



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	353552	SarcoCare + D
<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>	25/01/2021	
<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 . SarcoCare + D**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	6/05/2021
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**Permitted Indications**

- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Helps in the maintenance of lean body mass in aging individuals
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle health in healthy elderly individuals
- Maintain/support muscle health
- Maintain/support muscle function
- Maintain/support muscle mass in aging individuals
- Maintain/support muscle protein stores in aging individuals
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support neuromuscular function

**Indication Requirements**

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.

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).

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

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

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physical activity.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

If symptoms persist consult your healthcare practitioner (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.

#### Additional Product information

#### Pack Size/Poison information

##### Pack Size

##### Poison Schedule

#### Components

##### 1 . Formulation 1

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

##### Visual Identification

#### Active Ingredients

<b>calcium beta-hydroxy-beta-methylbutyrate monohydrate</b>	<b>1000 mg</b>
Equivalent: calcium	137.1 mg
<b>colecalfiferol</b>	<b>.0083 mg</b>

#### Other Ingredients (Excipients)

##### Acacia

calcium carbonate

colloidal anhydrous silica

croscarmellose sodium

dl-alpha-tocopherol

hypromellose

macrogol 8000

magnesium stearate

maize starch

medium chain triglycerides

microcrystalline cellulose

povidone

silicon dioxide

sucrose

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