Public Summary

Summary for ARTG Entry:	315373 C-Max
ARTG entry for	Medicine Listed
Sponsor	Biomedica Nutraceuticals Pty Ltd
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	13/03/2019
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 . C-Max

Product Type Single Medicine Product **Effective Date** 12/07/2022

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
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
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 serious immunological diseases.

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

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

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 lowering or raising blood cholesterol levels from outside of the normal healthy range

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).

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	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients

ascorbic acid	**310 mg/g**
betacarotene	**.36 mg/g**
calcium ascorbate dihydrate	**88.4 mg/g**
Equivalent: ascorbic acid	73.03 mg/g
Equivalent: calcium	8.31 mg/g
calcium phosphate	**20 mg/g**
Equivalent: phosphorus	3.7 mg/g
Equivalent: calcium	7.75 mg/g
d-alpha-tocopheryl acetate	**11.78 mg/g**
glycine	**150 mg/g**
hesperidin	**20 mg/g**
magnesium ascorbate monohydrate	**41.25 mg/g**
Equivalent: ascorbic acid	37 mg/g
Equivalent: magnesium	2.56 mg/g
magnesium phosphate pentahydrate	**20 mg/g**
Equivalent: magnesium	4.13 mg/g
Equivalent: phosphorus	3.512 mg/g
Phyllanthus emblica fruit Extract dry concentrate	**4.8 mg/g**
Equivalent: Phyllanthus emblica (Dry)	24 mg/g
potassium ascorbate dihydrate	**38.58 mg/g**
Equivalent: ascorbic acid	27 mg/g
Equivalent: potassium	6.03 mg/g
rutoside	**12 mg/g**
sodium ascorbate	**53.51 mg/g**
Equivalent: ascorbic acid	47.3 mg/g
Equivalent: sodium	

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	6.21 mg/g
zinc citrate dihydrate	**3.11 mg/g**
Equivalent: zinc	1 mg/g

Other Ingredients (Excipients)

Acacia
ascorbic acid
ascorbyl palmitate
citric acid
colloidal anhydrous silica
dl-alpha-tocopherol
Flavour
glycine
maltodextrin
Olive Oil
purified water
silicon dioxide
sodium bicarbonate
sucrose
thaumatin

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