



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	315328	INNER HEALTH PLUS BABY & KIDS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	12/03/2019	
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 . INNER HEALTH PLUS BABY & KIDS

Product Type	Effective Date
Single Medicine Product	12/03/2019

Permitted Indications

- Maintain/support ear health in healthy infants
- Maintain/support ear health in healthy children
- Maintain/support general health and wellbeing in healthy infants
- Maintain/support general health and wellbeing in healthy children
- Maintain/support digestive system health in healthy infants
- Maintain/support digestive system health in healthy children
- Maintain/support intestinal good/beneficial/friendly flora in healthy infants
- Maintain/support intestinal good/beneficial/friendly flora in healthy children
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in healthy infants
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in healthy children
- Help restore good/beneficial/friendly gut flora after antibiotic use in healthy infants
- Help restore good/beneficial/friendly gut flora after antibiotic use in healthy children
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in healthy infants
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in healthy children
- Maintain/support immune system health in healthy infants
- Maintain/support immune system health in healthy children
- Maintain/support healthy immune system function in healthy infants
- Maintain/support healthy immune system function in healthy children
- Helps reduce occurrence of symptoms of upper respiratory tract infections in healthy children

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Helps reduce occurrence of symptoms of upper respiratory tract infections in healthy infants

Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
 Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (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.

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).

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 animalis ssp lactis	5 billion organisms/g
Lactobacillus rhamnosus	5 billion organisms/g

Other Ingredients (Excipients)

maltodextrin
 sodium ascorbate
 sucrose

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