THE DE SIMONE FORMULATION
BY THE NUMBERS

STUDIES PER DISEASE


e.g. placebo-controlled,

DOUBLE-BLIND, CROSS-OVER,

RANDOMIZED

CONTROLLED AND/OR

OBSERVATIONAL STUDIES

TOTAL NUMBER OF PATIENTS EXAMINED

1,682

12

ADULTS

5,319

43

CONTROLLED STUDY (MC)

GERIATRIC

295

9

UNCONTROLLED STUDY (OL)

UNKNOWN

43

10

PROOF OF CONCEPT

7

11

OTHER

CIRRHOSIS

3,330

3

SEROUS EFFUSIONS.

TOTAL NUMBER OF PATIENTS EXAMINED

STUDIES PER AGE GROUP


49

10

PEDiatric

3

11

LIVER

STUDIES PER REGION


5

7

OPEN LABEL

GERIATRIC

PEDIATRIC

5

4

GERIATRIC

PEDIATRIC ADULT

STUDIES PER DISEASE


FORMULATIONS AND AVAILABILITY

Visbiome Regular

Product Code: 69355-002-01

450 BILLION BACTERIA

Visbiome Unflavored

Product Code: 69355-002-02

450 BILLION BACTERIA

Visbiome Extra Strength

Product Code: 69355-002-03

112.5 BILLION BACTERIA

Product

Product Code

Bacteria Count (CFU)

Dosage Format

Counter Per Box/Bottle

Visbiome Capsules

69355-002-10

500 Billion (2 caplets)

Capsules

50 caplets

Visbiome Unflavored

69355-002-11

500 Billion (2 caplets)

Powder

10 packets

Visbiome Extra Strength

69355-002-12

500 Billion (2 caplets)

Powder

10 packets

Important Safety Information: Mild abdominal bloating has been reported in the first few days of consuming Visbiome®. This is generally a physiological adaptation of the microflora, which usually diminishes within 3-4 days. If bloating persists, the patient should reduce their intake for a few days. This product should not be used in premature infants in the Neonatal Intensive Care Unit (NICU) setting.


PRESCRIPTION ONLY AVAILABLE BY

PROVEN BY RESEARCH.

HIGH-POTENCY. NO SHORTCUTS.

Visbiome® is a medical food for the dietary management of dysbiosis associated with:

- Intestinal Bowel Syndrome (IBS)
- Ulcerative Colitis (UC)
- Pouchitis
- Hepatic Encephalopathy (HE)

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Medical food for the dietary management of dysbiosis associated with IBS, ulcerative colitis, pouchitis, and hepatic encephalopathy.

*Visbiome*™ is a non-drug therapy that addresses distinct nutritional requirements to promote microbial balance in people with IBS, ulcerative colitis, pouchitis, and hepatic encephalopathy which cannot be addressed by modification of diet alone.

Eight strains of live bacteria in high concentrations

*Visbiome*™ capsules are encompassed by the Activ-Vial technology to reduce moisture exposure.

Contains original De Simone Formulation probiotic blend, one of the most widely studied probiotics available with over 60 human clinical trials in IBS, UC, Pouchitis, liver disease and more.

### High Potency Probiotic

**Available in 4 Formulations**

- **Regular, Unflavored, and Capsules**
  - 112.5 Billion Bacteria capsules
  - 450 Billion Bacteria regular powder
  - 450 Billion Bacteria unflavored powder
  - 900 Billion Bacteria extra strength powder

- **Capsules**
  - Extra strength (available by prescription only)

The Beneficial Effects of Probiotics are Highly Strain-Specific

**High Potency Probiotic**

**AVAILABLE IN 4 FORMULATIONS**

<table>
<thead>
<tr>
<th>Strain Reference Number</th>
<th>Genus</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSM 24733</td>
<td>Lactobacillus</td>
<td>paracasei</td>
</tr>
<tr>
<td>DSM 24730</td>
<td>Lactobacillus</td>
<td>plantarum</td>
</tr>
<tr>
<td>DSM 24735</td>
<td>Lactobacillus</td>
<td>acidophilus</td>
</tr>
<tr>
<td>DSM 24734</td>
<td>Lactobacillus</td>
<td>delbrueckii sub species bulgaricus</td>
</tr>
<tr>
<td>DSM 24736</td>
<td>Bifidobacterium</td>
<td>longum</td>
</tr>
<tr>
<td>DSM 24737</td>
<td>Bifidobacterium</td>
<td>infantis</td>
</tr>
<tr>
<td>DSM 24732</td>
<td>Bifidobacterium</td>
<td>breve</td>
</tr>
<tr>
<td>DSM 24731</td>
<td>Streptococcus</td>
<td>thermophilus</td>
</tr>
</tbody>
</table>

* Recently reclassified as Lactobacillus helveticus

† Recently reclassified as Bifidobacterium lactis

**Visbiome in the Dietary Management of Hepatic Encephalopathy**

Hepatic Encephalopathy (HE) is associated with significant dysbiosis of the bacterial gut flora.1,2 Standard drug therapy for HE is focused on modulating the gut microbiome through probiotic and antibiotic activity.2,4 The *Visbiome*™ probiotic, consumed as a monotherapy or concomitantly with standard drug therapy may aid in the dietary management of dysbiosis associated with HE.

### Visbiome in the Dietary Management of Hepatic Encephalopathy

- **Improved management of overt HE in patients with a prior episode of overt HE.5**
- **Improvement in abnormal psychometric testing vs. control.**
- **Reduction in arterial ammonia levels comparable to lactulose.5,7**
- **May be consumed concomitantly with standard drug therapy (lactulose, rifaximin).8,9**

When used as a medical food, multiple controlled studies have found the De Simone Formulation in *Visbiome*™ is associated with:

- **Improved management of overt HE in patients with a prior episode of overt HE.**
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**Number of Patients**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Number of Patients</th>
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<tbody>
<tr>
<td>IBS</td>
<td>4</td>
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<td>UC</td>
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<td>Pouchitis</td>
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**Number of Studies**

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**As a Medical Food the Formulation in Visbiome has been associated with:***

- **Reductions in bloating**
- **Decrease in flatulence**
- **Improvement in UCDAI scores by up to 50%**
- **Achievement of remission**
- **Decrease of rectal bleeding**
- **85% patients remained in remission after nine months**
- **Decrease bowel frequency**
- **Reduction in arterial ammonia levels comparable to lactulose.**

**RECOMMENDED DAILY INTAKE**

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Medical food for the dietary management of dysbiosis associated with IBS, ulcerative colitis, pouchitis, and hepatic encephalopathy.

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Eight strains of live bacteria in high concentrations

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**High Potency Probiotic**

**Available in 4 Formulations**

- **112.5 Billion Bacteria Capsules**
- **450 Billion Bacteria Regular Powder** (Lemon Cream Flavor)
- **450 Billion Bacteria Unflavored Powder** (powder by De Simone only)
- **900 Billion Bacteria Extra Strength Powder** (available by prescription only)

The Beneficial Effects of Probiotics are Highly Strain-Specific

**Visbiome in the Dietary Management of Hepatic Encephalopathy**

Hepatic Encephalopathy (HE) is associated with significant dysbiosis of the bacterial gut flora. Standard drug therapy for HE is focused on modulating the gut microbiome through prebiotic and antibiotic activity. The Visbiome® probiotic, consumed as a monotherapy or concomitantly with standard drug therapy may aid in the dietary management of dysbiosis associated with HE.

**RECOMMENDED DAILY INTAKE**

When used as a medical food, multiple controlled studies have found the De Simone Formulation in Visbiome™ is associated with:

- Improved management of overt HE in patients with a prior episode of overt HE.
- Improvement in abnormal psychometric testing vs. control.
- Reduction in arterial ammonia levels comparable to lactulose.
- May be consumed concomitantly with standard drug therapy (lactulose, rifaximin).

**Numerous clinical studies have been conducted on the formulation as a medical food in the dietary management of:**

**Visbiome in the Dietary Management of hepatic encephalopathy**

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- **Improvement in abnormal psychometric testing vs. control.**
- **Reduction in arterial ammonia levels comparable to lactulose.**
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### The Beneficial Effects of Probiotics are Highly Strain-Specific

<table>
<thead>
<tr>
<th>Probiotic Strain</th>
<th>Reference Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactobacillus paracasei</td>
<td>DSM 24733</td>
</tr>
<tr>
<td>Lactobacillus plantarum</td>
<td>DSM 24730</td>
</tr>
<tr>
<td>Lactobacillus acidophilus</td>
<td>DSM 24735</td>
</tr>
<tr>
<td>Lactobacillus delbrueckii subspecies bulgaricus</td>
<td>DSM 24734</td>
</tr>
<tr>
<td>Bifidobacterium longum±</td>
<td>DSM 24736</td>
</tr>
<tr>
<td>Bifidobacterium infantis±</td>
<td>DSM 24737</td>
</tr>
<tr>
<td>Bifidobacterium breve</td>
<td>DSM 24732</td>
</tr>
<tr>
<td>Streptococcus thermophilus</td>
<td>DSM 24731</td>
</tr>
</tbody>
</table>

*Recently reclassified as Lactobacillus helveticus
±Recently reclassified as Bifidobacterium lactis

### RECOMMENDED DAILY INTAKE

<table>
<thead>
<tr>
<th>Adult Dietary Management of</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBS</td>
<td>4</td>
</tr>
<tr>
<td>UC</td>
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### Visbiome in the Dietary Management of Hepatic Encephalopathy

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### AVAILABLE IN 4 FORMULATIONS

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Bacteria Concentration</th>
<th>Capsule Count</th>
<th>Strain Reference Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular Powder</td>
<td>112.5 Billion Bacteria/Capsule</td>
<td>450</td>
<td>Lactobacillus acidophilus DSM 24735</td>
</tr>
<tr>
<td>Unflavored Powder</td>
<td>450 Billion Bacteria/Capsule</td>
<td>450</td>
<td>Bifidobacterium longum± DSM 24736</td>
</tr>
<tr>
<td>Extra Strength Powder</td>
<td>900 Billion Bacteria/Capsule</td>
<td>900</td>
<td>Bifidobacterium breve DSM 24732</td>
</tr>
</tbody>
</table>

### When used as a medical food, multiple controlled studies have found the De Simone Formulation in Visbiome™ is associated with:

- Improved management of overt HE in patients with a prior episode of overt HE.
- Improvement in abnormal psychometric testing vs. control.
- Reduction in arterial ammonia levels comparable to lactulose.
- May be consumed concomitantly with standard drug therapy (lactulose, rifaximin).
**THE DE SIMONE FORMULATION BY THE NUMBERS**

**STUDIES PER DISEASE**
- Liver Disease, Cirrhosis: 1,162
- Other: 7

**STUDIES PER AGE GROUP**
- Pediatric: 3,330
- Adult: 295
- Geriatric: 10

**TOTAL NUMBER OF PATIENTS EXAMINED**
- Adults: 1,882
- Pediatric: 5,319
- Geriatric: 3,330
- Unknown: 3,330

**TYPES OF STUDIES**
- Controlled Open-Label: 60
- Uncontrolled Open-Label: 7
- Proof of Concept: 10

**FORMULATIONS AND AVAILABILITY**

<table>
<thead>
<tr>
<th>Product</th>
<th>Bacteria Count (CFU)</th>
<th>Dosage Format</th>
<th>Count per Box/Bottle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visbiome Regular Powder</td>
<td>450 Billion</td>
<td>Powder</td>
<td>12 packets</td>
</tr>
<tr>
<td>Visbiome Unflavored</td>
<td>450 Billion</td>
<td>Capsules</td>
<td>60 capsules</td>
</tr>
<tr>
<td>Visbiome Capsules Extra Strength</td>
<td>112.5 Billion</td>
<td>Powder</td>
<td>30 capsules</td>
</tr>
</tbody>
</table>

**Important Safety Information**
- Mild abdominal bloating has been reported in the first few days of consuming Visbiome®. This is generally a physiological adaptation of the microbiota, which usually diminishes within 3 days. If bloating persists, the patient should discontinue taking for a few days. This product should not be used in pregnant infants in the intestinal tolerance test (ITT) setting.

**PROVEN BY RESEARCH. HIGH-POTENCY. NO SHORTCUTS.**

Visbiome™ is a medical food for the dietary management of dysbiosis associated with:
- Irritable Bowel Syndrome (IBS)
- Ulcerative Colitis (UC)
- Pouchitis
- Hepatic Encephalopathy (HE)