Public Summary

Summary for ARTG Entry:	217896	BioFlam
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	29/11/2013	
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 . BioFlam

Product Type Single Medicine Product **Effective Date** 26/07/2019

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
Anti-inflammatory/relieve inflammation
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Helps maintain/supports healthy joint cartilage growth/development/production
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
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration

Indication Requirements

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

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

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

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.

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 any form of arthritis or osteoarthritis unless qualified as mild.

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

alpha lipoic acid	**20 mg**
ascorbic acid	**40 mg**
bromelains	**100 mg**
Citrus bioflavonoids extract	**50 mg**
copper gluconate	**1.79 mg**
Equivalent: copper	250 microgram
Curcuma longa rhizome Extract dry concentrate standardised	**23.08 mg**
Equivalent: Curcuma longa (Dry)	1.5 g
cyanocobalamin	**100 microgram**
d-alpha-tocopheryl acid succinate	**20.66 mg**
folic acid	**160 microgram**
manganese amino acid chelate	**5 mg**
Equivalent: manganese	500 microgram
papain	**20 mg**
pyridoxine hydrochloride	**15 mg**
Equivalent: pyridoxine	12.34 mg
quercetin dihydrate	**100 mg**
riboflavin	**50 mg**
rutoside	**50 mg**
zinc amino acid chelate	**10 mg**
Equivalent: zinc	2 mg

Other Ingredients (Excipients)

alginic acid

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calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
ethylcellulose
hypromellose
maltodextrin
microcrystalline cellulose
purified water
stearic acid