



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	293261	SI Complex
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	28/08/2017	
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 . SI Complex

Product Type	Single Medicine Product	Effective Date	19/01/2023
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Permitted Indications

Traditionally used in Chinese medicine to decrease/reduce/relieve diarrhoea
Traditionally used in Western herbal medicine to decrease/reduce/relieve diarrhoea
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
 Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
 Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Maintain/support small intestine health
Traditionally used in Western herbal medicine to helps enhance/promote healthy digestive system function
Traditionally used in Western herbal medicine to maintain/support healthy digestion
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal pain/discomfort
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Indication Requirements

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Label statement: If symptoms persist, talk to your health professional.

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).

Label statement: If symptoms persist or worsen talk to your medical practitioner.

Product presentation must only refer to medically diagnosed IBS.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).



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If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, enteric coated

Route of Administration Oral

Visual Identification

Active Ingredients

Allium sativum bulb Extract dry concentrate standardised	13 mg
Equivalent: Allium sativum (Fresh)	650 mg
Berberis vulgaris root Extract dry concentrate standardised	25 mg
Equivalent: Berberis vulgaris (Dry)	250 mg
coptis chinensis root Extract dry concentrate standardised	62.5 mg
Equivalent: coptis chinensis (Dry)	250 mg
Origanum vulgare leaf Oil essential	75 mg
Peppermint Oil	112.5 mg
Phellodendron amurense stem bark Extract dry concentrate standardised	153.09 mg
Equivalent: Phellodendron amurense (Dry)	3.0619 g
Thyme Oil	10 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
ethylcellulose
hydrochloric acid
hypromellose
macrogol 8000
magnesium stearate
maltodextrin
medium chain triglycerides
microcrystalline cellulose
oleic acid
povidone
purified water
sodium alginate
stearic acid
strong ammonia solution

Public Summary

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