



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333742	IBS Relief
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	8/04/2020	
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.

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 . IBS Relief

Product Type	Single Medicine Product	Effective Date	3/06/2020
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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
- Helps reduce occurrence of constipation
- 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

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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 lowering blood lipids, blood fats and triglycerides.

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

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

Product presentation must only refer to medically diagnosed IBS.

Respiratory tract infections must be qualified by 'mild'.

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

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

Product presentation must only refer to mild eczema.

Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).

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

Product presentation must not refer to or imply weight loss.

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.

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

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

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

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 only refer to detoxification in relation to natural body processes.

Label statement: Drink plenty of water (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.

Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children



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under the age of 12 months except on professional health advice.

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

If symptoms persist, seek the advice of a healthcare professional.

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium infantis	1.33 billion CFU
bovine colostrum powder	33.33 mg
Ganoderma lucidum mushroom Powder	83.3 mg
glutamic acid	33.3 mg
glutamic acid hydrochloride	33.3 mg
high chromium yeast	8.33 mg
Equivalent: chromium	16.67 microgram
high molybdenum yeast	10.41 mg
Equivalent: molybdenum	20.8 microgram
high selenium yeast	24.5 mg
Equivalent: selenium	.049 mg
Iberis amara herb flowering and fruiting Extract dry concentrate	33.3 mg
Equivalent: Iberis amara (Dry)	333 mg
Lactobacillus acidophilus	1.33 billion CFU
Lactobacillus casei	1.33 billion CFU
Lactobacillus gasseri	.667 billion CFU
Lactobacillus paracasei subsp. paracasei	1.33 billion CFU
Lactobacillus plantarum	1.33 billion CFU
Lactobacillus reuteri	.667 billion CFU
Lactobacillus rhamnosus	.667 billion CFU
Lactobacillus salivarius ssp salivarius	.667 billion CFU
Saccharomyces cerevisiae	8.3 mg
Saccharomyces cerevisiae	11.9 mg
Saccharomyces cerevisiae (Boulardii)	8.33 mg
Streptococcus thermophilus	.667 billion CFU
Yucca gloriosa leaf Extract dry concentrate	33.33 mg
Equivalent: Yucca gloriosa (Dry)	333 mg

Other Ingredients (Excipients)

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

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

potassium acetate

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Public Summary