Risk Evaluation and Mitigation Strategy (REMS)

Shared System for Alosetron

Selective 5-HT₃ antagonist

I. GOAL(S):

The goals and objectives of the Alosetron REMS Program are to mitigate the risks of ischemic colitis (IC) and serious complications of constipation (CoC) associated with alosetron hydrochloride (hereinafter, referred to as alosetron) by:

- Informing prescribers of alosetron about:
  - the serious risks of IC and serious CoC associated with alosetron
  - the importance of understanding that alosetron should only be used in severely affected diarrhea-predominant irritable bowel syndrome patients for whom the benefits exceed the risks.
  - the importance of counseling patients about the risks of IC and serious CoC
- Informing patients about the risks of IC and CoC and actions to take should they experience early warning signs and symptoms of these risks.

II. REMS ELEMENTS:

A. Elements to Assure Safe Use
1. **Training will be provided to healthcare providers who prescribe alosetron.**

   a. The Alosetron Sponsors will ensure that training provided to healthcare providers who prescribe alosetron includes information on the serious risks of IC and CoC associated with alosetron, the importance of understanding that alosetron should only be used in severely affected diarrhea-predominant irritable bowel syndrome patients for whom the benefits exceed the risks, and the importance of counseling patients about the risks of IC and serious CoC, using the Alosetron Prescribing Information and the following materials in the REMS Training Kit:

      i. REMS letter to Healthcare Providers
      ii. Alosetron REMS Program Prescriber Education Slide Deck
      iii. Alosetron REMS Program Safety Information Fact Sheet for Prescribers
      iv. Alosetron REMS Program Patient Education Sheet
      v. Prescriber Completion of Alosetron REMS Program Training Form

   b. In order to facilitate training, the Alosetron Sponsors will:

      i. Monitor distribution and prescription data monthly.
      ii. Contact all prescribers identified as not having completed training and provide training within 30 days of identification by mailing or emailing the REMS Training Kit. Contact and provide training to all prescribers who do not report completion of training after the first contact up to two additional times, or until the prescriber reports completion, within 180 days of being first identified.
      iii. Ensure that prescribers can notify the Alosetron Sponsors when they have completed training via the Alosetron REMS Program website or by faxing a Prescriber Completion of Training Form.
      iv. Provide acknowledgement of completion of training electronically to prescribers upon receiving notification that training was completed.
      v. Make REMS Training Materials available at professional society meetings and at medical educational venues where the Alosetron Sponsors have a presence.
      vi. Maintain an Alosetron REMS Program website [www.AlosetronREMS.com] and contact center (1-844-267-8675) to support prescribers.
      vii. Maintain a validated, secure database of healthcare providers who have notified the Alosetron Sponsors of completion of training, which will be defined as all training materials were reviewed independently by the healthcare provider.
      viii. Ensure that the REMS materials listed below are available on the Alosetron REMS Program website or by calling the REMS contact center.
The following materials are part of the REMS and are appended:

- **REMS Training Kit**
  - REMS letter for Healthcare Providers
  - 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

- **Other appended REMS materials:**
  - Alosetron REMS Program website Prescriber Section screenshots
  - Alosetron REMS Program website Patients Section screenshots
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