



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299717	Colon Support
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	16/02/2018	
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 . Colon Support

Product Type	Single Medicine Product	Effective Date	26/02/2021
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Permitted Indications

Aids/assists body's natural channels of elimination
Aids/assists excretion of metabolic waste products
Aids/assists body waste elimination
Maintain/support body waste elimination
Maintain/support general health and wellbeing
Decrease/reduce/relieve constipation
Helps reduce occurrence of constipation
Promote/increase bowel evacuation
Stimulant laxative
Enhance/improve/promote/increase bowel regularity
Maintain/support bowel regularity
Enhance/improve/promote/increase bowel waste elimination
Maintain/support healthy bowel/colon function
Maintain/support healthy digestive system function
Decrease/reduce/relieve symptoms of indigestion/dyspepsia
Relieve digestive discomfort

Indication Requirements

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

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

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

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

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 detoxification in relation to natural body processes.

Product presentation must not refer to or imply weight loss.



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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Prolonged use may cause serious bowel problems.

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

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

Use in children under 12 years is not recommended.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification

Active Ingredients

Frangula purshiana stem bark Powder standardised	130 mg
Gentiana lutea root Powder	5 mg
Glycyrrhiza glabra root Powder	40 mg
Mentha X piperita leaf Powder	15 mg
Peppermint Oil	1.2 mg
Senna alexandrina leaf Extract dry concentrate standardised	60 mg
Equivalent: Senna alexandrina (Dry)	240 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
croscarmellose sodium
magnesium stearate
microcrystalline cellulose
silicon dioxide
stearic acid

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