



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

## Public Summary

<b>Summary for ARTG Entry:</b>	330174	Alka Cap
<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>	19/02/2020	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Alka Cap

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/02/2020
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### Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild rheumatic aches and pains

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of occasional episodes of gout

Traditionally used in Western herbal medicine to helps reduce the occasional occurrence of symptoms of gout

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint inflammation/swelling

Traditionally used in Western herbal medicine to maintain/support urinary tract health

Traditionally used in Western herbal medicine to enhance/promote/increase urine output

### Indication Requirements

Product presentation must not imply or refer to kidney disease.

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

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 only refer to mild joint symptoms.

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

Product presentation must only refer to mild rheumatic aches/pains.

### Standard Indications

No Standard Indications included on Record

### Specific Indications



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

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**

<b>Apium graveolens seed Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Apium graveolens (Dry)	1000 mg
<b>magnesium citrate</b>	<b>100 mg</b>
Equivalent: magnesium	16.17 mg
<b>potassium citrate</b>	<b>30 mg</b>
Equivalent: potassium	10.85 mg
<b>Prunus cerasus fruit Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Prunus cerasus (Fresh)	5 g

**Other Ingredients (Excipients)**

carrageenan  
colloidal anhydrous silica  
ethylcellulose  
hypromellose  
isoleucine  
maltodextrin  
microcrystalline cellulose  
potassium acetate  
potassium bicarbonate  
purified water  
sodium bicarbonate  
stearic acid

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