



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	333905	SarcoCare
<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>	10/04/2020	
<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 . SarcoCare

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	10/04/2020
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### Permitted Indications

- Helps enhance/promote general health and wellbeing in aging individuals
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in aging individuals
- Helps enhance/promote/increase lean body mass during resistance training in aging individuals
- Helps in the maintenance of lean body mass in aging individuals
- Helps in the maintenance of lean body mass during resistance training in aging individuals
- Maintain/support healthy body fat/muscle composition during resistance training in aging individuals
- Maintain/support muscle health in aging individuals
- Maintain/support muscle health during resistance training
- Maintain/support muscle health
- Maintain/support muscle function
- Maintain/support muscle mass in aging individuals
- Maintain/support muscle mass in aging individuals
- Maintain/support muscle strength during resistance training
- Maintain/support muscle strength during resistance training in aging individuals

### Indication Requirements

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.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record



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**Warnings**

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

**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**

**calcium beta-hydroxy-beta-methylbutyrate monohydrate** **57.69 mg/g**

Equivalent: calcium 7.91 mg/g

**creatine monohydrate** **96.15 mg/g**

**Pisum sativum seed Extract dry concentrate** **576.92 mg/g**

Equivalent: Pisum sativum (Dry) 5.7692 g/g

**Other Ingredients (Excipients)**

**cocoa powder**

**Flavour**

**silicon dioxide**

**Steviol glycosides**

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