Dear Pharmacist:

**Important Information for Pharmacists**

The generic supplier of alosetron, Roxane Laboratories Inc., would like to inform you about important aspects of alosetron tablets and a Risk Evaluation and Mitigation Strategy (REMS) for alosetron.

Alosetron is a selective serotonin 5-HT₃ antagonist indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have:

- chronic irritable bowel syndrome symptoms (generally lasting 6 months or longer),
- had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and
- not responded adequately to conventional therapy.

Diarrhea-predominant irritable bowel syndrome is severe if it includes diarrhea and one 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 irritable bowel syndrome.

Serious gastrointestinal adverse reactions have been reported with the use of alosetron. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization, and rarely, blood transfusion, surgery, and death. Patients who develop constipation or symptoms of ischemic colitis should discontinue use of alosetron immediately. Patients who develop ischemic colitis should not resume alosetron therapy. Because of the serious gastrointestinal adverse reactions associated with alosetron, the indication is restricted to those patients for whom the benefit-to-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of alosetron in men.

The Alosetron REMS Program was implemented in order to ensure that the benefits of alosetron treatment outweigh the potential risks. You, the pharmacist, play an important role in the Alosetron REMS Program. To become familiar with the Alosetron REMS Program, please read the attached Prescribing Information and Medication Guide.

**In order to comply with the Alosetron REMS Program, pharmacists need to:**