



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	345562	AlkaMin Calm
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	8/10/2020	
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.

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 . AlkaMin Calm

Product Type	Single Medicine Product	Effective Date	26/02/2021
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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
Aids/assists natural body cleansing/detoxification processes
Maintain/support natural body cleansing/detoxification processes
Maintain/support natural liver cleansing/detoxification processes
Maintain/support energy production
Maintain/support healthy eye function
Maintain/support eye health
Maintain/support healthy eyesight/vision
Helps maintain/support healthy acid/alkali balance in the body
Maintain/support healthy growth and development
Maintain/support general health and wellbeing
Maintain/support hair growth
Maintain/support hair health
Maintain/support healthy teeth
Maintain/support nail health/strength/thickness
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Helps maintain/support joint cartilage health
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Helps maintain/support healthy blood sugar/glucose
Maintain/support blood health
Helps maintain/support haemoglobin formation/synthesis

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Maintain/support cardiovascular system health
Helps maintain/support healthy heart function
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production
Maintain/support smell sensation
Maintain/support taste sensation
Maintain/support bile production
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Maintain/support healthy muscle contraction function
Maintain/support muscle health
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps decrease/reduce homocysteine levels in healthy individuals
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps maintain/support cellular uptake of (state vitamin/mineral/nutrient)
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Support healthy stress response in the body
Decrease/reduce/relieve symptoms of mild anxiety
Maintain/support nerve conduction
Maintain/support neuromuscular function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
Decrease/reduce/relieve symptoms of premenstrual tension
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones
Maintain/support sperm production
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing in healthy individuals
Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.



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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 only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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).

Product presentation must only refer to mild anxiety.

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

Product presentation must not imply or refer to hormone imbalances.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to any thyroid related diseases.

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

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

If symptoms persist, seek the advice of a healthcare professional.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	38.46 microgram/g
calcium ascorbate dihydrate	93.63 mg/g
Equivalent: calcium	8.8 mg/g
Equivalent: ascorbic acid	76.92 mg/g
calcium citrate	140.32 mg/g
Equivalent: calcium	30.77 mg/g
calcium pantothenate	2.52 mg/g
Equivalent: pantothenic acid	2.31 mg/g
Equivalent: calcium	.21 mg/g
chromic chloride hexahydrate	39 microgram/g
Equivalent: chromium	7.7 microgram/g
glycine	115.39 mg/g
magnesium citrate	142.45 mg/g
Equivalent: magnesium	

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menaquinone 7	23.08 mg/g
molybdenum trioxide	3.46 microgram/g
Equivalent: molybdenum	6.92 microgram/g
nicotinamide	4.615 microgram/g
potassium citrate	1.92 mg/g
Equivalent: potassium	63.82 mg/g
pyridoxal 5-phosphate monohydrate	23.08 mg/g
Equivalent: pyridoxine	6.03 mg/g
riboflavin sodium phosphate	3.85 mg/g
Equivalent: riboflavin	1.01 mg/g
selenomethionine	.77 mg/g
Equivalent: selenium	6 microgram/g
taurine	2.42 microgram/g
thiamine hydrochloride	230.77 mg/g
Equivalent: thiamine	1.96 mg/g
zinc citrate dihydrate	1.54 mg/g
Equivalent: zinc	5.99 mg/g
1.92 mg/g	
Other Ingredients (Excipients)	
citric acid	
colloidal anhydrous silica	
Flavour	
glycine	
maltodextrin	
sodium bicarbonate	
Stevia rebaudiana	

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