

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, Bar Australia	nyo, Brisbane, QLD, 4014	
ARTG Start Date	10/04/2020		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines	3	
Conditions			

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.

roducts						
1 . SarcoCare						
Product Type	Single Medicine Product	Effective Date	6/09/2023			
Permitted Indication	ons					
Maintain/support energy production						
Maintain/support general health and wellbeing						
Helps in the maintenance of lean body mass in aging individuals						
Maintain/support mu	Maintain/support muscle health					
Maintain/support muscle health in aging individuals						
Maintain/support muscle function						
Maintain/support mu	Maintain/support muscle mass in aging individuals					
Maintain/support mu	uscle protein stores					
Indication Require	ements					
If product is indicate physical activity.	ed for weight loss, label statement: When use	ed in conjunction with a program of	reduced intake of dietary calories and increased			
Standard Indicatio	ns					
No Standard Indicat	tions included on Record					
Specific Indication	IS					
No Specific Indication	No Specific Indications included on Record					
Warnings						
No Warnings includ	No Warnings included on Record					
Additional Product information						
Pack Size/Poison i	information					
Pack Size		Poison Schedule				
Components						
1. Formulation	1					
Dosage Form	Powder, oral					
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Route of Administration Oral

Visual Identification

Active	Ingred	ients
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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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