

From: Bayer Consumer Health



Dear Healthcare Professional:

Because you are a valued partner, we are informing you about an important development for prescription laxatives that will affect some of your patients.

The US Food & Drug Administration (FDA) has withdrawn approval of the abbreviated new drug applications (ANDAs) for single-ingredient prescription PEG 3350 laxative products, effective November 2, 2018.

The FDA has determined that there is **no “meaningful difference” between single-ingredient prescription PEG 3350 and OTC PEG 3350 products**; therefore, their simultaneous marketing is prohibited according to requirements of Federal Food, Drug, and Cosmetic (FD&C) Act §503(b).

PEG 3350 laxatives have been available both by prescription (generic) and OTC (MiraLAX® and generic). While initially available only by prescription, MiraLAX was approved by the FDA for OTC use in 2006, recognizing it as a **safe and effective OTC treatment for occasional constipation**.

Due to the FDA ruling, the availability of prescription PEG 3350 inventories is uncertain. Additionally, prescription PEG 3350 may be blocked through pharmacy formulary networks. Once these prescription products are no longer available, **patients will be responsible for purchasing PEG 3350 over the counter**.

There may be some confusion regarding this ruling, and there may be an increased demand for OTC PEG 3350 products, including MiraLAX—the #1 doctor-recommended laxative. In order to help support your patients during this transition, Bayer is taking the following steps:

- **Providing free samples and high-value coupons** to support patients as they transition to MiraLAX
- **Reaching out to healthcare professionals and pharmacists** to educate them on the FDA ruling
- **Working directly with you** to help make this process as easy as possible for your patients

Our goal is to make MiraLAX easily accessible and to instill confidence in your patients that they are receiving the same medication they had before. Not only is MiraLAX the **same, original prescription strength**, but it is also the **doctor-recommended, patient-approved** treatment for relief of occasional constipation.



Start with MiraLAX

- ✓ **AGA guidelines recommend PEG laxatives** as a first-line treatment for constipation¹
- ✓ **#1 recommended laxative by pharmacists,* doctors, and GIs**
- ✓ **96%** patient satisfaction rate²

Access **FREE** samples and coupons [here](#)

AGA=American Gastroenterological Association.

*Pharmacy Times Survey of Pharmacists' OTC Recommendations, 2018.

References: 1. Bharucha AE, Dorn SD, Lembo A, Pressman A; American Gastroenterological Association. American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013;144(1):211-217. 2. Survey of 672 consumers, August 2017, Bayer Consumer Health.

Use as directed.

The Bayer Cross, MiraLAX, and the MiraLAX Pink Cap are registered trademarks of Bayer.

© 2018 Bayer November 2018 1203-PP-MLX-BASE-US-0535

