



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	293261	SIBOGuard
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	PO Box 6454, ALEXANDRIA, NSW, 2015 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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . SIBOGuard

Product Type	Single Medicine Product	Effective Date	23/02/2018
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Helps maintain healthy digestive function.
 Treatment of mild digestive disorders. [Warning S required]

Specific Indications

- Coptis Chinensis (Huang Lian) has been traditionally used in traditional Chinese medicine to manage digestive complaints such as bacterial diarrhoea.
- Berberis Vulgaris has been traditionally used in western herbal medicine for digestive complaints such as dyspepsia, diarrhoea, bloating and symptoms associated with microbial over growth.
- Garlic is traditionally used in Ayurvedic medicine as a carminative in the management of mild digestive complaints such as dyspepsia, flatulence and colic.
- Garlic is traditionally used in Ayurvedic medicine as an anthelmintic.
- Peppermint oil has been traditionally used in western herbal medicine as a carminative to help relieve dyspepsia and flatulence.
- Peppermint Oil has been traditionally used in western herbal medicine to aid digestion.
- Peppermint Oil may help to relieve symptoms associated with medically diagnosed IBS.
- Phellodendron is traditionally used in traditional Chinese medicine for symptoms of abdominal pain, diarrhoea and gastroenteritis.
- Berberis vulgaris (Barberry) has been traditionally used in Western Herbal Medicine as an antimicrobial.

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Warnings

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

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).

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	13 mg
Equivalent: allicin	130 microgram
Equivalent: Allium sativum	650 mg
Berberis vulgaris	25 mg
Equivalent: Berberis vulgaris	250 mg
Equivalent: berberine	1 mg
coptis chinensis	62.5 mg
Equivalent: coptis chinensis	250 mg
Equivalent: berberine	6.25 mg
Origanum vulgare	75 mg
Peppermint Oil	112.5 mg
Phellodendron amurense	153.09 mg
Equivalent: Phellodendron amurense	3.0619 g
Equivalent: berberine	72.75 mg
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

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