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MIRALAX™ POLYETHYLENE GLYCOL 3350, NF POWDER FOR SOLUTION: THE #1 PRESCRIBED LAXATIVE

Since its initial introduction to the marketplace in 1999, **MiraLax™** has been the #1 prescription laxative available, as reported in IMS Health (*1*). MiraLax (polyethylene glycol 3350, NF powder for solution) has been the first new Rx laxative in 23 years for the treatment of occasional constipation. Nearly a decade of research, development, and clinical trials has proven that prescription MiraLax therapy is safe and effective. MiraLax is tasteless and gritless, and it quickly dissolves in water, juice, soda, coffee, or tea. The daily dosage need not be increased to maintain efficacy during the two-week therapy. MiraLax is an osmotic agent that softens the stool and increases the frequency of bowel movements by retaining water in the stool. The action of the osmotic agent targets only the stool, not the colon. Because it is not fermented, cramping and gas are minimal. Safe, effective relief begins in two to four days. For consumer convenience, MiraLax is available in a 255-gram bottle, 527-gram bottle, or 17-gram single dose (12 packets per carton).

Constipation is the most common gastrointestinal complaint in the United States. More than 4 million people have frequent constipation, a prevalence of about 2%. Constipation accounts for an estimated 2.5 million physician visits per year. Our busy, modern lifestyles may be responsible for most cases of constipation: not eating enough fiber or drinking enough water, not getting enough exercise, and not taking the time to respond to an unmistakable urge to defecate. Emotional and psychological problems can contribute to the problem. Persistent, chronic constipation also may be a symptom of more serious conditions, including irritable bowel syndrome, colorectal cancer, diabetes, Parkinson's disease, multiple sclerosis, and depression.

In one clinical study, patients with less than three bowel movements per week were randomized to MiraLax, 17 grams, or placebo for 14 days. An increase in bowel movement frequency was observed for both treatment groups during the first week of treatment. MiraLax was statistically superior to placebo during the second week of treatment. In another study, patients with three bowel movements or less per week and/or less than 300 grams of stool per week were randomized to two-dose levels of MiraLax or placebo for 10 days. Success was defined by an increase in bowel movement frequency and daily stool weight. For both parameters, superiority of the 17-gram dose of MiraLax over placebo was demonstrated. According to Jack DiPalma, MD, Director of Gastroenterology at the University of South Alabama College of Medicine, "Remedies such as bulk laxatives are typically not well tolerated, lubricants have been generally ineffective, and stimulants can cause cramping. MiraLax is an osmotic agent that has been highly effective and extremely well tolerated by patients over the last several years while it has been prescribed—it is the first line of defense

for idiopathic constipation." Rapid onset of action (between 24 and 48 hours) makes an osmotic a good choice for patients who have constipation that fails to respond to bulk and saline laxatives.

MiraLax is indicated for the treatment of occasional constipation. This product should be used for 2 weeks or less, or as directed by physician. The recommended daily dosage of MiraLax is 17 grams of powder, taken as needed or as directed by a physician. MiraLax should be taken by mouth after being dissolved with 8 ounces of water, juice, soda, coffee, or tea. MiraLax has no discernible taste; it can be taken at any time, either on a full or empty stomach. Two to four days may be required to produce a bowel movement after beginning MiraLax treatment. Most common adverse events are nausea, abdominal bloating, cramping, and flatulence. MiraLax is contraindicated in patients with known or suspected bowel obstruction and allergy to polyethylene glycol. Warnings: symptoms suggestive of bowel obstruction should be ruled out before initiating MiraLax therapy. Precautions: patients should be evaluated for bowel obstruction or metabolic disorders. Prolonged, frequent or excessive use of MiraLax may result in electrolyte imbalance and dependence on laxatives.

MiraLax was developed and commercialized by **Braintree Laboratories**, **Inc.** (Braintree, MA), a manufacturer and marketer of high-quality prescription pharmaceuticals. Braintree Laboratories, Inc. was founded in 1982 and strives to bring value to the healthcare marketplace by continuously developing and successfully marking innovative pharmaceutical technologies that enhance patients' quality of life. From the start, the company quickly established itself as a leader in niche product markets, specifically focusing on the fields of gastroenterology and nephrology. Braintree Laboratories, Inc. currently has 3 product lines in the U.S. markets, all of which are prescription medications, and holds leadership positions in two therapeutic categories: gastrointestinal lavages and prescription laxatives. The company is currently pursuing additional indications for its products. Braintree Laboratories, Inc. is a fully integrated pharmaceutical company maintaining its own manufacturing facilities, warehousing operations, and sales and marketing divisions and a pioneering research and development team. Braintree's mission is to supply healthcare professionals and their patients with continuously innovative and quality products that provide superior value.

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> *Jack DiPalma, MD*

For more information concerning MiraLax, contact a Braintree representative at DDW, booth, #2951, or visit the product Web site at www.miralax.com.

Reference:

1. IMS Health. National Prescription Audit, January 2001-December 2003, based on TRxs.