



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311565	Orthoplex LM II
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	15/11/2018	
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 LM II

Product Type	Single Medicine Product	Effective Date	11/01/2022
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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 general health and wellbeing
Maintain/support smell sensation
Maintain/support taste sensation
Maintain/support digestion/assimilation of nutrients
Maintain/support healthy liver function
Maintain/support liver health
Maintain/support immune system health
Maintain/support healthy immune system function
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)

Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Product presentation must not imply or refer to serious immunological diseases.
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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

calcium folinate	50 microgram
Equivalent: folic acid	46.3 microgram
choline bitartrate	200 mg
curcumin	9 mg
cysteine hydrochloride	65.04 mg
Equivalent: cysteine	50 mg
glutamine	100 mg
glycine	100 mg
inositol	150 mg
magnesium citrate	370.37 mg
Equivalent: magnesium	60 mg
manganese amino acid chelate	25 mg
Equivalent: manganese	2.5 mg
mecobalamin (co-methylcobalamin)	50 microgram
methionine	100 mg
molybdenum trioxide	37.5 microgram
Equivalent: molybdenum	25 microgram
palm tocotrienols complex	.9999 mg
potassium sulfate	60.17 mg
Equivalent: potassium	27 mg
pyridoxal 5-phosphate monohydrate	5.41 mg
Equivalent: pyridoxine	3.45 mg
riboflavin sodium phosphate	5 mg
Equivalent: riboflavin	3.8 mg
selenomethionine	124 microgram
Equivalent: selenium	50 microgram
taurine	100 mg
zinc citrate dihydrate	15.97 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

- betaine hydrochloride
- calcium hydrogen phosphate dihydrate
- calcium saccharate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- hypromellose

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lecithin
macrogol 400
magnesium stearate
microcrystalline cellulose
Palm Fruit Oil
povidone
starch sodium octenyl succinate

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