

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	287766	C BioActive
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals	Limited
Postal Address	Care of Blackmo Australia	res Ltd PO Box 1725, Warriewood, NSW, 2102
ARTG Start Date	11/04/2017	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	
0		

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. C BioActive	e						
Product Type	Single Medicine Product	Effective Date	2/11/2021				
Permitted Indicati	ons						
Antioxidant/Reduce	e free radicals formed in the body						
Maintain/support collagen formation							
Maintain/support er	nergy levels						
Maintain/support er	Maintain/support energy production						
Relieve weariness/farigue/feeling of weakness							
Maintain/support he	ealthy immune system function						
Maintain/support in	nmune system to fight illness						
Maintain/support at	osorption of dietary (state vitamin/mineral/nutrient)						
Maintain/support (s	tate vitamin/mineral/nutrient) levels in the body						
Maintain/support ne	erve conduction						
Aid/assist/helps syr	nthesis of neurotransmitters						
Maintain/support ne	ervous system function						
Maintain/support sp	perm health						
Maintain/support w	ound healing						
Indication Require	ements						
Product presentati	on must not imply or refer to chronic fatigue syndro	ome.					
Label statement: If	symptoms persist, talk to your health professional	l.					

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to infertility.

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.

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.

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown. Visit www.tga.gov.au for contact information



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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

Not recommended for use by pregnant and lactating women (or words to that effect).

Additional Product information

Image: Note of the series of	Container information						
Pack Size/Poison information Pack Size Poison Schedule Components I.Formulation 1 Dosage Form Powder, oral Oral Oral Visual Identification Oral Visual Identification Active Ingredients Equivalent: ascorbic acid Citrus bioflavonoids extract Discord Pack Size/Poison Discord Powder, oral P	Туре М	Material	Life Time	Temperature	Closure	Conditions	
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