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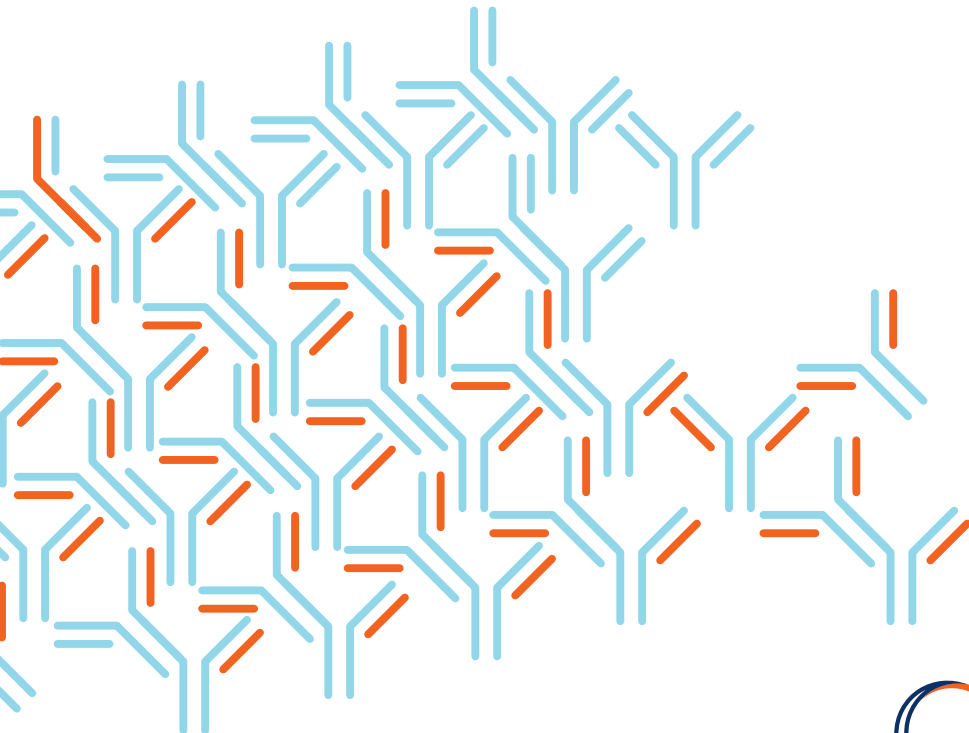
## A Clinical Series: IBS Patients

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Case series of 10 drug-refractory IBS patients who respond to oral serum-derived bovine immunoglobulin/protein isolate (SBI)

Hilal R, Mitchell P, Guerra E, Burnett B.

**Methodology:** 10 patients with chronic, symptomatic, and drug-refractory histories of irritable bowel syndrome with diarrhea (IBS-D; n=6) and IBS undefined (IBS-U; n=4) were administered 5 g/day of EnteraGam™, a medical food containing serum-derived bovine immunoglobulin/protein (SBI). Patient-reported improvement in overall IBS symptoms (ie, abdominal pain, diarrhea, gas/bloating/distention, and flatulence) was assessed after 4 weeks using a ranging scale between 0 and 100% (0-25%, 25-50%, 50-75%, and 75-100%). Patients continued taking EnteraGam™ for up to 28 weeks to assess long-term side effects.<sup>1</sup>





In as little as 2-4 weeks (average), patients taking EnteraGam™ started to experience a reduction in GI symptoms<sup>1</sup>

### Summary of Cases and Observed Response and Improvement With EnteraGam™

| Patient                                 | GI Symptoms  | Key Symptom Response After Taking EnteraGam™  | Overall Symptom Improvement |
|---|--|---|-----------------------------|
| Hispanic female, age 66 (IBS-D)         | Urgent exploding diarrhea (mainly in morning) with abdominal cramping, and fecal incontinence. | Formed bowel movements after morning meal with no urgency.  | 75-100%                     |
| African-American female, age 59 (IBS-D) | Watery stools with urgency, abdominal pain and distention, and nausea/vomiting.                | Decreased frequency, urgency, and bloating in <1 month. One watery stool first, followed by 2 soft stools per day.  | 75-100%                     |
| White male, age 63 (IBS-D)              | Abdominal pain, diarrhea, and bloating/distention.   | Improved diarrhea and bloating after 1 week (continued improvement in symptoms over 9 weeks). When patient stopped taking EnteraGam™, diarrhea and bloating returned. Reinitiation of EnteraGam™ resolved symptoms after 2 weeks. | 75-100%                     |
| White female, age 71 (IBS-D)            | Worsening epigastric pain, abdominal pain, diarrhea, and bloating/distention.                  | Significantly decreased symptoms, including diarrhea and bloating/distention.   | 75-100%                     |
| White female, age 62 (IBS-U)            | Chronic and severe abdominal pain, and bloating/distention with occasional dyspepsia.          | Significant improvement in bloating/distention.   | 75-100%                     |

Half of patients reported a 75-100% improvement in symptoms ( $P=0.002$ )

| Patient                          | GI Symptoms   | Key Symptom Response After Taking EnteraGam™   | Overall Symptom Improvement |
|----------------------------------|---|--|-----------------------------|
| Hispanic female, age 37 (IBS-U)  | Chronic abdominal pain, diarrhea, bloating/distention, and positive hydrogen breath test.                                     | Improved abdominal pain, diarrhea, and bloating/distention.  | 50-75%                      |
| White female, age 53, (IBS-U)    | Chronic abdominal pain, epigastric pain, bloating/distention, flatus, and nausea.   | Decreased abdominal pain and bloating/distention.  | 50-75%                      |
| Hispanic female, age 63, (IBS-D) | Chronic watery, non-bloody diarrhea with urgency occurring 2-3 times a day.   | Normally formed bowel movements with notably reduced urgency. Patient stopped EnteraGam™, resulting in watery loose stool several times a day. Reinitiation of EnteraGam resolved symptoms within 2 weeks. | 50-75%                      |
| Hispanic female, age 54 (IBS-U)  | Chronic abdominal pain, moderate epigastric pain after meals, nonulcer dyspepsia, and bloating/distention.                    | Significant decrease in bloating/distention.   | 50-75%                      |
| White female, age 52 (IBS-D)     | Abdominal pain, chronic diarrhea, early satiety, foul smelling gas and flatulence, bloating/distention, nausea, and vomiting. | Significant decrease in bloating in 8 weeks with continued improvement in abdominal pain, diarrhea, and bloating/distention. Patient still had recurrent nausea with vomiting.                             | 50-75%                      |

## Notable outcomes

All 10 patients, who were previously refractory to drug therapies, reported improvement in IBS symptoms with EnteraGam™ within 4 weeks. No adverse events were reported in patients who took EnteraGam™ for up to 28 weeks.

# Conclusion

“Based on the safety profile and reported outcomes in this case report, SBI [EnteraGam™] should be considered as a nutritional option for management in IBS-D and IBS-U.”



## Important Safety Information:

EnteraGam™ contains beef protein; therefore, patients who have an allergy to beef or any component of EnteraGam™ 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™ has not been studied in pregnant or nursing women, so the choice to administer EnteraGam™ for patients who are pregnant or nursing is at the clinical discretion of the prescribing physician.

EnteraGam™ does not contain any milk products such as lactose, casein, or whey. It is gluten-free, dye-free, and soy-free. EnteraGam™ 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. Hilal R, Mitchell P, Guerra E, Burnett B. Case series of 10 drug-refractory IBS patients who respond to oral serum-derived bovine immunoglobulin/protein isolate (SBI). *Open J Gastroenterol.* 2014;4:321-328.

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