• Dispense only prescriptions that have an Alosetron REMS sticker\(^2\) - never fill telephone, facsimile, or computer-generated prescriptions; refills are only permitted on written prescriptions (Figure 1)

• If an Alosetron REMS sticker is not present on the prescription, call the Alosetron REMS Program contact center at 1-844-267-8675 to confirm that the prescriber is enrolled in the Alosetron REMS Program.

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**Alosetron Tablets**

The sticker indicates that this prescription is in compliance with the Alosetron REMS

**REFILL PERMITTED**

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**Figure 1. The Alosetron REMS sticker ensures appropriate prescribing and dispensing of alosetron**

We have enclosed a copy of the Alosetron Medication Guide (MG), which must be provided to patients with every filled prescription. This Medication Guide contains information that can be used to facilitate discussions about the risks of therapy. The Medication Guide explains the dosing regimen for initiating therapy with alosetron.

Only prescribers who have enrolled in the Alosetron REMS Program should prescribe alosetron. Alosetron is indicated only for women with severe diarrhea-predominant irritable bowel syndrome who have not responded adequately to conventional therapy.

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.

Enclosed for your reference are the following educational materials that will provide additional details on alosetron and the Alosetron REMS Program:

• The Alosetron full Prescribing Information

\(^2\) In the alternative, a prescription for alosetron may be dispensed in the presence of a Prescribing Program for LOTRONEX™ sticker, if generic substitution of alosetron is permitted pursuant to State substitution laws.
• The Alosetron Medication Guide

For more information on the Alosetron REMS Program, including an educational slide deck (Alosetron REMS Program Pharmacist Education Slide Deck) designed to educate pharmacists on their role within the program, please call 1-844-267-8675 or visit the program website at www.AlosetronREMS.com.

Sincerely,

Roxane Laboratories Inc., The Generic Supplier of alosetron