



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	330522	AlkaMin Essentials
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio Concepts Pty Ltd	
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
<b>ARTG Start Date</b>	27/02/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

Public Summary



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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.

Product presentation must not imply or refer to infertility.

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 hormone imbalances.

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

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**

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