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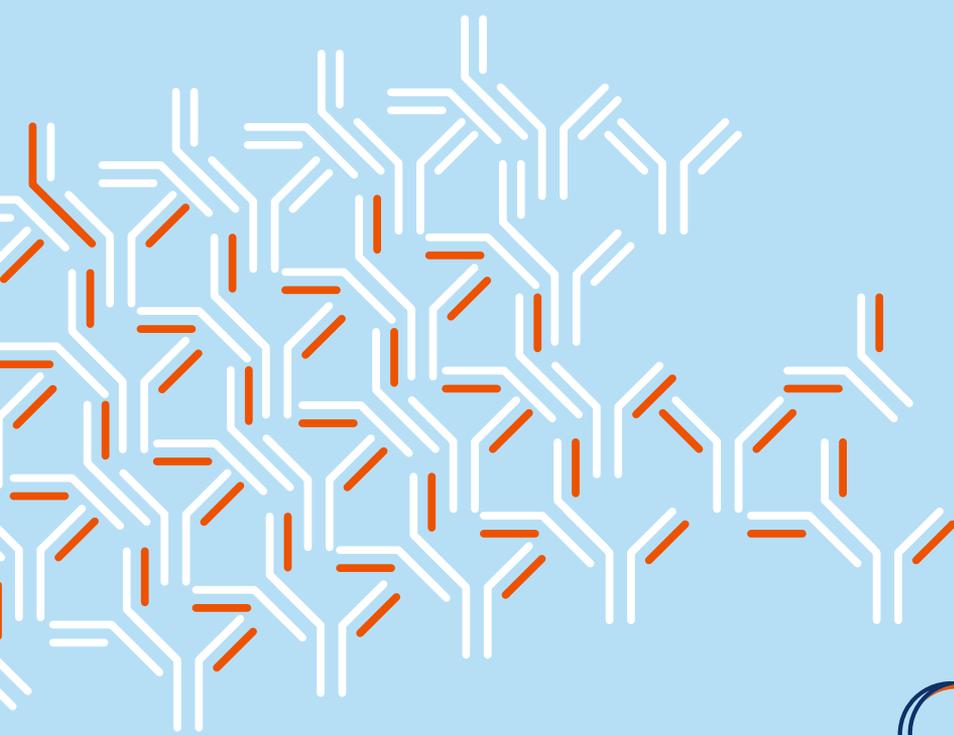
## Retrospective Case Series: IBD Patients

To view the full article: [www.ShafranIBDReprint.com](http://www.ShafranIBDReprint.com)

### Management of inflammatory bowel disease with oral serum-derived bovine immunoglobulin

Shafran I, Burgunder P, Wei D, Young HE, Klein G, Burnett BP.

**Methodology:** Single-center, retrospective chart review of 45 inflammatory bowel disease (IBD) patients (38 with Crohn's disease and 7 with ulcerative colitis) with limited to no response to traditional therapies, including anti-TNF- $\alpha$  agents, anti-inflammatory drugs, and immunomodulators. All patients experienced persistent diarrhea and diminished quality of life due to ongoing lack of symptom and disease management. Other symptoms included abdominal pain, urgency, tenesmus, and fatigue. Add-on therapy with EnteraGam<sup>®</sup> (5 g QD) was provided for nutritional management. Patients were contacted at least monthly during a 12-week period to assess response to EnteraGam<sup>®</sup> for symptom management (measured by a Likert scale [0 = none; 1 = minimal; 2 = moderate; 3 = significant; 4 = complete]). The average score of patients' responses to EnteraGam<sup>®</sup> improved across all patient demographics by Week 12 with no reported side effects.<sup>1</sup>

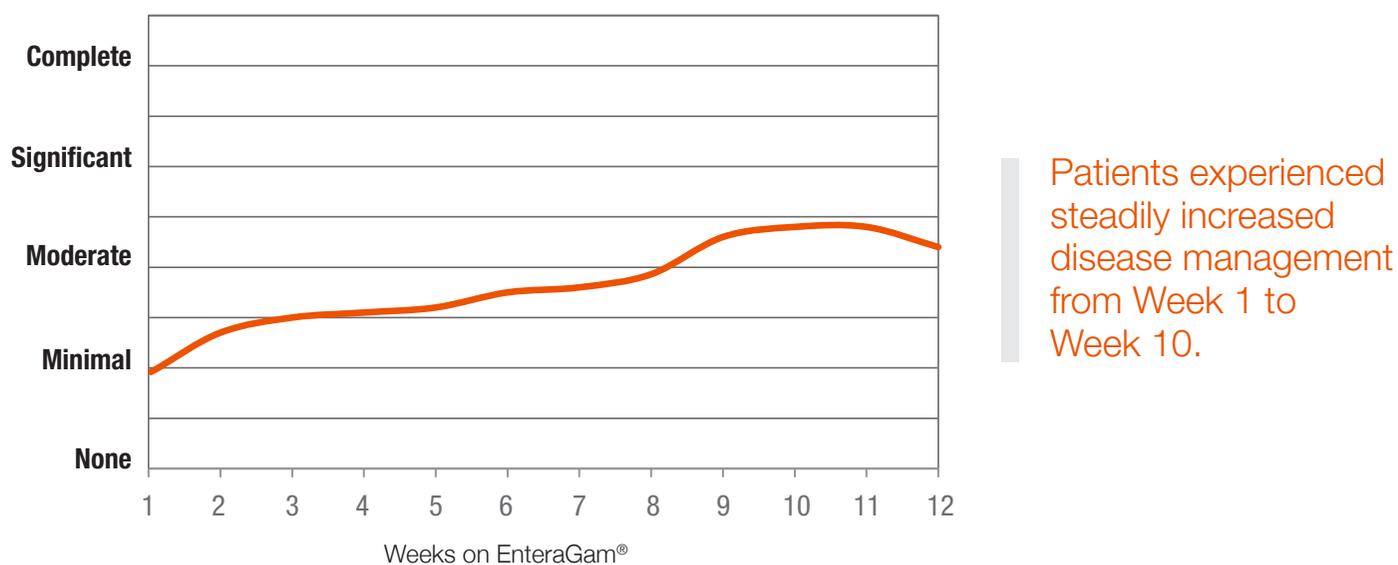


# Overall, patients showed increased, steady response to EnteraGam<sup>®</sup>

## Patients were 2.8 times more likely to report clinical improvement in symptom scores after adding EnteraGam<sup>®1,\*</sup>

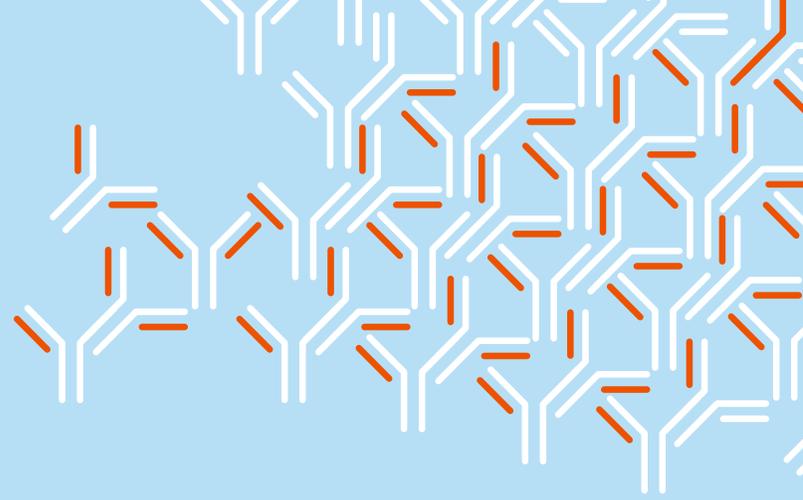
- Percentage of patients who responded to therapy with EnteraGam<sup>®</sup> increased from 49% at Week 1 to 76% at Week 12
- Patients whose conditions were refractory to biologics and other drugs for years demonstrated steadily greater management starting at Week 1 through Week 10 with one EnteraGam<sup>®</sup> packet daily (now considered a suboptimal dose for IBD patients, based on other case series evidence)

### Average Reported Improved Response of All IBD Patients (N = 45)



“The overall response to the addition of SBI [EnteraGam<sup>®</sup>] in IBD patients suggests that the longer patients are on therapy, the better their outcomes.”

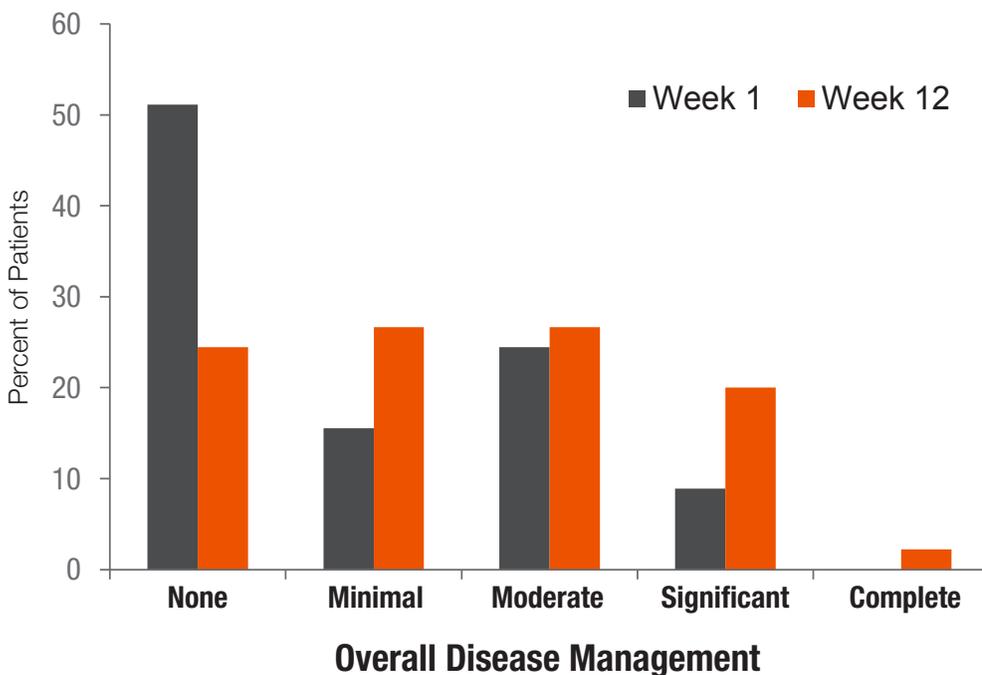
\*Based on calculated odds ratio to determine overall disease management (95% confidence interval [CI] 1.266–6.016,  $P = .011$ ).



## Patients reporting significant symptom improvement with EnteraGam<sup>®</sup> more than doubled<sup>1</sup>

- Over the 12-week period, the percent change in patients experiencing significant disease management with EnteraGam<sup>®</sup> improved from 9% to 20%

### Percent Change in Disease Management (Week 1 vs Week 12)



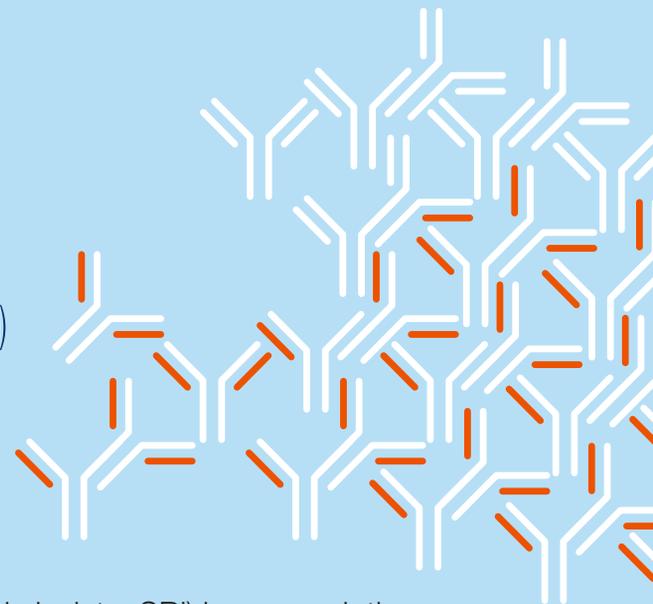
**76%** of patients had a response, ranging from minimal to complete management.

“It is possible that addition of SBI [EnteraGam<sup>®</sup>] with other therapies used concomitantly resulted in further or even synergistic benefit in these patients.”

# Conclusion<sup>1</sup>

“These results suggest that SBI [EnteraGam<sup>®</sup>] improves clinical management of IBD patients who are not fully managed on traditional therapies.”

“SBI [EnteraGam<sup>®</sup>] should be considered for the nutritional support of IBD regardless of disease activity, location, phenotype, duration, or complexity.”



## **Intended Use:**

EnteraGam<sup>®</sup> (serum-derived bovine immunoglobulin/protein isolate, SBI) is a prescription medical food product intended to provide for distinctive nutritional requirements that are unique for the clinical dietary management of specific intestinal disorders (eg, in irritable bowel syndrome with diarrhea [IBS-D], inflammatory bowel disease [IBD], and HIV-associated enteropathy). EnteraGam<sup>®</sup>, as a medical food, must be used under physician supervision.

## **Important Safety Information:**

EnteraGam<sup>®</sup> contains beef protein; therefore, patients who have an allergy to beef or any component of EnteraGam<sup>®</sup> should not take this product. The most commonly reported adverse events in clinical studies (incidence of 2%-5%) include mild nausea, constipation, stomach cramps, headache, and increased urination. EnteraGam<sup>®</sup> has not been studied in pregnant or nursing women, so the choice to administer EnteraGam<sup>®</sup> for patients who are pregnant or nursing is at the clinical discretion of the prescribing physician.

EnteraGam<sup>®</sup> does not contain any milk products such as lactose, casein, or whey. It is gluten-free, dye-free, and soy-free. EnteraGam<sup>®</sup> contains 5 g of SBI and other ingredients such as dextrose (5 g) and trace amounts of sunflower lecithin.

**Please see full Prescribing Information including contraindications.**

**Reference: 1.** Shafran I, Burgunder P, Wei D, Young HE, Klein G, Burnett BP. Management of inflammatory bowel disease with oral serum-derived bovine immunoglobulin. *Therap Adv Gastroenterol.* 2015;8(6):331-339.

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