serious immunological 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 vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to any thyroid related diseases.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to infertility.
Product presentation must not imply or refer to hormone imbalances.
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

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 serious cardiovascular conditions.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Product presentation must not imply or refer to neurological conditions or developmental delays.
Product presentation must not imply or refer to chronic fatigue syndrome.

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.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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. 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.

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	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

Brassica oleracea var. italica	50 mg
calcium folinate	216.07 microgram
Equivalent: folic acid	200 microgram
choline bitartrate	100 mg
Curcuma longa	75 mg
Equivalent: curcuminoids	48.75 mg
Equivalent: Curcuma longa	1.5 g
hydroxocobalamin	250 microgram
Linum usitatissimum	125 mg
Equivalent: Linum usitatissimum	12.5 g
Equivalent: lignans calc secoisolariciresinol diglucoside (Linum usitatissimum seed)	62.5 mg
molybdenum trioxide	93.28 microgram
Equivalent: molybdenum	62.5 microgram
nicotinamide	50 mg
potassium iodide	98 microgram
Equivalent: iodine	74.92 microgram
pyridoxal 5-phosphate	5 mg
Equivalent: pyridoxine	3.42 mg
Reynoutria japonica	20 mg
Equivalent: Resveratrol (of Reynoutria japonica)	10 mg
Equivalent: Reynoutria japonica	1.6 g
riboflavin sodium phosphate	7.5 mg
Equivalent: riboflavin	5.63 mg
Rosmarinus officinalis	200 mg
Equivalent: cineole	0 mg
Equivalent: camphor	0 mg
Equivalent: Rosmarinus officinalis	1 g
selenomethionine	187.5 microgram
Equivalent: selenium	75 microgram
zinc citrate dihydrate	31.2 mg
Equivalent: zinc	10.14 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- calcium saccharate
- Carnauba Wax

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chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone

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