

FDA Required Lotronex/alosetron hydrochloride Safety Information

What is LOTRONEX/alosetron hydrochloride?

- LOTRONEX/alosetron hydrochloride is a prescription medicine 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/alosetron hydrochloride has not been shown to help men with irritable bowel syndrome (IBS) or patients under age 18.

What is the most serious risk information about LOTRONEX/alosetron hydrochloride treatment?

- About 1 out of every 1,000 women who take LOTRONEX/alosetron hydrochloride may get serious complications of constipation. About 3 out of every 1,000 women who take LOTRONEX/alosetron hydrochloride over a 6-month period may get a serious problem where blood flow to parts of the large bowel is reduced (ischemic colitis).
- The serious condition of ischemic colitis, and other serious complications of constipation, can happen suddenly. These complications may lead to a hospital stay, and in rare cases, blood transfusions, surgery, and death.
- Certain patients may be more likely to develop a serious bowel condition while taking LOTRONEX/alosetron hydrochloride. These include older patients, those who have other health problems and those who take other medicines that may cause constipation.

What should I tell my doctor before I start taking LOTRONEX/alosetron hydrochloride?

- Tell your doctor about any illnesses you have, or other medicines you are taking or planning to take.

How do I take LOTRONEX/alosetron hydrochloride?

- Take LOTRONEX/alosetron hydrochloride exactly as your doctor prescribes it.

When should I stop taking LOTRONEX/alosetron hydrochloride and call my doctor?

- Stop taking LOTRONEX/alosetron hydrochloride and call your doctor right away if you get constipated, if you have new or worse pain in your stomach area (abdomen), or if you see blood in your bowel movements.
- Call your doctor again if the constipation you called about before has not gotten better.
- Do not start taking LOTRONEX/alosetron hydrochloride again unless your doctor tells you to do so, if you stopped taking it because you got constipated.
- Talk with your doctor 4 weeks after starting LOTRONEX/alosetron hydrochloride to recheck your IBS symptoms.
- Stop taking LOTRONEX/alosetron hydrochloride and call your doctor if your IBS symptoms have not improved after 4 weeks of taking 1 mg of LOTRONEX/alosetron hydrochloride 2 times a day.
- If you see other doctors about your IBS or possible side effects from LOTRONEX/alosetron hydrochloride, tell the doctor who prescribed LOTRONEX/alosetron hydrochloride.

This education sheet only discusses the most serious risk information of LOTRONEX/alosetron hydrochloride. For more safety information about LOTRONEX/alosetron hydrochloride please see the Medication Guide available at www.LotronexREMS.com

Please visit www.LotronexREMS.com for further information.