To: Prescriber Name
From: Alosetron REMS Program
Phone: 1-844-267-8675 Fax: 1-800-535-6805
Date: Current Date

Dear Prescriber Name,

The Alosetron REMS Program is an FDA mandated Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of alosetron outweigh the risks. Our records indicate that you have prescribed alosetron without having completed training in the Alosetron REMS Program. The Alosetron REMS Program states that you should complete training prior to prescribing alosetron.

To support your training in the Alosetron REMS Program, the following Training Kit materials are enclosed:

- Alosetron REMS Program Prescriber Education Slide Deck
- Alosetron REMS Program Safety Information Fact Sheet for Prescribers
- Alosetron REMS Program Patient Education Sheet
- Prescriber Completion of Alosetron REMS Program Training Form

The Training Kit is also available online at www.AlosetronREMS.com or you can request the Training Kit by calling the Alosetron REMS Program at 1-844-267-8675.

To become trained in the Alosetron REMS Program, review the training materials listed above, complete the Prescriber Completion of Alosetron REMS Program Training Form, and fax it to the program at 1-800-535-6805.

Alternatively, you can complete training on the Alosetron REMS Program website at www.AlosetronREMS.com.

REMS Safety Information for Alosetron Tablets

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

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 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, or 1-800-FDA-1088 or to the Alosetron REMS Program at 1-844-267-8675.

Sincerely,

The Alosetron REMS Program