




# Comflor®

Lyophilized Concentrated Probiotic Mixture  
4.5x10<sup>11</sup> CFU / Capsule

• For Patients with Ulcerative Colitis and Pouchitis

*L. plantarum, L. casei, L. acidophilus, L. bulgaricus, B. infantis, B. longum, B. breve, S. thermophilus\**

\* Comflor® is designed and formulated according to VSL#3®

25°C  No Need  
to be Refrigerated





## Efficacy Assurance of Comflor®



1. Resistant to Gastric Acid and Bile Compounds <sup>1,2,3</sup>



2. Freeze Drying Manufacturing Method: According to The United States Pharmacopeia (USP), freeze drying maintains cell viability more than other methods during transferring or storage periods <sup>4</sup>

Global Guidelines <sup>5,6</sup>	Adults Disorder Action	Evidence / Consensus
 <b>European Crohn's and Colitis Organisation</b>	UC Induction of Remission	There is some evidence for a therapeutic benefit of probiotics when added to standard therapy to induce remission, particularly Concentrated Probiotic Mixture*.
	Prevention of Pouchitis	Concentrated Probiotic Mixture* has been shown to prevent pouchitis within the first year after surgery in a randomised, double blind, placebo-controlled study. A Cochrane systematic review reports this mixture was more effective than placebo for the prevention of pouchitis.
	Maintenance of Remission in Chronic Pouchitis	Once remission has been achieved in chronic pouchitis, treatment with the Concentrated Probiotic Mixture* helps to maintain remission.
 <b>ESPEN</b> The European Society for Clinical Nutrition and Metabolism	Induction of Remission in Mild to Moderate UC	Probiotic therapy using Escherichia coli Nissle 1917 or Concentrated Probiotic Mixture*, but not necessarily other probiotics, can be considered for use in patients with mild to moderate UC for the induction of remission. Grade of Recommendation B, Strong Consensus (92% agreement)
	UC Maintenance of Remission	Probiotic therapy should be considered for the maintenance of remission in Ulcerative Colitis. Grade of Recommendation B, Strong Consensus (96% agreement)
	Prevention of Pouchitis	The Concentrated Probiotic Mixture* may be used for primary and secondary prevention of pouchitis in patients with ulcerative colitis who have undergone Colectomy and Pouch-anal Anastomosis. Grade of Recommendation B, Strong Consensus (100% agreement)

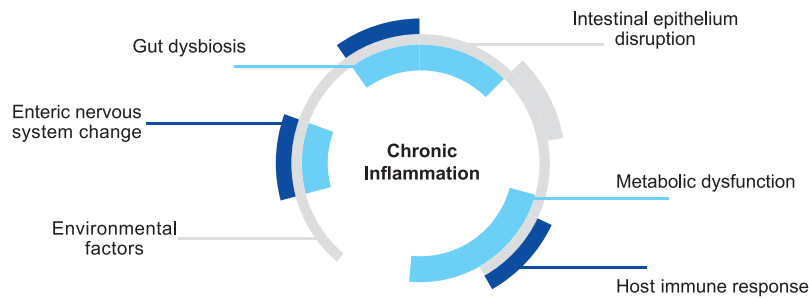
\* 450 billion bacteria (4.5 x 10<sup>11</sup> CFU) of eight different strains

## ✓ Safety Assurance of Comflor®

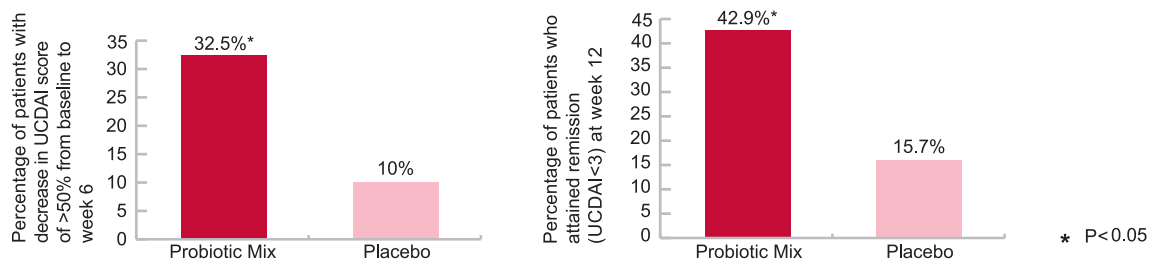


• **Antimicrobial Resistance Assessment of a Bacterial Strain Used as Probiotics:** We checked all bacterial strains for having acquired resistance to antimicrobials that is shown to be due to the acquisition of genetic determinants, according to Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA <sup>7,8</sup>

## Contributing Factors in the Development of Immune-mediated Inflammatory Disease <sup>9</sup>

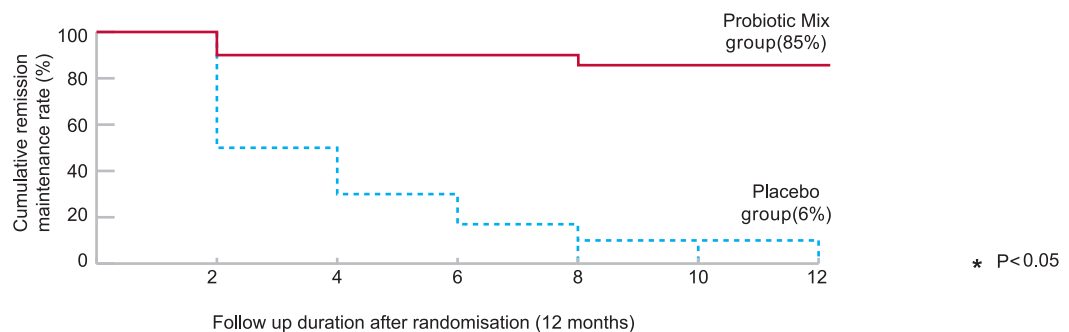


## Concentrated Probiotic Mix Achieves Clinical Responses and Remission in Mild-to-Moderately Active Ulcerative Colitis <sup>10</sup>



Ulcerative Colitis Disease Activity Index (UCDAI) score: stool frequency score, blood in the stool score, mucosal appearance, and physician's global assessment

## Concentrated Probiotic Mix Maintains Remission in Refractory Pouchitis <sup>11</sup>



### Description

Each Comflor<sup>®</sup> capsule contains 200 mg lyophilized live friendly bacterias, *Lactobacillus plantarum*, *Lactobacillus casei*, *Lactobacillus acidophilus*, *Lactobacillus bulgaricus*, *Bifidobacterium infantis*, *Bifidobacterium longum*, *Bifidobacterium breve* and *Streptococcus thermophilus* ( $4.5 \times 10^{11}$  CFU).

### Indication

Comflor<sup>®</sup> capsule is indicated in adults ( $\geq 12$  years) for:

- Inducing remission in ulcerative colitis
- Maintenance of clinical remission in ulcerative colitis
- Treatment of active pouchitis
- Maintenance of clinical remission in pouchitis

### Dosages and duration of administration

- Adults, take 1-2 capsules for ulcerative colitis (maintenance), 4-8 capsules for ulcerative colitis (acute), 2- 4 capsules for pouchitis .
- For the best results, it is recommended to take Comflor<sup>®</sup> capsule up to 2 months.

### Direction for usage

- Comflor<sup>®</sup> capsule should be used with full glass of water, with or without foods.

### Side effects

- No common side effect has been reported for the use of Comflor<sup>®</sup>capsule.
- A severe allergic reaction with this product is rare but if you experience itching, swelling, severe dizziness and respiratory problems consult with your healthcare practitioner immediately.

### Interaction with other medications and foods

- No interaction has been reported for the use of Comflor<sup>®</sup> capsule but if antibiotics are being used at the same time, take at least 2-3 hours before or after taking antibiotics.
- Comflor<sup>®</sup> capsule has no interaction with foods.

### Pregnancy and Lactation

- Probiotics are safe during pregnancy and lactation but it is better to take probiotics when needed. Consult with your healthcare practitioner about benefits and risk of probiotics during pregnancy and lactation.

### Storage condition

- Store in a cool and dry place (below 25°C). No need to be refrigerated.

### References

1. Ipek Goktepe, Vijay K. Juneja, Mohamed Ahmedna. Probiotics in Food Safety and Human Health. by Taylor & Francis Group, LLC; 2006.
2. Probiotic microorganisms-Specifications and In Vitro test methods. Iranian National Standardization Organization; 2014.
3. Colum Dunne, et al. In vitro selection criteria for probiotic bacteria of human origin: correlation with in vivo findings. Am J Clin Nutr 2001; 73(suppl):386S–92S.
4. USP-42.
5. Fernando Magro, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 1: Definitions, Diagnosis, Extra-intestinal Manifestations, Pregnancy, Cancer Surveillance, Surgery, and Ileo-anal Pouch Disorders. Journal of Crohn's and Colitis, 2017, 1–39.
6. Alastair Forbes, et al. ESPEN guideline: Clinical nutrition in inflammatory bowel disease. Clinical Nutrition 36 (2017) 321e347.
7. Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal (2007) 587, 1-16.
8. EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). Guidance on the characterization of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp.
9. Charles N. Bernstein. Gut Microbiome in Inflammatory Bowel Disease and Other Chronic Immune-Mediated Inflammatory Diseases. Inflamm Intest Dis 2017;2:116–123.
10. Ajit Sood, et al. The Probiotic Preparation, VSL#3 Induces Remission in Patients With Mild-to-Moderately Active Ulcerative Colitis. Clinical Gastroenterology and Hepatology 2009;7:1202–1209.
11. T. Mimura, et al. Once daily high dose probiotic therapy (VSL#3) for maintaining remission in recurrent or refractory pouchitis. Gut 2004;53:108–114.