Public Summary

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

Product Type	Single Medicine Product	**Effective Date**	29/08/2019

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

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.
Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.
Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
Product presentation must only refer to mild eczema.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
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.
Respiratory tract infections must be qualified by 'mild'.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must only refer to detoxification in relation to natural body processes.
Product presentation must not imply or refer to drugs/alcohol.
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.

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

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

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