



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	213046	Orthoplex GIT ImmunoBiotic
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	9/08/2013	
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 . Orthoplex GIT ImmunoBiotic

Product Type	Effective Date
Single Medicine Product	8/07/2019

Permitted Indications

- Helps maintain/support healthy acid/alkali balance in the body
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Maintain/support healthy digestive system function
- Maintain/support healthy digestion
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support digestive system health
- Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa
- Maintain/support gastrointestinal system health when travelling
- Maintain/support gastrointestinal system health
- Traditionally used in Western herbal medicine to maintain/support gastrointestinal system health
- Maintain/support healthy gastrointestinal function
- Maintain/support healthy gastrointestinal function when travelling
- Traditionally used in Western herbal medicine to maintain/support healthy gastrointestinal function
- Maintain/support gastrointestinal mucosal membrane health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes
- Traditionally used in Western herbal medicine to maintain/support stomach function
- Traditionally used in Western herbal medicine to maintain/support stomach health

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Maintain/support immune system health
 Maintain/support healthy immune system function
 Maintain/support healthy gastrointestinal immune function

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to disease in any body organ.
 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

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral

Visual Identification

Active Ingredients

glutamine	400 mg/g
pectin	20 mg/g
Saccharomyces cerevisiae (Boulardii)	50 mg/g
Ulmus rubra stem bark inner Powder	100 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica
 glycine
 Stevia rebaudiana

Public Summary

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