



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	215745	INNER HEALTH POWDER
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	8/10/2013	
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.

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 . INNER HEALTH POWDER

Product Type	Single Medicine Product	Effective Date	18/11/2020
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Permitted Indications

- Maintain/support general health and wellbeing in adults
- Maintain/support general health and wellbeing in children
- Maintain/support healthy digestive system function in adults
- Maintain/support healthy digestion in adults
- Maintain/support intestinal good/beneficial/friendly flora in adults
- Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth in adults
- Maintain/support gastrointestinal system health in adults
- Decrease/reduce/relieve abdominal pain/discomfort in adults
- Maintain/support immune system health in children
- Maintain/support immune system health in adults
- Maintain/support healthy gastrointestinal immune function in children
- Maintain/support healthy gastrointestinal immune function in adults

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- If symptoms persist consult your healthcare practitioner (or words to that effect).
- Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.

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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

Bifidobacterium lactis	5 billion organisms/g
bovine colostrum powder	100 mg/g
fructooligosaccharides	120 mg/g
Lactobacillus acidophilus	5 billion organisms/g

Other Ingredients (Excipients)

fructose

glucose monohydrate

Lactalbumin

maltodextrin

sucrose

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