



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	322446	SIBO Balance
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Factors Group Australia Pty Ltd	
<b>Postal Address</b>	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
<b>ARTG Start Date</b>	29/08/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . SIBO Balance

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/08/2019
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#### Permitted Indications

Aids/assists natural cleansing/detoxification processes of the gastrointestinal system/gut

Helps maintain/support healthy acid/alkali balance in the body

Helps enhance/promote general health and wellbeing

Maintain/support healthy mouth flora

Maintain/support healthy bowel/colon function

Reduce occurrence of excess intestinal wind/gas

Decrease/reduce/relieve excess intestinal gas

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome

Help reduce occurrence of symptoms of medically diagnosed Irritable Bowel Syndrome

Maintain/support small intestine health

Maintain/support intestinal transit time

Maintain/support healthy small intestine function

Helps stimulate/increase digestive enzymes

Maintain/support healthy digestive system function

Maintain/support healthy digestion

Stimulates/increases digestive gastric hydrochloric acid secretion

Helps enhance/promote gastrointestinal system mucosa health

Helps decrease/reduce dietary fat absorption in digestive system

Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid

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Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa  
Maintain/support intestinal good/beneficial/friendly flora  
Helps maintain/support good/beneficial/friendly gut flora during antibiotic use  
Helps restore good/beneficial/friendly intestinal/gut/bowel flora  
Helps restore good/beneficial/friendly intestinal/gut/bowel flora  
Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth  
Helps enhance/improve/promote/increase intestinal good/beneficial/friendly bacteria growth  
Nourish good/beneficial/friendly intestinal flora  
Maintain/support small intestine good/beneficial/friendly flora  
Helps enhance/promote gastrointestinal system health  
Maintain/support healthy gastrointestinal function  
Maintain/support gastrointestinal mucosal membrane health  
Aids/assists repair of gastrointestinal/gut wall lining  
Decrease/reduce/relieve abdominal bloating/distention  
Helps reduce occurrence of abdominal bloating  
Helps decrease/reduce/relieve mild gastrointestinal tract inflammation  
Soothe gastro-intestinal tract mucous membranes  
Decrease/reduce/relieve digestive spasms  
Decrease/reduce/relieve symptoms of hayfever  
Maintain/support immune system health  
Enhance/improve/promote immune defence/immunity  
Enhance/improve/promote immune defence/immunity  
Helps enhance/improve/promote immune system function  
Maintain/support healthy gastrointestinal immune function  
Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections  
Decrease/reduce/relieve symptoms of common cold  
Decrease/reduce/relieve symptoms of mild eczema/dermatitis

**Indication Requirements**

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

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

Respiratory tract infections must be qualified by 'mild'.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must only refer to mild eczema.

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must only refer to medically diagnosed IBS.

Product presentation must not imply or refer to drugs/alcohol.

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

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

**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**

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**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Allium sativum clove Powder</b>	<b>100 mg</b>
<b>Arthrospira platensis</b>	<b>50 mg</b>
<b>Iberis amara herb flowering and fruiting Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Iberis amara (Dry)	500 mg
<b>Lactobacillus brevis</b>	<b>1 billion CFU</b>
<b>Lactobacillus delbrueckii ssp bulgaricus</b>	<b>2 billion CFU</b>
<b>Lactobacillus fermentum</b>	<b>1 billion CFU</b>
<b>Lactobacillus helveticus</b>	<b>1 billion CFU</b>
<b>Lactobacillus paracasei subsp. paracasei</b>	<b>1 billion CFU</b>
<b>Lactobacillus reuteri</b>	<b>1 billion CFU</b>
<b>Lactobacillus rhamnosus</b>	<b>1 billion CFU</b>
<b>Lactobacillus salivarius ssp salivarius</b>	<b>1 billion CFU</b>
<b>lipase</b>	<b>1.2 thousand LipU</b>
<b>Streptococcus thermophilus</b>	<b>1 billion CFU</b>
<b>Wolfiporia cocos mushroom Extract dry concentrate</b>	<b>125 mg</b>
Equivalent: Wolfiporia cocos (Dry)	1.25 g

**Other Ingredients (Excipients)**

- colloidal anhydrous silica
- disodium edetate
- gellan gum
- hypromellose
- magnesium stearate
- maltodextrin
- microcrystalline cellulose
- potable water
- potassium acetate
- potato starch

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