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**FILE: ■Peppermint (*Mentha x piperita*) Oil
■Irritable Bowel Syndrome
■Mintoil®**

HC 080679-345

Date: January 31, 2008

RE: Peppermint Oil Capsules Reduce Irritable Bowel Syndrome Symptoms

Cappello G, Spezzaferro M, Grossi L, Manzoli L, Marzio L. Peppermint oil (Mintoil®) in the treatment of irritable bowel syndrome: a prospective double blind placebo-controlled randomized trial. *Dig Liver Dis.* Jun 2007;39(6):530-536.

The symptoms of irritable bowel syndrome (IBS), including abdominal distension, bloating, abdominal pain, constipation, and diarrhea, can be confused with the symptoms of other gastrointestinal disorders. It has been suggested that illnesses with similar symptoms should be ruled out in IBS clinical trials. Therefore, the authors of this clinical trial on peppermint oil and IBS have excluded patients with small intestinal bacterial overgrowth, lactose intolerance, and celiac disease.

Patients with IBS symptoms meeting the Rome II criteria with a negative lactose breath test, negative lactulose breath test, and without celiac disease were included in this double-blind, placebo-controlled clinical trial. They were randomized to receive 2 capsules twice daily of a mint-flavored placebo or enteric-coated peppermint (*Mentha x piperita*) oil capsules (225 mg Mintoil®, Cardiogroup, Rome, Italy) for 4 weeks. The capsules were designed to open in the intestines and were taken 1 hour before meals to prevent premature opening in the stomach. The patients' symptoms, including abdominal bloating and pain, diarrhea, constipation, pain at evacuation, urgency of bowel movement, sense of incomplete evacuation, and passage of gas or mucus, were rated on a scale of 0-4 (intensity: absent-most severe; frequency: absent-3 times/week). The symptoms were assessed at baseline, week 4, and 4 weeks after the end of treatment (week 8).

A total of 57 patients began the trial and 3 from each group did not return for the final examination. An additional patient withdrew from the peppermint oil group due to severe heartburn and a minty taste, probably due to the patient chewing the capsules or to premature opening of the capsules in the stomach. This left 50 patients 24 in the peppermint oil group and 26 in the placebo group. At baseline, there was no significant difference

between the IBS symptoms of the 2 groups. At the end of 4 weeks of treatment, a significantly greater number of patients in the peppermint oil group experienced a greater than 50% reduction in symptoms, compared with the placebo group in both the intention to treat (ITT) and per protocol (PP) group analyses. Both the peppermint oil group and the placebo group experienced significant reductions in total IBS symptoms at week 4 ($P < 0.01$ and $P < 0.05$). This effect persisted in the peppermint oil group 4 weeks after treatment ended (week 8, $P < 0.05$), but not in the placebo group. Furthermore, the peppermint oil group experienced significantly fewer total IBS symptoms compared with the placebo group at week 4 and week 8, as evidenced by total IBS symptoms scores ($P < 0.05$ for both).

These results indicate that 4 weeks of treatment with peppermint oil capsules is superior to a placebo in the treatment of IBS symptoms. In addition, the beneficial effect of peppermint oil persists 4 weeks after treatment has ended, possibly due to antibacterial actions of peppermint oil on enteric bacteria. This beneficial effect may also be mediated through the relaxant effects of peppermint oil on smooth muscle tissue, which may help to alleviate both the constipation and diarrhea associated with IBS. The placebo also reduced diarrhea and bloating in this study, possibly due to the effects of the maltodextrin included in the placebo capsules. Future clinical studies with longer treatment periods are needed to confirm the results of this study. The authors suggest that the mixed results of prior studies¹ may be due to flawed study designs and the possible inclusion of patients with illnesses other than IBS but with similar symptoms, such as celiac disease, lactose intolerance, and small intestinal bacterial overgrowth.

—*Marissa N. Oppel, MS*

Reference

¹Grigoleit HG, Grigoleit P. Peppermint oil in irritable bowel syndrome. *Phytomed.* 2005; 12: 601-606.

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