

LOTRONEX[®] REMS Program
Safety Information Fact Sheet for Prescribers

FDA Required REMS* Safety Information

- **RISK OF SERIOUS GASTROINTESTINAL ADVERSE REACTIONS**
 - Infrequent but serious gastrointestinal adverse reactions have been reported with the use of LOTRONEX/alosetron hydrochloride. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization and, rarely, blood transfusion, surgery, and death.
- **INDICATED ONLY for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have not responded adequately to conventional therapy**
- **DISCONTINUE** LOTRONEX/alosetron hydrochloride immediately in patients who develop constipation or symptoms of ischemic colitis. Do not resume LOTRONEX/alosetron hydrochloride in patients who develop ischemic colitis
- **Contraindicated in patients with:**
 - Constipation
 - History of chronic or severe constipation or sequelae from constipation; intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; ischemic colitis; impaired intestinal circulation, thrombophlebitis, or hypercoagulable state; Crohn's disease or ulcerative colitis; diverticulitis; severe hepatic impairment
 - Concomitant use of fluvoxamine (LUVOX[®])

Risk of Serious Gastrointestinal Adverse Reactions

- **Counsel** patients to discontinue LOTRONEX/alosetron hydrochloride immediately and contact you right away if they develop constipation or symptoms of ischemic colitis
- **Evaluate** patients with signs of ischemic colitis (e.g., rectal bleeding, bloody diarrhea, new or worsening abdominal pain)
- **Discontinue** LOTRONEX/alosetron hydrochloride immediately if signs of ischemic colitis occur, such as rectal bleeding, bloody diarrhea, or new or worsening abdominal pain.

Appropriate Patient Selection

Prescribers should select the appropriate patients to receive LOTRONEX/alosetron hydrochloride in accordance with the approved indication. LOTRONEX is contraindicated in patients with constipation, history of chronic or severe constipation or sequelae from constipation; intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; ischemic colitis; impaired intestinal circulation, thrombophlebitis, or hypercoagulable state; Crohn's disease or ulcerative colitis; diverticulitis; severe hepatic impairment and patients on fluvoxamine (LUVOX).

***What is the Lotronex REMS Program?**

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. FDA has determined that a REMS is necessary to ensure that the benefits of Lotronex and its authorized generic alosetron hydrochloride tablets outweigh serious gastrointestinal adverse reactions in patients. This factsheet is required by the FDA as part of the Lotronex REMS program. Please visit www.LotronexREMS.com for further information.

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

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, or 1-800-FDA-1088 or Sebela Pharmaceuticals Inc. at 1-844-732-3521.

This factsheet does not contain the complete safety profile for Lotronex/alosetron hydrochloride. Please refer to the Prescribing Information, including Boxed Warning, for further information.

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