

DRUG NAME: Lotronex (alosetron HCl), Tablets: 1mg

MANUFACTURER: GlaxoWellcome

INDICATIONS FOR USE: IRRITABLE BOWEL SYNDROME: For the treatment of irritable bowel syndrome (IBS) in women whose predominant bowel syndrome is diarrhea. The safety and efficacy of alosetron HCl in men have not been established.

In order to assist you with your patient counseling, we recommend the use of the following Patient Advisory Label(s) when you dispense *Lotronex*:

A-42



Research: Package insert under Drug/Food Interactions state that Lotronex absorption is decreased by about 25% by *coadministration* with food. However with a mean delay of 15 minutes between the administration of Lotronex and food, a decrease in absorption does not exist. Therefore it is recommended to be administered with or without food.

A-5



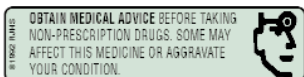
Research: All patients should be advised that solid dose medications be taken with sufficient water to assure rapid and complete dissolution. In the case of this medication, sufficient water intake may help to reduce the constipation that this medication may cause.

A-13



Research: This label is considered the “universal” counseling label that informs the patient to “follow his/her physician’s instructions” in order to obtain the desired therapeutic outcome.

A-14



Research: Concern is with the use of any over the counter product that may cause constipation further complicating the use of Lotronex.

Please Note: The Patient Advisor® is intended to provide the healthcare professional with easily accessible, practical drug counseling information to use when verbally communicating about a particular drug with a patient. The information printed here is designed to assist, not replace, professional judgement. Professional judgement must always be used when considering what type of information is to be supplied to the patient. The author, manufacturer or distributor make no claims regarding proper use of this information.

References available upon request.

To obtain Labels or other Patient Counseling Information:



R•J Health Systems, Inc.

P.O. Box 290616 • Wethersfield, CT 06129-0616 • Phone: 860-563-1223 Fax: 860-563-1650 • or on the Web: www.rjhealthsystems.com

LOTRONEX (alosetron HCl)

Be sure to read all this information and contact your doctor or pharmacist if you have any questions that are not answered here.

THIS MEDICATION IS USED:

To treat irritable bowel syndrome (IBS) in women who have diarrhea as a major symptom. This medication is not effective in men with IBS.

PROPER USE OF THIS MEDICATION:

- Take this medication exactly as your doctor has instructed.
- This medication may be taken with or without food. Take each dose with a full glass of water (4 ounces).

IMPORTANT INFORMATION TO REMEMBER:

- This medication may cause constipation. If this occurs, you should call your doctor, he/she may increase the amount of fiber in your diet or have you take a laxative.
- DO NOT stop your medication abruptly or change the amount taken without first talking with your doctor or pharmacist.
- DO NOT use this medicine if pregnant, planning to become pregnant or breastfeeding. Consult with your doctor.
- DO NOT use any non-prescription drugs such as diet pills; cough; cold or allergy medicines without first talking with your doctor or pharmacist. Some may affect this medicine or aggravate your condition.
- KEEP in a cool, dry place. DO NOT keep in your bathroom medicine cabinet or a cabinet above the stove. Heat or moisture may cause the medication to break down.
- KEEP all medicines out of the reach of children.

POSSIBLE SIDE EFFECTS:

Constipation (may treat with laxatives, fiber, or brief periods without medications), abdominal pain, bloating, stomach upset, headache.

MISSED DOSE INSTRUCTIONS:

If you miss a dose, take it as soon as possible. BUT if it is almost time for the next dose, DO NOT take the missed dose or DO NOT DOUBLE the next dose. Instead, continue with your regular dosing schedule.