

Alosetron REMS Program Patient Education Sheet

FDA Required Alosetron Safety Information

What is alosetron?

- Alosetron 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. Alosetron 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 alosetron treatment?

- About 1 out of every 1,000 women who take alosetron may get serious complications of constipation. About 3 out of every 1,000 women who take alosetron 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 alosetron. 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 alosetron?

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

How do I take alosetron?

- Take alosetron exactly as your doctor prescribes it.

When should I stop taking alosetron and call my doctor?

- Stop taking alosetron 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 alosetron 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 alosetron to recheck your IBS symptoms.
- Stop taking alosetron and call your doctor if your IBS symptoms have not improved after 4 weeks of taking 1 mg of alosetron 2 times a day.
- If you see other doctors about your IBS or possible side effects from alosetron, tell the doctor who prescribed alosetron.

This education sheet only discusses the most serious risk information of alosetron. For more safety information about alosetron please see the alosetron medication guides available at www.AlosetronREMS.com

Please visit www.AlosetronREMS.com for further information.