



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	378035	Qiara Infant Drops
ARTG entry for	Medicine Listed	
Sponsor	PUREMEDIC HEALTH (OPERATIONS) PTY LTD	
Postal Address	Level 10 30 Collins St, Melbourne, VIC, 3000 Australia	
ARTG Start Date	16/11/2021	
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 . Qiara Infant Drops

Product Type	Single Medicine Product	Effective Date	22/11/2023
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Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support healthy digestive system function
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use
- Help restore good/beneficial/friendly gut flora after antibiotic use
- Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth
- Maintain/support gastrointestinal system health
- Maintain/support immune system health
- Maintain/support immune system to fight illness
- Maintain/support healthy gastrointestinal immune 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

For further information, seek the advice of your healthcare professional.
If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Lactobacillus fermentum 1.95 mg/mL

Other Ingredients (Excipients)

dl-alpha-tocopherol

maltodextrin

sodium ascorbate

sodium chloride

sucrose

Sunflower Oil

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