



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	107643	Nutrition Care Polybac 8
ARTG entry for	Medicine Listed	
Sponsor	Nutrition Care Pharmaceuticals Pty Ltd	
Postal Address	25-31 Keysborough Avenue, Keysborough, VIC, 3173 Australia	
ARTG Start Date	7/09/2004	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Nutrition Care Polybac 8

Product Type	Single Medicine Product	Effective Date	13/03/2020
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Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support intestinal health
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support small intestine good/beneficial/friendly flora
- Maintain/support gastrointestinal system health
- Maintain/support gastrointestinal mucosal membrane health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function

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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium lactis	1.5 billion organisms/g
Bifidobacterium longum	1.5 billion organisms/g
Lactobacillus acidophilus	2.5 billion organisms/g
Lactobacillus casei	2.5 billion organisms/g
Lactobacillus plantarum	2.5 billion organisms/g
Lactobacillus rhamnosus	3 billion organisms/g
Lactobacillus salivarius ssp salivarius	1 billion organisms/g
Streptococcus thermophilus	500 million organisms/g

Other Ingredients (Excipients)

ascorbic acid

microcrystalline cellulose

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