



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333905	SarcoCare
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	10/04/2020	
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 . SarcoCare

Product Type	Single Medicine Product	Effective Date	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 during resistance training
- Maintain/support muscle health in aging individuals
- 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 in aging individuals
- Maintain/support muscle strength during resistance training

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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