

# PATIENT-PHYSICIAN AGREEMENT FOR LOTRONEX

## SECTION FOR THE PHYSICIAN

I am enrolled in the Prescribing Program for LOTRONEX, and I will continue to follow the requirements of the Program.

I, or a healthcare provider under a physician's direction, have given the patient named above:

- a copy of the Medication Guide for LOTRONEX, and instructed the patient to read it carefully before signing this Agreement, and to take it home.
- counseling about the benefits and risks of LOTRONEX.
- appropriate instructions for taking LOTRONEX.
- answers to all of the patient's questions about treatment with LOTRONEX.
- a prescription for LOTRONEX that has the program sticker affixed on it to alert pharmacists I am enrolled in the Prescribing Program for LOTRONEX.

*The patient signed the Patient-Physician Agreement in my presence after I counseled the patient, asked if the patient had any questions about treatment with LOTRONEX, and answered all questions to the best of my ability.*

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Name of Physician (print)

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Signature

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Date

*After the patient and the physician sign this Patient-Physician Agreement, give a copy to the patient and put the original signed form in the patient's medical record.*

**Important: Form begins on reverse side.**



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## PATIENT-PHYSICIAN AGREEMENT FOR LOTRONEX

LOTRONEX (alosetron hydrochloride) 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. LOTRONEX has not been shown to help men with IBS or patients under age 18.

My doctor, or a healthcare provider under a doctor's direction, answered my questions about treatment with LOTRONEX. I have read and I understand the Medication Guide for LOTRONEX, and

- I understand that some patients using LOTRONEX have had serious bowel conditions (ischemic colitis and complications of constipation). I understand that these serious conditions can happen suddenly, and that they may lead to a hospital stay, and in rare cases, blood transfusions, surgery, and death. I also understand that certain patients may be more likely to develop a serious bowel condition while taking LOTRONEX. These include older patients, those who have other health problems and those who take other medicines that may cause constipation.
- My doctor and I agree that my IBS is severe and that other treatments have not given me the relief that I need. I also agree that I meet all of the requirements described in the section of the Medication Guide "What is the most important information I should know about LOTRONEX?" I understand that these requirements help to make sure that LOTRONEX is used only by patients who are likely to have more benefit from treatment than risk.
- I don't have any problems listed in the section of the Medication Guide "Who should not take LOTRONEX?" that prevents me from taking LOTRONEX.
- I will follow instructions in the Medication Guide about:
  - **telling my doctor**, before taking LOTRONEX, about any illnesses I have, or other medicines I am taking or planning to take.
  - **taking LOTRONEX** exactly as my doctor prescribes it.
  - **stopping LOTRONEX** and calling my doctor right away if I get constipated, if I have new or worse pain in my 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 LOTRONEX 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 LOTRONEX** to recheck my IBS symptoms.
  - **stopping LOTRONEX and calling my doctor** if my IBS symptoms have not improved after 4 weeks of taking 1 mg 2 times a day.

I understand that LOTRONEX should be prescribed only by doctors who have signed up with the company that makes the drug. Doctors in the program must:

- fully discuss the drug's benefits and risks with each patient.
- sign this agreement with each patient before giving the initial prescription. It is not necessary to sign an agreement more than once.
- use a special sticker on all written LOTRONEX prescriptions so that pharmacists know the doctor has signed up. No telephone, facsimile, or computerized prescriptions are permitted with this program. Refills may be written on prescriptions.

If I see other doctors about my IBS or possible side effects from LOTRONEX, I will let the doctor who prescribed LOTRONEX know.

*My signature below indicates I have read, understood, and agree with all the statements made above.*

*I would like to begin treatment with LOTRONEX.*

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Name of Patient (print)

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Signature

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Date

**Important: Form continues on reverse side.**