Alosetron REMS Program
Patient Acknowledgment Form

Alosetron is only for women with severe irritable bowel syndrome (IBS) whose main problem is diarrhea and who did not get the relief needed from other treatments. Alosetron has not been shown to help men with irritable bowel syndrome (IBS) or patients under age 18. My doctor, or a healthcare provider under a doctor’s direction, answered my questions about treatment with alosetron. I have read and I understand the Medication Guide for alosetron including the section “Who should not take alosetron?” and,

- I understand that about 1 out of every 1,000 women who take alosetron may get serious complications of constipation. I understand that about 3 of every 1,000 women who take alosetron over a 6-month period may get a serious problem where blood flow to parts of the large bowel is reduced (ischemic colitis). I understand that the serious condition of ischemic colitis, and other serious complications of constipation, can happen suddenly. These serious complications may lead to a hospital stay, and in rare cases, blood transfusions, surgery, and death.

- I understand that certain people may be more likely to develop a serious bowel condition while taking alosetron, including people who:
  - are older,
  - have other health problems,
  - take other medicines that may cause constipation.

- I understand alosetron is a medicine that should only be used for some women with severe chronic irritable bowel syndrome (IBS), whose main problem is diarrhea, and whose IBS symptoms have not been helped enough by other treatments.

- I will follow instructions in the Alosetron Medication Guide about:
  - telling my doctor, before taking alosetron, about any illnesses I have, or other medicines I am taking or planning to take.
  - taking alosetron exactly as my doctor prescribes it.
  - stopping alosetron and calling my doctor right away if I get constipated, if I have new or worse pain in my stomach area (abdomen), or if I see blood in my bowel movements.
- **calling my doctor** again if the constipation I called about before has not gotten better.
- **not starting alosetron again** unless my doctor tells me to do so, if I stopped taking it because I got constipated.
- **talking with my doctor 4 weeks after starting alosetron** to recheck my IBS symptoms.
- **stopping alosetron and calling my doctor** if my IBS symptoms have not improved after 4 weeks of taking 1 mg alosetron 2 times a day.

- If I see other doctors about my IBS or possible side effects from alosetron, I will tell the doctor who prescribed alosetron.

My signature below indicates that I have read, understood, and agree with all the statements made above, that I have asked all the questions that I have about alosetron treatment. I would like to begin treatment with alosetron.

**Patient Signature** _________________________________  **Date** __________________________

**First Name** __________________________  **Last Name** _______________________________

After the patient signs this Alosetron REMS Program Patient Acknowledgement Form, the patient should receive a copy and the original signed form should be kept in the patient’s medical record.

For questions regarding the Alosetron REMS Program, please call 1-844-267-8675 or visit the program website at [www.AlosetronREMS.com](http://www.AlosetronREMS.com).