



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

## Public Summary

<b>Summary for ARTG Entry:</b>	398358	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>	25/10/2022	
<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.

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>	25/10/2022
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### Permitted Indications

Aids/assists natural body cleansing/detoxification processes

Maintain/support natural body cleansing/detoxification processes

Maintain/support natural liver cleansing/detoxification processes

Maintain/support energy levels

Maintain/support energy production

Maintain/support body electrolyte balance

Helps maintain/support healthy acid/alkali balance in the body

Maintain/support general health and wellbeing

Maintain/support bone health

Aids/assists healthy bone development/growth/building

Maintain/support bone mass/density/integrity

Maintain/support bone strength

Help maintain/support bone mineralisation

Maintain/support blood health

Maintain/support cardiovascular system health

Helps maintain/support healthy heart function

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Maintain/support healthy muscle contraction function

Maintain/support muscle health

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes

Maintain/support (state vitamin/mineral) within normal range

Maintain/support nerve conduction

Maintain/support neuromuscular function



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Maintain/support nervous system health  
Maintain/support nervous system function  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones

#### Indication Requirements

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

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

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

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 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.

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 chronic fatigue syndrome.

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 only refer to detoxification in relation to natural body processes.

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.

Product presentation must not imply or refer to infertility.

#### 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.

#### 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

<b>calcium citrate</b>	<b>259.1 mg/g</b>
Equivalent: calcium	62.5 mg/g
<b>chromic chloride hexahydrate</b>	<b>38.4 microgram/g</b>
Equivalent: chromium	7.4 microgram/g
<b>magnesium citrate</b>	<b>231.48 mg/g</b>
Equivalent: magnesium	37.5 mg/g
<b>menaquinone 7</b>	<b>11.3 microgram/g</b>
<b>molybdenum trioxide</b>	<b>11.3 microgram/g</b>
Equivalent: molybdenum	7.5 microgram/g
<b>potassium citrate</b>	<b>34.5 mg/g</b>
Equivalent: potassium	12.47 mg/g

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<b>selenomethionine</b>	<b>9.4 microgram/g</b>
Equivalent: selenium	3.8 microgram/g
<b>zinc citrate dihydrate</b>	<b>3.89 mg/g</b>
Equivalent: zinc	1.25 mg/g

**Other Ingredients (Excipients)**

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

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