



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

## Public Summary

<b>Summary for ARTG Entry:</b>	394696	Bioglan Medlab Optima Heart
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Natural Bio Pty Limited	
<b>Postal Address</b>	PO Box 384, MONA VALE, NSW, 1660 Australia	
<b>ARTG Start Date</b>	25/08/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

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 . Bioglan Medlab Optima Heart

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/08/2022
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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 energy production  
Maintain/support general health and wellbeing  
Helps in the maintenance of healthy blood lipids/blood fats  
Helps maintain/support healthy cholesterol  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support heart health  
Maintain/support artery health  
Maintain/support blood vessel health  
Maintain/support healthy muscle contraction function  
Maintain/support muscle health when sun exposure is inadequate  
Maintain/support muscle function when sun exposure is inadequate  
Maintain/support (state vitamin/mineral/nutrient) levels in the body

### Indication Requirements

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 serious cardiovascular conditions.

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 lowering or raising blood cholesterol levels from outside of the normal healthy range

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record



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Warnings

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. Do not take while on warfarin therapy without medical advice.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

colecalfiferol	20 microgram
d-alpha-tocopherol	268.61 mg
ubidecarenone	150 mg

Other Ingredients (Excipients)

chlorophyllin-copper complex  
Gelatin  
glycerol  
hydrogenated vegetable oil  
lecithin  
purified water  
Soya Oil  
yellow beeswax

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