



**visbiome**<sup>®</sup>  
HIGH POTENCY PROBIOTIC

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



Visbiome<sup>®</sup> is a medical food probiotic for the dietary management of dysbiosis associated with:

**Irritable Bowel Syndrome (IBS)**

**Ulcerative Colitis (UC)**

**Antibiotic Associated Diarrhea (AAD)**

**Pouchitis**

**Hepatic Encephalopathy (HE)**



# THE DE SIMONE FORMULATION

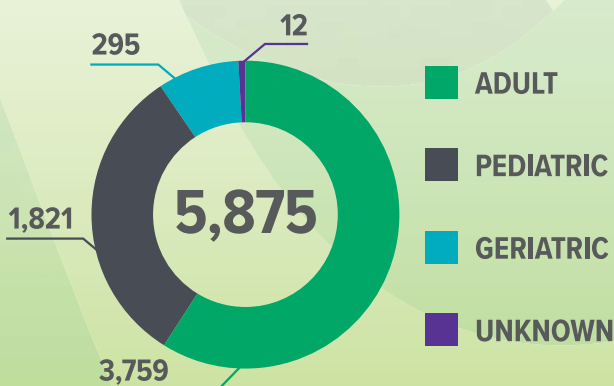
Visbiome® is the only probiotic on the market powered by the original **De Simone Formulation**. This high potency probiotic medical food contains eight strains of active bacteria specifically selected from Master Cell Banks for their individual characteristics and synergistic properties.

Genus	Species	Deposit References
<i>Lactobacillus</i>	<i>paracasei</i>	DSM 24733/SD5218
<i>Lactobacillus</i>	<i>plantarum</i>	DSM 24730/SD5209
<i>Lactobacillus</i>	<i>acidophilus</i>	DSM 24735/SD5212
<i>Lactobacillus</i>	<i>delbrueckii</i> subspecies <i>bulgaricus</i> *	DSM 24734/SD5210
<i>Bifidobacterium</i>	<i>longum</i> ‡	DSM 24736/SD5219
<i>Bifidobacterium</i>	<i>infantis</i> ‡	DSM 24737/SD5220
<i>Bifidobacterium</i>	<i>breve</i>	DSM 24732/SD5206
<i>Streptococcus</i>	<i>thermophilus</i>	DSM 24731/SD5207

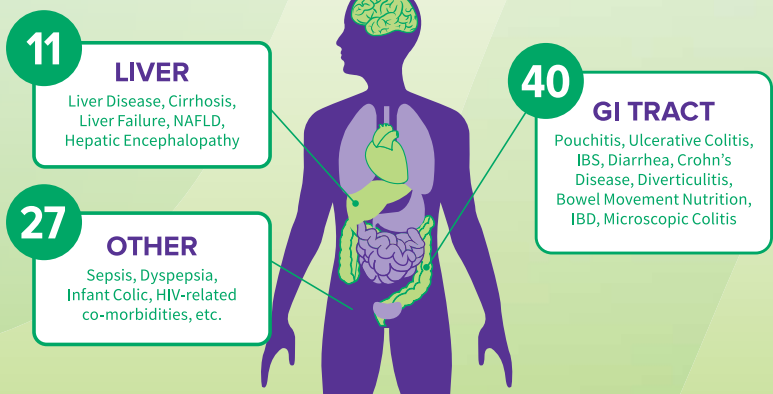
\*Reclassified as *Lactobacillus helveticus*, ‡Reclassified as *Bifidobacterium lactis*

The De Simone Formulation has been the subject of **MORE THAN 75 STUDIES**

## TOTAL NUMBER OF PATIENTS EXAMINED



## DISEASE STUDIES



# Better Gut Health Demands Highly Potent Precision

Many probiotics advertise their “high potency” and billions of CFUs. But it’s not simply the numbers that foster a healthy gut flora. Microbial balance requires specific bacteria, in precise ratios, working together to provide digestive relief.



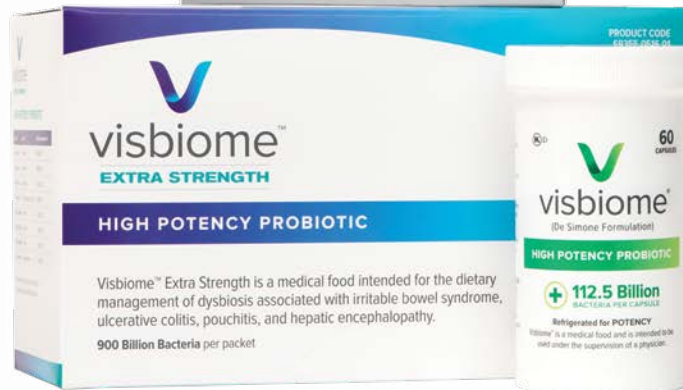
**450**  
BILLION BACTERIA  
UNFLAVORED POWDER

Product Code: 69355-0412-02

**900**  
BILLION BACTERIA  
EXTRA  
STRENGTH  
POWDER

(Prescription only)

Product Code: 69355-0516-01



**112.5**  
BILLION BACTERIA  
CAPSULES

Product Code: 69355-0412-03

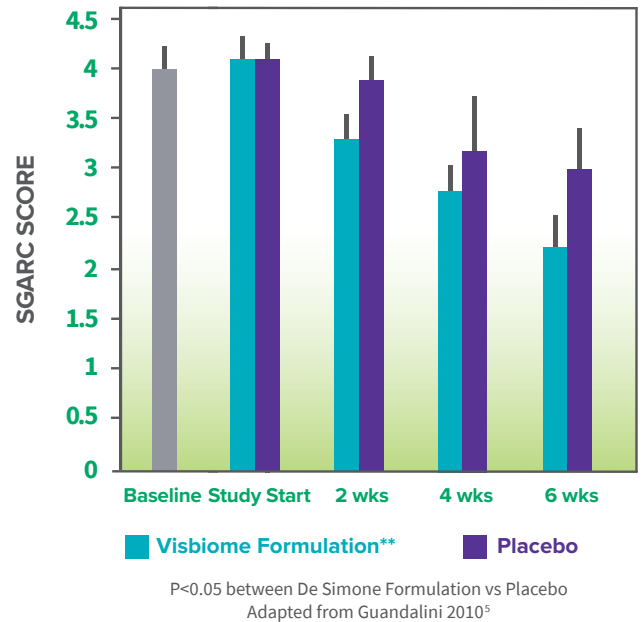
## FOR THE DIETARY MANAGEMENT OF:

	IBS	Ulcerative Colitis	Antibiotic Associated Diarrhea (AAD)	Hepatic Encephalopathy	Pouchitis
<b>Number of Studies</b>	Ten <sup>(1-10)</sup>	Eight <sup>(11-18)</sup>	One <sup>(19)</sup>	Five <sup>(20-24)</sup>	Four <sup>(27-30)</sup>
<b>Number of Patients</b>	More than 370	More than 500	More than 140	More than 775	More than 190
<b>Relief Provided</b>	Reduction in bloating Reduction in flatulence	Achievement of remission Decrease in rectal bleeding Reduction in UCDAI scores by up to 50%	Reduces diarrhea in antibiotic treated patients Restores microbial balance during antibiotic use.	Improved liver histology in adult patients with non-alcoholic fatty liver disease (NAFLD) <sup>25</sup> Improved cognitive function and inflammatory response in cirrhotic patients, while decreasing their risk of falls <sup>26</sup>	Decrease in bowel frequency 85% of patients still in remission after 9 mos.
<b>Recommended Daily Intake</b>	Capsules: 2-4 Powder: ½ to 1 packet ES: ¼ to ½ packet	<b>Maintenance:</b> Capsules: 4-8 Powder: 1-2 packets ES: ½ to 1 packet <b>Active:</b> Capsules: n/a Powder: 4-8 packets ES: 2-4 packets	<b>Under antibiotic treatment:</b> Capsules: 4, Powder: 1 packet, ES: ½ packet <b>After antibiotic treatment:</b> Capsules: 2, Powder: ½ packet, ES: N/A	Capsules: 2-8 Powder: 1-2 packets ES: ½ to 1 packet	Capsules: n/a Powder: 2-4 packets ES: 1-2 packets

# The Dietary Management of Irritable Bowel Syndrome (IBS)

Clinical research has demonstrated that Visbiome’s formula, the De Simone Formulation, can aid in the dietary management of common symptoms related to Irritable Bowel Syndrome (IBS) such as reductions in abdominal pain, flatulence, and bloating.

As shown in the following graph, children 4-18 years old who consumed the De Simone Formulation experienced a reduction in IBS symptoms using the Subject’s Global Assessment of Relief (“SGAR”), modified for children (“SGARC”).

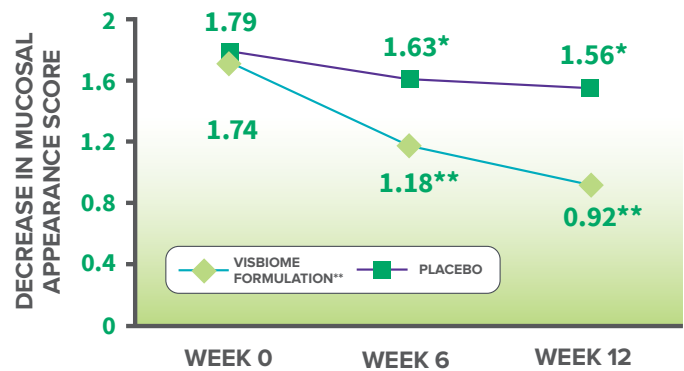
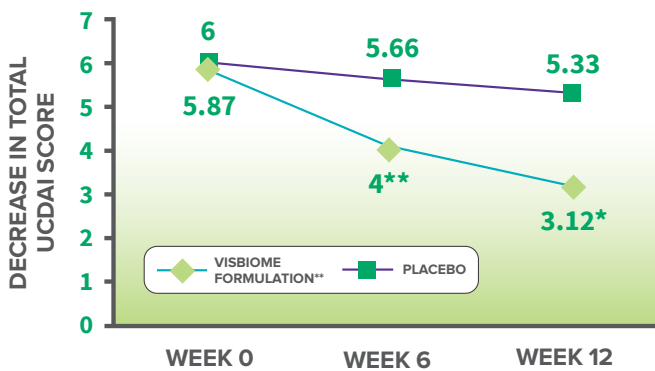


# The Dietary Management of Ulcerative Colitis

The De Simone Formulation is one of the few probiotics with an established clinical response in the dietary management of Ulcerative Colitis (UC). Studies have examined pediatrics between the ages of 1.7-17 years and adults between the ages of 18-70. Visbiome can be used concomitantly with standard drug treatments.

## HELPING PATIENTS REACH REMISSION WITH DIETARY THERAPY

One study evaluated how Visbiome’s formulation, the De Simone formulation, helped patients with UC reach remission. The following graph depicts the significant decrease in stool frequency, rectal bleeding, mucosal appearance, physician’s global assessment, and the UC disease activity scores in Sood et al 2009.<sup>14</sup>



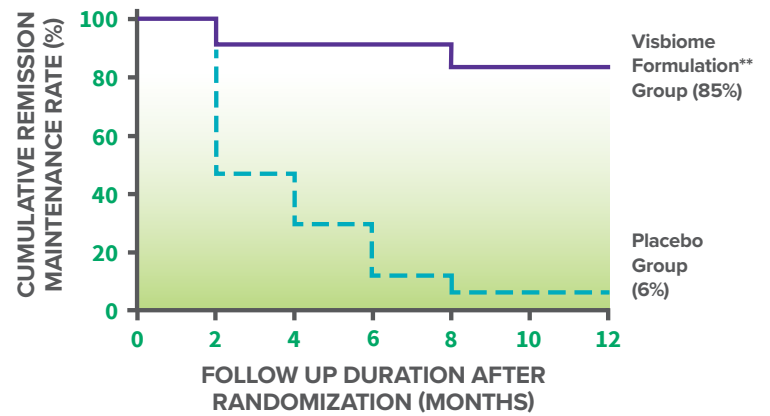
\*P<.05; \*\*P<.001 Adapted from Sood et al 2009<sup>14</sup>

# The Dietary Management of Pouchitis

## CUMULATIVE REMISSION & MAINTENANCE RATES WITH VISBIOME

The following graph shows 85% of patients with pouchitis who received the De Simone Formulation remained in remission after a year post study—significantly higher than the placebo group (6%).

When used as a medical food, in multiple studies, Visbiome and the De Simone Formulation have been shown to help patients with pouchitis reach and maintain remission, decrease bowel frequency, and/or improve their quality of life.



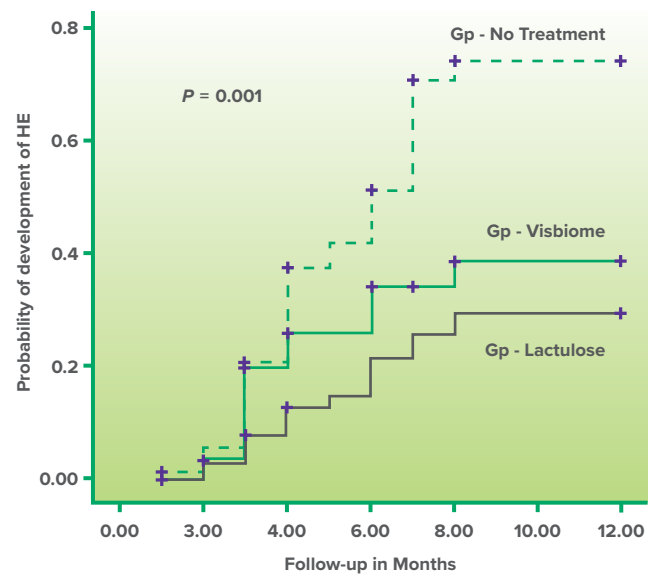
Adapted from Mimura et al 2004<sup>29</sup>

# The Dietary Management of Hepatic Encephalopathy

Hepatic Encephalopathy (HE) is associated with significant dysbiosis of the bacterial gut flora.<sup>31,32</sup> Standard drug therapy for HE is focused on modulating the gut microbiome through prebiotic and antibiotic activity.<sup>32,33</sup>

When consumed as a monotherapy or concomitantly with standard drug therapies (lactulose, rifaximin),<sup>34,35</sup> Visbiome may aid in the dietary management of dysbiosis associated with HE. Multiple controlled studies have found the De Simone Formulation in Visbiome to be associated with:

- Improved management of overt HE in patients with a prior episode of overt HE.<sup>21</sup>
- Improvement in abnormal psychometric testing vs. control
- Reduction in arterial ammonia levels comparable to lactulose.<sup>20,21</sup>



Adapted from Agrawal et al, 2012<sup>21</sup>

## NEW OPTION FOR HE

PREBIOTIC

**Lactulose** enhances beneficial “probiotic” gut bacteria such as *Lactobacilli* and *Bifidobacterium* species.<sup>32</sup>

PROBIOTIC



visbiome®

ANTIBIOTIC

**Rifaximin** is selective for beneficial species without significant changes in the overall relative abundance.<sup>32–35</sup>

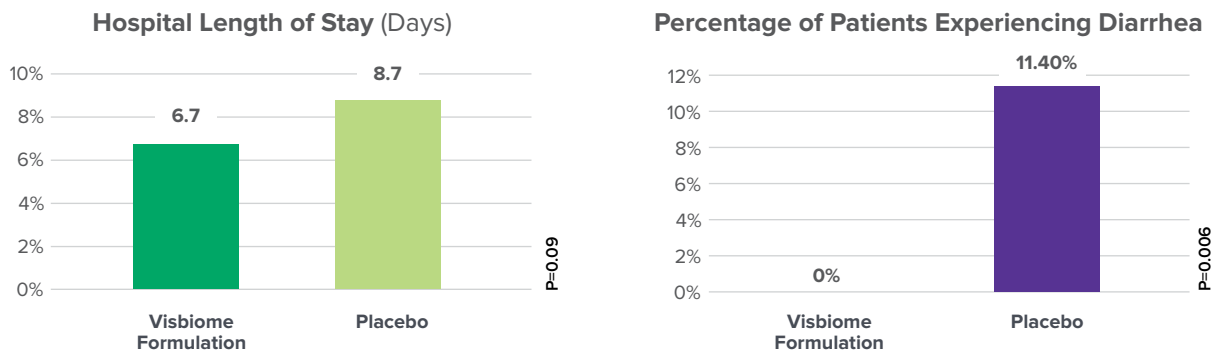
235 cirrhotic patients who had prior episodes of HE were evaluated after consuming the De Simone Formulation, lactulose or no therapy. There was a significant difference in the development HE in the probiotic vs. no treatment groups (p=0.02) and in the lactulose vs. no treatment group (p=0.001) but no difference between the probiotic group vs. lactulose (p=0.134)





## Visbiome and the dietary management of antibiotic-treated patients.

In a controlled clinical trial, the formulation in Visbiome was shown to support patients consuming Antibiotics.<sup>19</sup> None of the patients that received the De Simone Formulation while being treated with antibiotics presented with diarrhea, while 11.4% of patients that received the placebo experienced diarrhea. The length of hospitalization of the patients that received the De Simone Formulation was also shorter than patients that received the placebo; 6.7 vs 8.7 days.



**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.

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\*VSL#3<sup>®</sup> is a registered trademark and is manufactured exclusively for, VSL Pharmaceuticals, Inc. Visbiome<sup>®</sup> is manufactured exclusively for ExeGi Pharma, LLC and is not affiliated with, endorsed by, or distributed by VSL Pharmaceuticals, Inc. \*\* Visbiome's Formula is the same formulation found in VSL#3<sup>®</sup> before June 2016, known as the De Simone Formulation.