



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	269433	Qiara Pregnancy & Breastfeeding
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	PUREMEDIC HEALTH (OPERATIONS) PTY LTD	
<b>Postal Address</b>	Ground Floor 35 Cotham Road, Kew, VIC, 3101 Australia	
<b>ARTG Start Date</b>	8/02/2016	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/11/2021
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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 decrease/reduce/relieve symptoms of mild mastitis while lactating/breastfeeding  
Helps reduce occurrence of symptoms of mild mastitis while lactating/breastfeeding

#### Indication Requirements

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 mastitis due to infection.  
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).

#### 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).  
For further information, seek the advice of your healthcare professional.

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

**Lactobacillus fermentum** 19.5 mg/g

**Other Ingredients (Excipients)**

maltodextrin

sodium ascorbate

sodium chloride

sucrose

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Public Summary