



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	358259	Bio-Film Clear
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
ARTG Start Date	30/03/2021	
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.

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 . Bio-Film Clear

Product Type	Single Medicine Product	Effective Date	30/03/2021
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Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms

Indication Requirements

- Product presentation must not imply or refer to eating disorders.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

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Active Ingredients

cellulase	1000 CU
Cinnamomum verum stem bark Extract dry concentrate	50 mg
Equivalent: Cinnamomum verum (Dry)	1 g
lipase	500 LipU
protease	60 Thousand HUT
Punica granatum fruit peel Extract dry concentrate standardised	62.5 mg
Equivalent: Punica granatum (Dry)	1.875 g

Other Ingredients (Excipients)

hypromellose
medium chain triglycerides
microcrystalline cellulose
purified water

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