FDA Required REMS Safety Information for Alosetron Tablets

**Important Safety Update**

The FDA has required this safety update as part of the Alosetron REMS Program to inform you that the Alosetron REMS Program **has changed** from the previous program.

**ENROLLED Prescriber Actions:**
- You are no longer required to affix prescribing program stickers to written prescriptions for alosetron
- You may prescribe alosetron electronically

**NON-ENROLLED Prescriber Actions:**
- Review the Alosetron REMS Program Training Kit and complete the Alosetron REMS Program Prescriber Completion Training Form which can be found at [www.AlosetronREMS.com](http://www.AlosetronREMS.com).
- You can also submit the enclosed form by fax to 1-800-535-6805.

You will find the Alosetron REMS Program Training Kit enclosed. The Training Kit is also available online at [www.AlosetronREMS.com](http://www.AlosetronREMS.com) or you can request the Training Kit by calling the Alosetron REMS Program at 1-844-267-8675.

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information about the risks of alosetron is enclosed.

**Summary of Changes to the REMS Program**
- Prescribers are **no longer** required to affix prescribing program stickers to written prescriptions for alosetron
- Pharmacies are **no longer** required to only dispense alosetron for a paper prescription with an affixed prescribing program sticker.

*Electronic prescriptions are now allowed*

- Patients are no longer required to complete and submit a Patient Acknowledgment Form. Instead, a Patient Education Sheet is available for the prescriber to discuss with the patient.
**Indication:**
Alosetron is a selective serotonin 5-HT3 antagonist indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have chronic IBS symptoms (generally lasting 6 months or longer), had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and not responded adequately to conventional therapy.

Severe IBS includes diarrhea and 1 or more of the following:
- frequent and severe abdominal pain/discomfort
- frequent bowel urgency or fecal incontinence
- disability or restriction of daily activities due to IBS

Please visit [www.AlosetronREMS.com](http://www.AlosetronREMS.com) for more information.

This letter does not contain the complete safety profile for alosetron. Please see the Prescribing Information and Medication Guide, enclosed.

**Reporting Adverse Events**
You are encouraged to report all suspected adverse events associated with alosetron to the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or 1-800-FDA-1088 or to the Alosetron REMS Program at 1-844-267-8675.

Sincerely,

The Alosetron REMS Program