



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

## Public Summary

<b>Summary for ARTG Entry:</b>	151986	INNER HEALTH IMMUNE BOOSTER KIDS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	30/04/2008	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

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 IMMUNE BOOSTER KIDS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/07/2020
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### Permitted Indications

Maintain/support intestinal good/beneficial/friendly flora in children over 2 years of age  
Maintain/support immune system health in children over 2 years of age  
Enhance/improve/promote immune defence/immunity in children over 2 years of age  
Helps enhance/improve/promote immune system function in children over 2 years of age  
Maintain/support healthy immune system function in children over 2 years of age  
Maintain/support immune system to fight illness in children over 2 years of age  
Helps stimulate a healthy immune system response in children over 2 years of age  
Decrease/reduce/relieve symptoms of common colds and flu in children over 2 years of age  
    Linked indication - Aids/assists with recovery from illness/convalescence  
    Linked indication - Helps reduce occurrence of common colds  
    Linked indication - Relieve runny/dripping nose  
    Linked indication - Decrease/reduce/relieve cough  
    Linked indication - Decrease/reduce/relieve common cold duration  
Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in children over 2 years of age  
Helps reduce occurrence of symptoms of upper respiratory tract infections in children over 2 years of age  
Decrease/reduce/relieve cough in children over 2 years of age  
Relieve runny/dripping nose in children over 2 years of age

### 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: If symptoms persist, talk to your health professional.  
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.  
  
Product presentation must not imply or refer to chronic fatigue syndrome.  
Respiratory tract infections must be qualified by 'mild'.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record



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#### Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

If coughing persists consult your doctor (or a healthcare professional) (or words to that effect).

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

**Route of Administration** Oral

##### Visual Identification

##### Active Ingredients

**Bifidobacterium lactis** 4.17 billion organisms/g

**Lactobacillus acidophilus** 4.17 billion organisms/g

##### Other Ingredients (Excipients)

fructooligosaccharides

maltodextrin

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