



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	269433	Qiara Pregnancy & Breastfeeding
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	8/02/2016	
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 . Qiara Pregnancy & Breastfeeding

Product Type	Single Medicine Product	Effective Date	22/05/2024
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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
Helps enhance/improve/promote immune system function
Maintain/support healthy gastrointestinal immune function
Helps stimulate a healthy immune system response
Helps decrease/reduce/relieve symptoms of mild mastitis while lactating/breastfeeding
Helps reduce occurrence of symptoms of mild mastitis while lactating/breastfeeding
Maintain/support healthy pregnancy
Maintain/support maternal health

Indication Requirements

Label statement: Seek medical advice if symptoms persist for more than 12 hours or you to start to feel unwell (or words to that effect).
Mastitis must be qualified by mild.
Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
Product presentation must not imply or refer to serious immunological diseases.
If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
Product presentation must not imply or refer to mastitis due to infection.
Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

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

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Lactobacillus fermentum 1.5 billion CFU/g

Other Ingredients (Excipients)

maltodextrin

sodium ascorbate

sucrose

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