



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	309125	Infloran
ARTG entry for	Medicine Listed	
Sponsor	Prinz-Herget Pty Ltd T/A Evidence Based Probiotics	
Postal Address	PO Box 7302, West Lakes, SA, 5021 Australia	
ARTG Start Date	10/09/2018	
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.

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 . Infloran

Product Type	Single Medicine Product	Effective Date	30/03/2019
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Permitted Indications

Decrease/reduce/relieve diarrhoea in adults

Decrease/reduce/relieve diarrhoea in children

Decrease/reduce/relieve diarrhoea in healthy infants

Helps reduce occurrence of diarrhoea in healthy infants

Helps reduce occurrence of diarrhoea in adults

Helps enhance/promote healthy digestive system function in healthy children under 2 years of age

Helps enhance/promote healthy digestive system function in formula fed healthy infants

Enhance/promote healthy digestion in formula fed healthy infants

Enhance/promote healthy digestion in healthy infants

Helps enhance/promote gastrointestinal system mucosa health in formula fed healthy infants

Maintain/support digestive system health in healthy infants

Helps maintain/support good/beneficial/friendly gut flora during antibiotic use

Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in children over 2 years of age

Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in healthy children under 2 years of age

Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in infants

Help restore good/beneficial/friendly gut flora after antibiotic use in children over 2 years of age

Help restore good/beneficial/friendly gut flora after antibiotic use in healthy children under 2 years of age

Help restore good/beneficial/friendly gut flora after antibiotic use

Help restore good/beneficial/friendly gut flora after antibiotic use in infants



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- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in healthy children
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in healthy infants
- Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth in healthy infants
- Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth in formula fed healthy infants
- Helps reduce occurrence of symptoms of indigestion/dyspepsia in healthy infants
- Decrease/reduce/relieve symptoms of indigestion/dyspepsia in healthy infants
- Maintain/support healthy gastrointestinal immune function in children
- Maintain/support healthy gastrointestinal immune function in healthy infants
- Maintain/support healthy gastrointestinal immune function
- Helps stimulate a healthy immune system response in healthy infants

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to gastro oesophageal reflux disease.
 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).
 Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].
 Contains lactose (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Bifidobacterium bifidum	1 billion CFU
Lactobacillus acidophilus	1 billion CFU

Other Ingredients (Excipients)

- dibasic potassium phosphate
- erythrosine
- Gelatin
- indigo carmine
- lactose monohydrate
- magnesium stearate
- quinoline yellow
- sodium citrate
- sucrose
- titanium dioxide

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