### **Australian Government**

## Department of Health, Disability and Ageing

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 204286 D-Complete

ARTG entry for Medicine Listed

Sponsor Biomedica Nutraceuticals Pty Ltd

Postal Address PO Box 7052, ALEXANDRIA, NSW, 2015

Australia

ARTG Start Date 21/12/2012

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. D-Complete

Product Type Single Medicine Product Effective Date 20/10/2025

# Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support general health and wellbeing

Maintain/support healthy teeth

Maintain/support bone health

Aids/assists healthy bone development/growth/building

Help maintain/support bone mineralisation

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support muscle health

Maintain/support muscle function

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 brain health

Maintain/support reproductive system health

Maintain/support healthy reproductive hormones

Maintain/support skin health

Maintain/support wound healing

Maintain/support skin repair/healing/regeneration

# Indication Requirements

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of the table in Part 2 of Schedule 1 to this instrument are also used.

Product presentation must not imply or refer to serious immunological diseases.

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Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

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 infertility.

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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to hormone imbalances.

Label statement: If symptoms persist, talk to your health professional.

#### **Standard Indications**

No Standard Indications included on Record

### **Specific Indications**

No Specific Indications included on Record

#### Warnings

Not to be taken by children under 2 years old (or words to that effect).

### **Additional Product information**

Pa	ck	Size/	Poison	informatio	n

Pack Size	Poison S	Schedu	ıle
Pack Size	Poison S	Schedu	IL

### Components

## 1 . Formulation 1

**Dosage Form** Capsule, soft

Route of Administration Ora

### Visual Identification

# **Active Ingredients**

borax	13.6 mg	
Equivalent: boron	1.5 mg	
colecalciferol	.025 mg	
d-alpha-tocopherol		
magnesium amino acid chelate		
Equivalent: magnesium	35 mg	
Olive Oil	400 mg	
zinc amino acid chelate		
Equivalent: zinc	4 mg	

# Other Ingredients (Excipients)

### Acacia

chlorophyllin-copper complex

dl-alpha-tocopherol

Gelatin

glycerol

lecithin

Lemon Oil

maize starch

medium chain triglycerides

purified water

silicon dioxide

Soya Oil

sucrose

yellow beeswax



# Department of Health, Disability and Ageing

Therapeutic Goods Administration

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