

**THREE-YEAR SAFETY DATA ANALYSIS INDICATES NO PATTERN OF HEARTBURN WITH IBgard®, AN ADVANCED TECHNOLOGY PEPPERMINT OIL, IN CONTRAST TO THE HEARTBURN ISSUES WITH OLDER TECHNOLOGIES**

Data from a 36-month, real-world, post-marketing study confirming the safety profile of IBgard® (PO-SST), a novel peppermint oil product in patented solid-state microspheres, is now available for review on the DDW e-poster website.

- In one of the longest-running post-marketing surveillance studies of its kind, involving an estimated 2.4 million users, data showed that IBgard® is a safe and well-tolerated option for managing IBS.
- No pattern of heartburn was seen with IBgard®. As noted in the 2018 American College of Gastroenterology (ACG) IBS Monograph<sup>1</sup>, among older, liquid-filled, “burst technology” peppermint oil products, heartburn is a common side effect. The 2018 ACG IBS Monograph called for a more distal delivery of peppermint oil.
- IBgard®, with its novel, triple-coated microsphere technology, provides more distal delivery by avoiding release in the stomach, by targeting the small intestine, and by then releasing over 4 hours.<sup>5</sup> It thus avoids the problems of older PO products, particularly heartburn.

BOCA RATON, Fla. – IM HealthScience® (IMH) today announced that the Irritable Bowel Syndrome Safety Update at 36 months (IBSSU36) study is now available for review as an e-poster on the Digestive Disease Week® (DDW) e-poster and e-paper web site:

<https://ddw.apprisor.org/epsAbstractDDW.cfm?id=1>

The peer-reviewed and published e-poster is titled, “36 MONTH SURVEILLANCE DATA CONFIRMS SAFETY PROFILE OF A NOVEL PEPPERMINT OIL FORMULATION FOR IBS (PO-SST).”

IBSSU36 is a real-world safety surveillance study reporting on the safety and tolerability profile of IBgard® and was conducted to determine if any issues, including heartburn or anal burning, were surfacing as a side effect. In the American College of Gastroenterology 2018 IBS Monograph, heartburn was noted as a side effect of conventional peppermint oil preparations.<sup>1</sup> In the same 2018 Monograph, it was noted that heartburn is an issue

because the IBS population has four times the heartburn as the general population.<sup>3</sup> The authors of the study poster note that older, liquid-filled, burst technology peppermint oil products showed that as high as 26 to 29.7% of patients experience adverse events (AEs), heartburn being the most common.<sup>4,5</sup> A key finding of this study is that no pattern of heartburn or anal burning was observed during the 36-month timeframe with IBgard®.

Commenting on the findings of the study, Brian Lacy, M.D., PhD, FACP, a leading gastroenterologist at the Mayo Clinic and the lead author of the study, said, “We know that peppermint oil improves the symptoms of IBS, but many older peppermint oil products can cause unwanted side effects, such as heartburn. IBgard®, with its targeted delivery to the small intestine, was shown in this study to avoid any pattern of heartburn or anal burning, even after 36 months and an estimated 2.4 million patients had taken the product.”

The 3-year data safety analysis also confirmed that no reports of serious adverse events and no significant pattern of non-serious adverse events had emerged. It is estimated that over 2.4 million individual patients used the product during the three-year surveillance period of October 5, 2015, to September 30, 2018.

“We are gratified that this important post-marketing study has been peer-reviewed and then published via a poster on the DDW website,” said Michael Epstein, M.D., FACP, AGAF, a leading gastroenterologist and Chief Medical Advisor for IM HealthScience. “It is important for health care professionals and patients to be aware of the excellent safety and tolerability profile of IBgard®.”

**About IBSSU36**

The Irritable Bowel Syndrome Safety Update at 36 Months (IBSSU36) is a real-world surveillance study reporting on the safety and tolerability profile of IBgard® among an estimated 2.4 million individual patients who used the product. An independent call center with pharmacovigilance-trained health care personnel in accordance with U.S. Food and Drug Administration (FDA) and global regulatory guidelines on properly reporting events was retained to receive and record IBgard® customer questions, product issues, and adverse

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events. The adverse events for this study were collected and processed from October 5, 2015, to September 30, 2018. An analysis of the data by reviewers showed that there were no reported serious adverse events associated with the use of IBgard® during this time frame.

**About IBgard®**

IBgard® is a medical food specially formulated for the dietary management of IBS. IBgard® capsules contain solid-state microspheres of peppermint oil, including its principal component l-Menthol, plus fiber and amino acids (from gelatin protein), in a unique delivery system.

With its patented Site-Specific Targeting (SST®) technology pioneered by IM HealthScience, IBgard® capsules release Ultramen®, an ultra-purified peppermint oil, quickly and reliably to the small intestine, where it is designed to release over 4 hours in a sustained release manner.<sup>2</sup> The food nutrients in IBgard® (peppermint oil along with fiber and amino acids) may help reduce the low-grade, localized, often temporary, reversible inflammation found in some IBS patients and help normalize gut mucosal barrier function. Additionally, peppermint oil has been shown to help normalize intestinal transit time.<sup>6</sup>

IBgard® previously was studied in a pivotal, randomized, placebo-controlled, double-blinded, multi-center trial called **IBSREST™** (Irritable Bowel Syndrome Reduction Evaluation and Safety Trial). Patients suffering from IBS-D and IBS-M (alternating IBS-C and IBS-D) were included in the study. This important study was presented at DDW in May 2015 to a standing-room-only audience. The study findings were accepted after peer review and then published in the February 2016 issue of Digestive Diseases and Sciences, a leading, peer-reviewed scientific journal.<sup>2,††</sup> The data showed that IBgard® demonstrated a statistically significant reduction in the Total IBS Symptom Score (TISS) in as early as 24 hours and at four weeks. The TISS represents a composite score of eight individual IBS symptoms.<sup>7</sup> In a secondary analysis, IBgard® also showed efficacy among IBS-M patients.<sup>8</sup> IBS-M has been observed to represent up to 74% of IBS patients.<sup>9,†</sup>

Additionally, results from a real-world observational study of 285 patients who took

IBgard®, called **IBSSACT™** (Irritable Bowel Syndrome Adherence and Compliance Trial), showed that there was a high level of patient satisfaction with the product even among those patients taking several capsules on a daily basis. One out of two IBS patients taking IBgard® needed only 1 to 2 capsules per day to obtain individualized relief from IBS symptoms. In addition, 75 percent of the patients felt relief of abdominal pain, discomfort and/or bloating within 2 hours, while 95 percent of patients reported relief within 24 hours after taking IBgard®.<sup>10,†</sup>

Currently, there are limited options for patients with IBS that offer effective and rapid relief, especially during flare-ups. Also, no Rx drug has been approved for IBS-M.

Over 10,000 healthcare practitioners, including 3,000 gastroenterologists, are estimated to have already used IBgard® for their patients. For five consecutive years, IBgard® continues to be the #1 recommended peppermint oil for IBS among gastroenterologists nationwide by an overwhelming margin.<sup>11</sup>

Like all medical foods, IBgard® does not require a prescription, but it must be used under medical supervision. Only a physician can confirm suspected IBS. Many physicians are now recommending taking IBgard® 30-90 minutes before a meal, as it enables the supportive effect of IBgard® to start as early as possible.

IBgard® is available to patients in the digestive aisle at most Walmart, Target, CVS/pharmacy, Walgreens, and Rite Aid stores nationwide as well as in grocery stores across the country and on Amazon.

**About IM HealthScience®**

IM HealthScience® (IMH) is the innovator of IBgard® and FDgard® for the dietary management of Irritable Bowel Syndrome (IBS) and Functional Dyspepsia (FD), respectively. In 2017, IMH added Fiber Choice®, a line of prebiotic fibers, to its product line via an acquisition. The sister subsidiary of IMH, Physician's Seal®, also provides REMfresh®, a well-known continuous release and absorption melatonin (CRA-melatonin) supplement for sleep. IMH is a privately held company based in Boca Raton, Florida. It was founded in 2010 by a team of highly experienced

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pharmaceutical research and development and management executives. The company is dedicated to developing products to address overall health and wellness, including conditions with a high unmet medical need, such as digestive health. The IM HealthScience advantage comes from developing products based on its patented, targeted-delivery technologies called Site-Specific Targeting (SST®). For more information, visit [www.imhealthscience.com](http://www.imhealthscience.com) to learn about the company, or, [www.IBgard.com](http://www.IBgard.com)®, [www.FDgard.com](http://www.FDgard.com), [www.FiberChoice.com](http://www.FiberChoice.com), and [www.REMfresh.com](http://www.REMfresh.com).

### About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers, and academics in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW 2020 was scheduled for May 2-5, 2020, in Chicago, but was canceled due to COVID-19 and the nationwide lockdown. More information can be found at [www.ddw.org](http://www.ddw.org).

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11. IQVIA. ProVoice Survey IBgard Is the #1 Gastroenterologist Recommended Peppermint Oil For Patients with IBS; 2019 [Among gastroenterologists who recommended peppermint oil for IBS].

††Based on **IBSREST™** (Irritable Bowel Syndrome Reduction Evaluation and Safety Trial), a randomized, placebo-controlled trial in 72 IBS patients. Patients taking IBgard on a daily and proactive basis experienced a statistically significant reduction versus placebo in the total IBS symptoms score (TISS), including abdominal pain and discomfort, at 24 hours, with continued and expanding benefits at 4 weeks. Cash BD, Epstein MS, Shah SM. A novel delivery system of peppermint oil is an effective therapy for irritable bowel syndrome symptoms. After peer review, published in *Dig Dis Sci*. 2016;61(2):560-571. doi:10.1007/s10620-015-3858-7.

§**IBSSACT™** (Irritable Bowel Syndrome Adherence and Compliance Trial), a real-world, patient-reported outcomes trial published in a peer-reviewed journal, showed IBgard efficacy in 1-2 hours. Cash BD, Epstein MS, Shah SM. Patient satisfaction with IBS symptom relief using a novel peppermint oil delivery system in a randomized clinical trial and in the general population. After peer review, published in *Int J Dig Dis*. 2016;2(2):1-5.

†Individual results may vary.

IBgard is protected by U.S. patents No: 8,808,736; 9,192,583; 9,393,279; 9,572,782; 9,707,260; 9,717,696; and 8,895,086. Additional patents are pending in the United States and other jurisdictions.

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