

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	354064	METAGENICS VIRACLEAR	
ARTG entry for	Medicine Listed		
Sponsor	Metagenics (Aust) Pty Ltd		
Postal Address	PO Box 675, VIF Australia	RGINIA BC, QLD, 4014	
ARTG Start Date	2/02/2021		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines	3	
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. METAGENI	1. METAGENICS VIRACLEAR					
Product Type	Single Medicine Product	Effective Date	2/02/2021			
Permitted Indication	ons					
Maintain/support co	llagen formation					
Maintain/support im	mune system health					
Maintain/support he	ealthy immune system function					
Aids/assists the boo	dy to cope with environmental stress					
Helps reduce occur	rence of facial cold sores					
Maintain/support sk	in health					
Maintain/support we	ound healing					
Maintain/support sk	in repair/healing/regeneration					
Indication Require	ements					
Label statement: If	symptoms persist, talk to your health profe	ssional.				
Product presentation	on must not imply or refer to serious immur	ological diseases.				
Standard Indicatio	ns					
No Standard Indica	tions included on Record					
Specific Indication	IS					
No Specific Indicati	ons included on Record					
Warnings						
If symptoms persist	consult your healthcare practitioner (or wo	rds to that effect).				
Vitamins and miner	als can only be of assistance if dietary intal	ke is inadequate OR Vitamin and/or m	ineral supplements should not replace a balanced diet.			
Additional Produc	t information					
	• • • · · · · • • · ·					
Pack Size/Poison	Information					
Pack Size		Poison Schedule				
Components						
Page 1 of 2 This is not an <i>I</i>	ARTG Certificate document.		Produced at 10.06.2022 at 03:09:10 AEST			

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1	Formulation	1

1. Formulation 1			
Dosage Form	Tablet, film coated		
Route of Administration	Oral		
Visual Identification			
Active Ingredients			
ascorbic acid		250 mg	
Astragalus membranaceus root Extract dry concentrate		200 mg	
Equivalent: Astragalus membranaceus (Dry)		2 g	
lysine hydrochloride		800 mg	
zinc sulfate monohydrate		32.93 mg	
Equivalent: zinc		12 mg	
Other Ingredients (Excipie	ents)		
croscarmellose sodium			
glycerol			
hypromellose			
magnesium stearate			
microcrystalline cellulose			
silicon dioxide			

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