Public Summary

Summary for ARTG Entry:	330174 Alka Cap
ARTG entry for	Medicine Listed
Sponsor	Biomedica Nutraceuticals Pty Ltd
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	19/02/2020
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.

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

Product Type Single Medicine Product **Effective Date** 19/02/2020

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.

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.

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 rheumatic aches/pains.

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

Apium graveolens seed Extract dry concentrate	**100 mg**
Equivalent: Apium graveolens (Dry)	1000 mg
magnesium citrate	**100 mg**
Equivalent: magnesium	16.17 mg
potassium citrate	**30 mg**
Equivalent: potassium	10.85 mg
Prunus cerasus fruit Extract dry concentrate	**200 mg**
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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