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.
- 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 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

1. Prescribers are no longer required to affix prescribing program stickers to written prescriptions for alosetron
2. Pharmacies are no longer required to only dispense alosetron for a paper prescription with an affixed prescribing program sticker.

Electronic prescriptions are now allowed

3. 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 Sponsors