FDA Required REMS* Safety Information

- **RISK OF SERIOUS GASTROINTESTINAL ADVERSE REACTIONS**
  - Infrequent but serious gastrointestinal adverse reactions have been reported with the use of alosetron hydrochloride tablets (alosetron). 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** alosetron immediately in patients who develop constipation or symptoms of ischemic colitis. Do not resume alosetron 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 alosetron 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** alosetron 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 alosetron in accordance with the approved indication. Alosetron 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 Alosetron 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 alosetron tablets outweigh serious gastrointestinal adverse reactions in patients. This factsheet is required by the FDA as part of the Alosetron REMS Program. Please visit [www.AlosetronREMS.com](http://www.AlosetronREMS.com) for further information.