PRESCRIBING PROGRAM FOR LOTRONEX™:

PHYSICIAN ATTESTATION OF QUALIFICATIONS AND

ACCEPTANCE OF RESPONSIBILITIES

I wish to participate in the Prescribing Program for LOTRONEX and by my signature below, attest that I have the qualifications and accept the responsibilities described below.

- I understand that for safety reasons LOTRONEX® (alosetron hydrochloride) is approved with marketing restrictions of which the Prescribing Program for LOTRONEX is a required element.
- I understand that because of serious gastrointestinal adverse events, some fatal, associated with this drug, LOTRONEX is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have chronic IBS symptoms generally lasting for 6 months or longer, had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and who have failed to respond to conventional therapy. Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following: (1) frequent and severe abdominal pain/discomfort; (2) frequent urgency or fecal incontinence; or (3) disability or restriction of daily activities due to IBS. Less than 5 per cent of IBS is considered severe.
- I understand that treatment benefits of LOTRONEX in populations other than adult women with diarrhea-predominant IBS have not been established.
- I have reviewed the complete prescribing information for LOTRONEX and am thoroughly familiar with the important information in the Boxed Warning, Indications and Usage, Contraindications, Warnings, Precautions, Adverse Reactions, Dosage and Administration, and Medication Guide sections. I have also reviewed and am familiar with all the components of the Patient-Physician Agreement for LOTRONEX.
- I can diagnose and treat IBS.
- I can diagnose and manage ischemic colitis.
- I can diagnose and manage constipation and complications of constipation.
- I understand the risks and benefits of treatment with LOTRONEX for severe diarrhea-predominant IBS, including information in the package insert, Medication Guide, and Patient-Physician Agreement.
- I will educate any patient who is considering treatment with LOTRONEX on the risks and benefits of treatment with LOTRONEX and obtain the patient's signature on the Patient-Physician Agreement form, sign it, place the original signed form in the patient's medical record, and give a copy to the patient.

- I will give any patient who is considering treatment with LOTRONEX a copy of the Medication Guide and instruct the patient to read it, and to ask any questions the patient may have, as a preliminary step to completing the Patient-Physician Agreement.
- I will report serious adverse events with LOTRONEX to GlaxoSmithKline at 1-888-825-5249 or to the Food and Drug Administration at 1-800-FDA-1088.
- I will affix program stickers to <u>all</u> prescriptions for LOTRONEX (i.e., the original and all subsequent refill prescriptions). Stickers will be provided as part of the GlaxoSmithKline Prescribing Program for LOTRONEX. I will not prescribe LOTRONEX by telephone, facsimile, or computer.

_____
Name of Physician (print)

_____ _____
Signature Date

DEA Number _____
Office Address: _____
_____
_____

Office Phone Number: _____
Office Fax Number: _____

Upon enrollment, you will receive a prescribing kit for LOTRONEX with the complete prescribing information, Prescription Program stickers, multiple copies of the Medication Guide and Patient-Physician Agreement for LOTRONEX, and instructions for ordering additional supplies of Program materials.

If you have any questions, please call the Prescribing Program for LOTRONEX at 1-888-825-5249 or visit www. LOTRONEX.com.

TO ENROLL, COMPLETE THIS FORM IN ITS ENTIRETY AND MAIL TO THE FOLLOWING ADDRESS:

Prescribing Program for Lotronex
Program Coordinator
12012 Sunset Hills Road
8th Floor
Reston, VA 20190-9870