



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	284828	MediHerb GIT Regenex
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	19/01/2017	
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 . MediHerb GIT Regenex

Product Type	Single Medicine Product	Effective Date	10/03/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Western herbal medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Western herbal medicine to nourish the body
- Traditionally used in Western herbal medicine to nutritive tonic
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in healthy adolescents
- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Western herbal medicine to decrease/reduce loose stools
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support gastrointestinal mucosal membrane health
- Aids/assists repair of gastrointestinal/gut wall lining
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation
- Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes
- Maintain/support immune system health in healthy adolescents
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy immune system function in healthy adolescents
- Maintain/support immune system to fight illness
- Maintain/support immune system to fight illness in healthy adolescents
- Maintain/support healthy gastrointestinal immune function

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- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy adolescents
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in elderly individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body In older females
- Maintain/support (state vitamin/mineral/nutrient) levels in the body In older males
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in active individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegetarians
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegans
- Maintain/support (state vitamin/mineral) within normal range in vegans
- Maintain/support (state vitamin/mineral) within normal range in active individuals
- Maintain/support (state vitamin/mineral) within normal range in breastfeeding women
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support (state vitamin/mineral) within normal range In older males
- Maintain/support (state vitamin/mineral) within normal range in vegetarians
- Maintain/support (state vitamin/mineral) within normal range in elderly individuals
- Maintain/support (state vitamin/mineral) within normal range In older females
- Maintain/support (state vitamin/mineral) within normal range in healthy adolescents

Indication Requirements

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

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

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (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).

Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Acacia	325.32 mg/g
glutamine	569.32 mg/g
Glycyrrhiza glabra	11.83 mg/g

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polaprezinc	12.2 mg/g
Equivalent: zinc	2.6 mg/g
Ulmus rubra stem bark Powder	81.33 mg/g
Other Ingredients (Excipients)	
colloidal anhydrous silica	

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