



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	330522	AlkaMin Essentials
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	27/02/2020	
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.

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 . AlkaMin Essentials

Product Type	Single Medicine Product	Effective Date	27/02/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support natural body 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 general health and wellbeing
- Aids/assists teeth development
- Maintain/support healthy teeth
- Maintain/support teeth mineralisation
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support bone mass/density/integrity
- Maintain/support (state mineral) absorption in bones
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support blood health
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function

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Maintain/support heart health
Maintain/support healthy thyroid gland function
Maintain/support thyroid gland health
Aid/assist thyroid hormone production
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid
Maintain/support immune system health
Maintain/support healthy immune system function
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
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)
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support nerve conduction
Maintain/support neuromuscular function
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones in healthy males
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

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 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 serious cardiovascular conditions.

Product presentation must only refer to detoxification in relation to natural body processes.

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

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

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.

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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

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).

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 infertility.

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 serious immunological diseases.

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.



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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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.

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.

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

calcium citrate	255.14 mg/g
Equivalent: calcium	61.54 mg/g
chromic chloride hexahydrate	37.9 microgram/g
Equivalent: chromium	7.4 microgram/g
magnesium citrate	227.9 mg/g
Equivalent: magnesium	36.92 mg/g
menaquinone 7	11.07 microgram/g
molybdenum trioxide	11.1 microgram/g
Equivalent: molybdenum	7.4 microgram/g
potassium citrate	102.1 mg/g
Equivalent: potassium	36.92 mg/g
selenomethionine	9.2 microgram/g
Equivalent: selenium	3.7 microgram/g
zinc citrate dihydrate	3.83 mg/g
Equivalent: zinc	1.23 mg/g

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
Flavour
glycine
malic acid
maltodextrin
sodium bicarbonate
Stevia rebaudiana

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