

# OTC polyethylene glycol 3350 and pharmacists' role in managing constipation

John R. Horn, Maria Marzella Mantione, and John F. Johanson

## Abstract

**Objectives:** To define constipation, assess the pharmacist's role in identifying and treating constipation, and review clinical evidence for the efficacy, safety, and tolerability of polyethylene glycol (PEG) 3350 (MiraLAX—Merck Consumer Care), an osmotic laxative now available over the counter (OTC), across a variety of patient populations routinely encountered in pharmacy settings.

**Data sources:** Systematic PubMed search of the primary literature for constipation treatment guidelines and clinical trial results for PEG 3350.

**Data synthesis:** Pharmacists have a unique role in assisting patients with identifying and managing constipation. Multiple controlled clinical trials have established the efficacy, safety, and tolerability of PEG 3350 at its recommended dose of 17 g once daily. On the basis of this evidence, various professional groups have recommended PEG 3350 for use in improving stool frequency and consistency in patients with constipation. PEG 3350 is approved for short-term use, including treatment of constipation caused by medications.

**Conclusion:** Pharmacists can play an important role in managing constipation with OTC agents. Compared with other available OTC agents, PEG 3350 can be recommended to patients suffering from constipation on the basis of a large body of clinical evidence supporting its efficacy and safety, as well as the high patient acceptance shown for its palatability and once-daily dosing.

**Keywords:** Constipation, polyethylene glycol 3350, laxatives, lactulose, polypharmacy.

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Pharmacists play an important role in helping patients manage constipation. They may be the first or only health professional consulted about constipation, as most patients initially self-treat before visiting a physician.<sup>1,2</sup> Among their key roles, pharmacists can identify the medications that are likely to cause constipation, alert patients about potential interactions between laxatives and other medications, and, when necessary, recommend consultation with a physician.

Pharmacists can also help patients decide which over-the-counter (OTC) treatments to use, what results to expect, and when to expect them. It is important for patients to understand that many conditions can cause constipation and that a thorough medical history and physical examination may be necessary to rule out secondary, treatable causes.

Constipation is a common symptom that may occur intermittently, but for many patients, it can be a chronic condition for which OTC treatments are an important component of management.<sup>3</sup> If it lasts for a prolonged period (usually >3 months), constipation is considered chronic, and no specifically approved OTC treatments exist for chronic constipation. Pharmacists should not recommend self-treatment of constipation for more than 7 days.

In a survey of U.S. patients with chronic constipation, 80% reported trying OTC treatments for constipation and 35% re-

ported trying prescription medications.<sup>2</sup> Of respondents, 70% reported having constipation symptoms for at least 2 years (mean 4.2 years) and 76% considered their symptoms extremely, very, or somewhat bothersome. Nevertheless, only 25% had sought physician care for constipation within the previous year. In a 2008 survey, 40% of U.S. adults with constipation reported using laxatives when symptoms occurred.<sup>4</sup> Fiber was the most common laxative used, but 79% of patients were not satisfied with the predictability of its effect and 66% did not believe that it relieved their symptoms completely.<sup>2</sup>

Recent clinical research, including both short- and long-term clinical trials, has confirmed the efficacy and tolerability offered by polyethylene glycol (PEG) 3350 (MiraLAX—Merck Consumer Care), an osmotic laxative that became available OTC in 2007.

## Objectives

The objectives of this review were to define constipation, explore the pharmacist's role in its identification and management, and describe the safety and effectiveness of PEG 3350 OTC in its treatment across a broad variety of patient populations routinely encountered in pharmacy settings. To identify appropriate literature for review, a PubMed search was undertaken in early 2010 using the following search terms: *constipation, laxatives, polyethylene glycol 3350, OTC, docusate, psyllium, senna, and bisacodyl*. The search was limited to human studies in English.

## Identifying and defining constipation

Epidemiological studies provide prevalence estimates for constipation ranging from 2% to 27% in the North American adult population.<sup>5</sup> This wide range in prevalence reflects the different definitions, methods, and patient populations used across studies. In general, studies show that constipation occurs more frequently in women than in men (2.2 times more often on average) and more commonly in older than in younger adults.<sup>5,6</sup> However, the sex-related difference in prevalence tends to decline with increasing age.<sup>7</sup>

Higher prevalence estimates are typically seen when patients self-report symptoms. When asked, patients commonly describe constipation or its symptoms as the need for excessive straining, hard stools, infrequent bowel movements, inability to defecate when desired, abdominal discomfort, or a sensation of incomplete evacuation after bowel movements.<sup>2,8</sup> Traditionally, health care providers have considered three or fewer bowel movements per week to indicate the presence of constipation, but this criterion, based on patient self-reporting, fails to identify at least 70% of patients who actually have constipation.<sup>9</sup>

A general lack of agreement on definitions of constipation and the importance of subjective symptoms led to the consensus development of diagnostic criteria for functional constipation, known as the Rome criteria.<sup>10–12</sup> Based on these criteria, functional constipation is defined by the presence of objective and subjective symptoms that may or may not be related to a known physiological dysfunction of the gastrointestinal tract (Table 1).<sup>12</sup> These criteria, first proposed in 1994 (termed

### At a Glance

**Synopsis:** Pharmacists have an important role in helping patients to identify and manage constipation. At its recommended dose of 17 g once daily, the efficacy, safety, and tolerability of polyethylene glycol (PEG) have been established in multiple controlled clinical trials. The only agent to receive a grade A recommendation from the American College of Gastroenterology (ACG), PEG 3350 is convenient (once daily, dissolved in 4–8 oz water or a beverage of choice) and its lack of odor, color, and taste makes it palatable and acceptable to patients of all ages.

**Analysis:** Many over-the-counter laxatives are available, including osmotic laxatives other than PEG, bulk-forming laxatives, stimulant laxatives, stool softeners, and emollients. Pharmacists often recommend the stool softener docusate for treating constipation, but the ACG Task Force found insufficient data to support its effectiveness. Because OTC laxatives differ in onset of action, pharmacists must help patients understand what to expect after they start using a specific product. Bulk laxatives typically have an onset within 2 to 3 days, whereas oral stimulant laxatives generally produce effects within 6 to 12 hours. At its recommended dose, PEG 3350 generally leads to a bowel movement within 24 to 72 hours. Pharmacists must also consider constipation as it pertains to specific populations (e.g., the elderly, children, pregnant women) and situations (e.g., medication-induced constipation).

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