Public Summary

Summary for ARTG Entry:	276097 Immune-5 Vanilla
ARTG entry for	Medicine Listed
Sponsor	Medlab Pty Ltd
Postal Address	PO Box 6452, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	2/06/2016
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 . Immune-5 Vanilla

Product Type Single Medicine Product **Effective Date** 27/07/2021

Permitted Indications

Helps enhance/promote general health and wellbeing

Maintain/support immune system health

Helps enhance/improve/promote immune system function

Helps stimulate a healthy immune system response

Indication Requirements

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

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).

Not suitable for use in children under the age of 12 months except on the advice of a health professional. (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.

Contains milk/milk products.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral

Visual Identification

Active Ingredients

Bifidobacterium animalis ssp lactis	**1 billion CFU/g**
bovine colostrum powder	**68 mg/g**
bovine lactoferrin	**40 mg/g**
Lactobacillus paracasei	**1 billion CFU/g**
Larix arabinogalactan	**450 mg/g**

Other Ingredients (Excipients)

colloidal anhydrous silica
Flavour
maltodextrin
Stevia rebaudiana

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