



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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.

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	10/02/2023
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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

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

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

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 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.



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

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

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)

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



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stearic acid

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