

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 94578 INNER HEALTH PLUS DAIRY FREE

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Australia

ARTG Start Date 29/05/2003

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 PLUS DAIRY FREE

Product Type Single Medicine Product Effective Date 7/11/2020

Permitted Indications

Maintain/support general health and wellbeing in children

Maintain/support general health and wellbeing in adults

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 adults

Maintain/support healthy gastrointestinal immune function in children

Indication Requirements

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

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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

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Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium lactis 12.5 billion organisms
Lactobacillus acidophilus 12.5 billion organisms

Other Ingredients (Excipients)

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

maltodextrin

potable water

potassium acetate

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