



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	343518	Pro4-50 Hard capsules
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Spectrumceuticals Pty Ltd	
<b>Postal Address</b>	10/5 Narabang Way, BELROSE, NSW, 2085 Australia	
<b>ARTG Start Date</b>	15/09/2020	
<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.

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 . Pro4-50 Hard capsules

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	15/09/2020
---------------------	-------------------------	-----------------------	------------

### 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

Public Summary



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

Pack Size

Poison Schedule

**Components**

1 . Formulation 1

Dosage Form                      Capsule, hard

Route of Administration      Oral

Visual Identification

**Active Ingredients**

Bifidobacterium breve	5 billion CFU
Bifidobacterium lactis	15 billion CFU
Bifidobacterium longum	5 billion CFU
Lactobacillus rhamnosus	25 billion CFU

**Other Ingredients (Excipients)**

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

microcrystalline cellulose

potable water

potassium acetate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary