

# FDA Required REMS Safety Information for LOTRONEX<sup>®</sup> 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](http://www.lotronexrems.com).
- You can also submit the enclosed form via e-mail to [LotronexREMS@UBC.com](mailto: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](http://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](mailto: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

- ❶ Prescribers are **no** longer required to affix prescribing program stickers to written prescriptions for LOTRONEX/alosetron hydrochloride
- ❷ 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.***
- ❸ 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-HT<sub>3</sub> 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 Sebelo Pharmaceuticals Inc. at 1-844-732-3521.

Sincerely,

Sebelo Pharmaceuticals Inc.