

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	168572	Silica Liquid
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	2/02/2010	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . Silica Liquid					
Product Type	roduct Type Single Medicine Product		28/05/2020		
Permitted Indicati	ons				
Maintain/support co	ollagen formation				
Maintain/support co	ollagen health				
Maintain/support ha	air health				
Maintain/support na	ail health/strength/thickness				
Maintain/support co	onnective tissue health				
Maintain/support bo	one health				
Maintain/support bo	one mass/density/integrity in pre-menopausal women				
Maintain/support bo	one strength in pre-menopausal women				
Help maintain/supp	ort bone mineralisation in pre-menopausal women				
Helps maintain/sup	port joint cartilage health				
Maintain/support te	ndon health				
Maintain/support sl	xin health				
Maintain/support sk	in integrity/structure				

Indication Requirements

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Page 1 of 2

This is not an ARTG Certificate document.

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Produced at 31.08.2021 at 03:18:41 AEST



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Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.

Additional Product information

Somponents 1. Formulation 1 Dosage Form Liquid, multipurpose Route of Administration Topical Oral Oral Visual Identification Topical Active Ingredients So mg/mL Equivalent: silicon 14 mg/mL Other Ingredients (Excipients) I 4 mg/mL citric acid Flavour Flavour Solitication hypromellose I 4 mg/mL purified water I 4 mg/mL	Pack Size		Poison Schedule	Poison Schedule		
1. Formulation 1 Dosage Form Liquid, multipurpose Route of Administration Topical Oral Visual Identification Topical Active Ingredients So mg/mL Equivalent: silicon 30 mg/mL Cother Ingredients (Excipients) 14 mg/mL Citric acid Flavour Flavour Liquid (Excipient) hypromellose Liquid (Excipient) purified water Liquid (Excipient)	Components					
Route of Administration Topical Oral Visual Identification Active Ingredients colloidal anhydrous silica 30 mg/mL Equivalent: silicon 14 mg/mL Other Ingredients (Excipients) citric acid Flavour hypromellose purified water	-					
Oral Visual Identification Active Ingredients colloidal anhydrous silica 30 mg/mL Equivalent: silicon 14 mg/mL Other Ingredients (Excipients) itric acid Flavour Flavour hypromellose jurified water	Dosage Form	Liquid, multipurpose				
Active Ingredients colloidal anhydrous silica 30 mg/mL Equivalent: silicon 14 mg/mL Other Ingredients (Excipients)	Route of Administration					
colloidal anhydrous silica 30 mg/mL Equivalent: silicon 14 mg/mL Other Ingredients (Excipients) itic acid citric acid Flavour hypromellose jurified water	Visual Identification					
Equivalent: silicon 14 mg/mL Other Ingredients (Excipients) citric acid Flavour hypromellose purified water	Active Ingredients					
Other Ingredients (Excipients) citric acid Flavour hypromellose purified water	colloidal anhydrous silica		30 mg/mL			
citric acid Flavour hypromellose purified water	Equivalent: silicon		14 mg/mL			
Flavour hypromellose purified water	Other Ingredients (Excipi	ents)				
hypromellose purified water	citric acid					
purified water	Flavour					
	hypromellose					
sodium benzoate	purified water					
	sodium benzoate					

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