

# PRESCRIBING LOTRONEX FOR YOUR APPROPRIATE PATIENTS

Before prescribing LOTRONEX, you must be thoroughly familiar with which patients are appropriate for therapy with LOTRONEX. Please consult the following indication criteria for prescribing LOTRONEX.

- LOTRONEX is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have:
  - chronic IBS 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 IBS 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 IBS
- Because of infrequent but serious gastrointestinal adverse events associated with LOTRONEX, 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 LOTRONEX in men
- Safety and effectiveness in pediatric patients have not been established



**LOTRONEX**<sup>®</sup>  
(alose<sup>tr</sup>on HCl) 0.5 & 1 MG  
TABLETS

Please see inside pages for Important Safety Information.

# PRESCRIBING PROGRAM FOR LOTRONEX™ (PPL)

**Enrollment:** Only physicians enrolled in the Prescribing Program for LOTRONEX may prescribe LOTRONEX.

**After identifying appropriate patients, physicians:**

- Counsel on therapy with LOTRONEX
- Review the Medication Guide and give a copy to the patient
- Review and sign the Patient-Physician Agreement Form with the patient, place the original in the patient's medical record, and give a copy of the signed Agreement to the patient
- Give the patient a prescription for LOTRONEX affixed with the Prescribing Program Sticker
- Encourage the patient to enroll in the Follow-Up Survey for LOTRONEX
- Report serious adverse events to GlaxoSmithKline at 1-888-825-5249 or the FDA at 1-800-FDA-1088

If you have questions or would like to enroll, please call 1-888-825-5249 or visit [www.LOTRONEX.com](http://www.LOTRONEX.com).

## Safety Considerations When Prescribing LOTRONEX

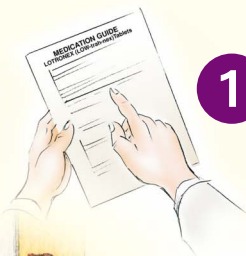
LOTRONEX should not be initiated in IBS patients who are constipated. LOTRONEX is contraindicated in patients with a history of chronic or severe constipation or a history of sequelae from constipation; with a history of intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; with a history of ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state; with current or a history of Crohn's disease or ulcerative colitis; with active diverticulitis or a history of diverticulitis; in patients who are unable to understand or comply with the Patient-Physician Agreement; and/or in patients with known hypersensitivity to any component of the product. Concomitant administration of alosetron with fluvoxamine is contraindicated.

### Dosing

To lower the risk of constipation, LOTRONEX should be started at a dosage of 0.5 mg twice a day. Patients well controlled on 0.5 mg twice a day may be maintained on this regimen. If, after 4 weeks, the 0.5-mg twice-daily dosage is well tolerated but does not adequately control IBS symptoms, then the dosage can be increased to up to 1 mg twice a day, the dose used in controlled clinical trials. LOTRONEX should be discontinued in patients who have not had adequate control of IBS symptoms after 4 weeks of treatment with 1 mg twice a day. LOTRONEX should be used with caution in debilitated patients, elderly patients, patients with hepatic impairment, and patients taking medications that decrease gastrointestinal motility.

# PRESCRIBING LOTRONEX FOR YOUR APPROPRIATE PATIENTS

## COUNSEL YOUR PATIENTS



**1** Review Medication Guide with patient



Complete Patient-Physician Agreement Form on initial visit

**2**



**3** Provide patient with prescription with affixed PPL sticker (refills are permitted)

### Important Safety Information

Infrequent but serious gastrointestinal adverse events have been reported with the use of LOTRONEX. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization, and rarely, blood transfusion, surgery, and death.

### Some patients have experienced serious complications of constipation or ischemic colitis without warning.

In IBS clinical trials, approximately 10% of patients on LOTRONEX withdrew prematurely because of constipation. The incidence of serious complications of constipation was approximately 0.1% (1 per 1,000 patients) in women receiving either LOTRONEX or placebo. In IBS clinical trials, the cumulative incidence of ischemic colitis in women receiving LOTRONEX was 0.2% (2 per 1,000 patients, 95% confidence interval 1 to 3) through 3 months and was 0.3% (3 per 1,000 patients, 95% confidence interval 1 to 4) through 6 months. Ischemic colitis was not reported in women receiving placebo. The patient experience in controlled clinical trials is insufficient to

estimate the incidence of ischemic colitis in patients taking LOTRONEX for longer than 6 months.

LOTRONEX should be discontinued immediately in patients who develop constipation or symptoms of ischemic colitis such as rectal bleeding, bloody diarrhea or new or worsening abdominal pain. Patients should immediately report constipation or symptoms of ischemic colitis to their physician. LOTRONEX should not be resumed in patients who develop ischemic colitis. Patients who have constipation should immediately contact their physician if the constipation does not resolve after LOTRONEX is discontinued. Patients with resolved constipation should resume LOTRONEX only on the advice of their treating physician.

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TABLETS

*Please see accompanying complete Prescribing Information.*



GlaxoSmithKline

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