Public Summary

Summary for ARTG Entry:	329886	PGX
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	13/02/2020	
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.

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 . PGX

Product Type	Single Medicine Product	**Effective Date**	13/02/2020

Permitted Indications

Helps reduce intestinal absorption of cholesterol from dietary sources

Helps maintain/support healthy cholesterol

Helps maintain/support healthy blood sugar/glucose

Promote/enhance feeling of satiety

Decrease/reduce/relieve constipation

Helps reduce occurrence of constipation

Maintain/support bowel regularity by increasing stool bulk

Enhance/improve/promote/increase bowel regularity

Maintain/support bowel regularity

Softens stool to ease bowel motions

Decrease/reduce/relieve diarrhoea

Helps reduce occurrence of diarrhoea

Decrease/reduce loose stools

Indication Requirements

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

Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range

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: Seek medical advice 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 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

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

Product presentation must not refer to or imply weight loss.

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

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral

Visual Identification

Active Ingredients

alginate-konjac-xanthan polysaccharide complex	**1 g/g**