



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	333088	C-CAPS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biomedica Nutraceuticals Pty Ltd	
<b>Postal Address</b>	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	1/04/2020	
<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 . C-CAPS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/11/2020
---------------------	-------------------------	-----------------------	-----------

### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support collagen formation  
Maintain/support general health and wellbeing  
Maintain/support gum health  
Maintain/support connective tissue health  
Aid/assist/helps connective tissue production/formation  
Maintain/support bone health  
Aids/assists healthy bone development/growth/building  
Helps maintain/supports healthy joint cartilage growth/development/production  
Helps maintain/support joint cartilage health  
Helps maintain/support healthy cholesterol  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support blood capillary health  
Maintain/support blood vessel health  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Maintain/support skin health  
Maintain/support wound healing

### Indication Requirements

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

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

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 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 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 Table 2 of this instrument are also used.

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

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).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
-----------	-----------------

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

ascorbic acid	400 mg
betacarotene	.55 mg
calcium ascorbate dihydrate	181.59 mg
Equivalent: calcium	17.07 mg
Equivalent: ascorbic acid	149.18 mg
Citrus bioflavonoids extract	20 mg
d-alpha-tocopheryl acid succinate	8.26 mg
Equivalent: d-alpha-tocopherol	10 IU
magnesium phosphate pentahydrate	35 mg
Equivalent: magnesium	7.23 mg
rutoside	25 mg
sodium ascorbate	227.26 mg
Equivalent: sodium	26.36 mg
Equivalent: ascorbic acid	200.9 mg

**Other Ingredients (Excipients)**

Acacia  
 colloidal anhydrous silica  
 hypromellose  
 magnesium stearate  
 microcrystalline cellulose  
 Pea Starch  
 purified water  
 sodium alginate

Public Summary



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

---

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary