In Patients with Irritable Bowel Syndrome-Mixed (IBS-M), a Novel Peppermint Oil Formulation Designed for Site Specific Targeting (PO-SST) in the Small Intestine Improves the 8 Symptoms that Comprise the Total IBS Symptoms Score (TISS)

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**Background**

Among adult patients diagnosed with IBS, a sizable proportion suffer from a mixed bowel habit pattern. Among adult patients diagnosed with IBS-M, there is no FDA approved therapy for IBS-M and it remains an unmet medical need. The mucosal barrier dysfunction has been linked to altered absorption and mucosal inflammation. This provides a biologically plausible basis to test the efficacy of anti-inflammatory compounds targeted to the mucosa and submucosa in IBS-M patients. Compounds with anti-inflammatory activity, such as the chelation component of peppermint oil (PO), may help restore homeostasis, resulting in IBS symptom improvement.

**Methods**

Subjects met Rome III criteria for IBS-M, had average daily IBS related abdominal pain of ≥4 on a 0-4 scale, and a TISS of ≥2 on a 0-4 scale. Subjects were randomly allocated to receive PO-SST (IBgard) 180 mg TID or identical placebo for 4 weeks. Primary analysis was based on the TISS score. Additional assessments included change from baseline in frequency and intensity of individual IBS symptoms.

**Results**

For all 8 IBS symptoms measured (Figures 3 and 4), the PO-SST arm had a greater reduction, compared to placebo, that was significant for abdominal pain (P=0.03) and frequency of IBS symptoms (P=0.03) with near significance (P=0.04) in the intensity of IBS symptoms (Figure 2).

**Conclusions**

After 4 weeks of treatment, the PO-SST arm demonstrated statistically significant reduction in the TISS score (P=0.03) and frequency of IBS symptoms (P=0.03) with near significance (P=0.04) in the intensity of IBS symptoms (Figure 2).

**Disclosures**

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**References**


