

**Australian Government** 

## **Department of Health**

## Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry:	285408	Qiara Kids	
ARTG entry for	Medicine Listed		
Sponsor	PUREMEDIC HEALTH (OPERATIONS) PTY LTD		
Postal Address	Ground Floor 35 Cotham Road, Kew, VIC, 3101 Australia		
ARTG Start Date	8/02/2017		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines	S	
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 Kids						
Product Type	Single Medicine Product	Effective Date	27/10/2021			
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						
Indication Requirements						
No Indication Requirements included on Record						
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.						
Additional Product information						
	• •					
Pack Size/Poison information Pack Size Poison Schedule						
	Pack Size					
Components						
1. Formulation 1						
Dosage Form	Powder, oral					
Route of Adminis	stration Oral					
Visual Identificat	ion					

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6.5 mg/g

Active Ingredients

Lactobacillus fermentum

Other Ingredients (Excipients)

maltodextrin sodium ascorbate

sodium chloride

sucrose

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