



PROFESSIONAL INFORMATION

Scheduling Status: **SO**

1. Proprietary Name

Broad Spectrum Probiotic 10 Strain

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each white capsule contains	
10 strain Probiotic Blend HOWARU® Lactobacillus Acidophilus La-14® HOWARU® Lactobacillus Rhamnosus HN001™ HOWARU® Bifidobacterium Lactis BI-04® HOWARU® Lactobacillus Paracasei Lpc-37® <i>Bifidobacterium bifidum</i> <i>Bifidobacterium longum</i> <i>Lactobacillus casei</i> <i>Lactobacillus gasseri</i> <i>Lactobacillus reuteri</i> <i>Lactobacillus salivarius</i>	>5 billion CFU

2.2 Sugar Free.

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical Form

60 white size 0 capsules containing cream coloured powder.

4. Clinical Information

4.1 Indications for Use

It is a health supplement of 10 strains of probiotics as per Composition Table. They are often taken as supplement that are supposed to help colonize the gut with good organisms. It can boost health when consumed in adequate amounts. Having the right gut bacteria has been linked to numerous health benefits including:

- Weight loss
- Improved digestion
- Enhanced immune function.
- Healthier skin
- Reduced risk of some diseases

4.2 Method of Administration and Posology

4.2.1 Administration

Orally.

4.2.2 Posology

Adults and children over 18 only.

Take 2 capsules daily.

Take capsules with a sufficient quantity of water.

Do not chew the capsules swallow whole.

Take capsules at approximately the same time every day.



4.3 Contraindications

Not recommended for individuals who are hypersensitive (allergic) to any of the ingredients contained in the product.

4.4 Special Warnings and Precautions

To be taken two hours before or after taking any antibiotics. Not recommended for individuals who are under the age of 18. Do not exceed the recommended daily dose.

4.5 Interactions

Taking antibiotic drugs with certain drugs may decrease the effectiveness of probiotics.

4.6 Pregnancy and Lactation

Possibly safe.

4.7 Effects on ability to drive and use machinery.

No known effect.

4.8 Side Effects

No known side effects.

5 Pharmacological Classification

Category D: 34.9 Probiotics.

Complementary Medicine.

6 Pharmacokinetic Properties

Lactobacillus

Absorption: When taken orally it is not absorbed in the gastrointestinal tract. Some might colonize the large bowel.

Bifidobacterium

Absorption: When taken orally it is not absorbed in the gastrointestinal tract. Some might colonize the large bowel.

7 Pharmaceutical Information

7.1 List of Excipients

Vegetarian capsules, milled rice flour.

7.2 Incompatibilities

None.

7.3 Shelf Life

24 months from date of manufacture.

7.4 Storage

Store in a cool dry place, between 15°C -25°C. Store in original container.

7.5 Presentation

60 white capsules packed in a 300 ml cylindrical white container with a lid and packaged in a single carton.

7.6 Disposal and handling of product

All unused medication should be disposed of in accordance with local regulatory authority.

8. Holder of certificate of registration

FoodGrown™©

371 Angus Crescent

Northlands Business Park

North Riding

Gauteng

South Africa



9. Registration Number

Still to be allocated

76

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10. Date of first authorisation

Still to be allocated

78

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11. Date of review

New

80

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12. Reference: <https://naturalmedicines.therapeuticresearch.com/>

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APPLICANT DETAILS:

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