



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	253932	INNER HEALTH IMMUNE BOOSTER
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	11/08/2015	
Product Category	Medicine	
Status	Active	
Approval Area	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

Product Type	Single Medicine Product	Effective Date	3/07/2020
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Permitted Indications

Aids/assists with recovery from illness/convalescence

Maintain/support general health and wellbeing

Maintain/support immune system health

Helps enhance/improve/promote immune system function

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Helps stimulate a healthy immune system response

Decrease/reduce/relieve common cold duration

Decrease/reduce/relieve the severity of common cold symptoms

Linked indication - Aids/assists with recovery from illness/convalescence

Relieve symptoms of sore throat/pharyngitis

Linked indication - Helps decrease/reduce/relieve the severity of symptoms of common colds and flu

Linked indication - Relieve symptoms of mild upper respiratory tract infections

Indication Requirements

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

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

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

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).

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).

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

Additional Product information



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Lactobacillus paracasei 500 million CFU

Lactobacillus plantarum 500 million CFU

Other Ingredients (Excipients)

disodium edetate

gellan gum

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

potable water

potassium acetate

silicon dioxide

sucrose

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