FDA Required REMS Safety Information for LOTRONEX® and its authorized generic alosetron hydrochloride

Important Safety Update

The FDA has required this safety update as part of the LOTRONEX REMS Program to inform you that the LOTRONEX REMS Program has changed from the previous Prescribing Program for LOTRONEX (PPL)

PPL-ENROLLED Prescriber Actions:
- You are no longer required to affix prescribing program stickers to written prescriptions for LOTRONEX/alosetron hydrochloride.
- You may prescribe LOTRONEX/alosetron hydrochloride electronically

NON-ENROLLED Prescriber Actions:
- Review the LOTRONEX REMS Program Training Kit and complete the Prescriber Completion of LOTRONEX REMS Program Training Form which can be found at www.lotronexrems.com.
- You can also submit the enclosed form via e-mail to LotronexREMS@UBC.com or by fax to the Lotronex REMS Program Coordinating Center at 1-877-744-0361.

You will find the LOTRONEX REMS Program Training Kit enclosed. The Training Kit is also available online at www.lotronexrems.com or by calling the Lotronex REMS Program Coordinating Center at 1-844-851-3395, or via e-mail to LotronexREMS@UBC.com.

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

Summary of Changes to the REMS Program

1. Prescribers are no longer required to affix prescribing program stickers to written prescriptions for LOTRONEX/alosetron hydrochloride
2. Pharmacies are no longer required to only dispense LOTRONEX/alosetron hydrochloride 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 (enclosed) is available for the prescriber to discuss with the patient.
**Indication:**
LOTRONEX/alosetron hydrochloride 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.lotronexrems.com](http://www.lotronexrems.com) for more information.

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

**Reporting Adverse Events:**
You are encouraged to report all suspected adverse events associated with LOTRONEX/alosetron hydrochloride to the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or 1-800-FDA-1088 or Sebela Pharmaceuticals Inc. at 1-844-732-3521.

Sincerely,

Sebela Pharmaceuticals Inc.

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