



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	285024	SB Floractiv
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	27/01/2017	
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 . SB Floractiv

Product Type	Single Medicine Product	Effective Date	2/11/2021
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Permitted Indications

Decrease/reduce/relieve diarrhoea in children
Decrease/reduce/relieve diarrhoea in adults
Helps reduce occurrence of symptoms of traveller's diarrhoea
Maintain/support intestinal health
Maintain/support healthy digestive system function
Maintain/support healthy mucous linings of the digestive system
Maintain/support intestinal good/beneficial/friendly flora
Maintain/support healthy immune system function

Indication Requirements

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

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

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

Public Summary



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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Saccharomyces cerevisiae (Boulardii) 250 mg

Other Ingredients (Excipients)

hypromellose

potable water

sorbitan monostearate

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