



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	20000	ORTHOPLEX TAURINE 500 TABLETS
<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>	4/10/1991	
<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.

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 TAURINE 500 TABLETS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	14/12/2021
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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 eye health  
Maintain/support cardiovascular system health  
Helps maintain/support healthy heart function  
Maintain/support healthy cardiovascular system function  
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid  
Maintain/support bile production  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Maintain/support general mental wellbeing  
Maintain/support nervous system health  
Maintain/support nervous system function

### Indication Requirements

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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.

### Standard Indications

No Standard Indications included on Record

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**Specific Indications**

No Specific Indications included on Record

**Warnings**

If symptoms persist consult your healthcare practitioner (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, uncoated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

taurine

500 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate

crospovidone

magnesium stearate

microcrystalline cellulose

povidone

silicon dioxide

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