



Is LOTRONEX RIGHT FOR YOU?

LOTROXEX is a medicine only for some women with severe chronic IBS whose:

- Main problem is diarrhea and
- IBS symptoms have not been helped enough by other treatments

LOTROXEX may be right for you if all of these things are true about you:

- Your doctor has told you that your symptoms are due to IBS
- Your IBS bowel problem is diarrhea
- Your IBS has gone on for a long time, 6 months or longer
- You have tried other IBS treatments and they haven't given you the relief you need
 - Prescription and nonprescription medicines
 - Supplements
 - Herbal remedies
 - Please list any other treatments that you've tried

- Your IBS is severe

You can tell that your IBS is severe if **at least one** of the following is true for you:

- You have lots of painful stomach cramps or bloating
- You often can't control the need to have a bowel movement or have "accidents" where your underwear gets dirty from diarrhea or bowel movements
- You can't lead a normal home or work life because you need to be near a bathroom.

Use this page as a guideline to talk with your doctor. Check off the boxes that apply to you. Then, bring the page with you to your next appointment and ask your doctor if LOTROXEX is right for you. Only your doctor can decide if LOTROXEX is right for you.

IMPORTANT PRODUCT INFORMATION FOR PATIENTS

1. What is the most important information I should know about LOTROXEX?

LOTROXEX is a medicine only for some women with severe chronic IBS whose:

- main problem is diarrhea and
- IBS symptoms have not been helped enough by other treatments.

A. Some patients have developed serious bowel side effects while taking LOTROXEX.

Serious bowel (intestine) side effects can happen suddenly, including the following two:

1. **Serious complications of constipation:** About 1 out of every 1,000 women who take LOTROXEX may get serious complications of constipation. These complications **may lead to a hospital stay, and in**

Important Product Information for Patients is continued on next page.

rare cases, blood transfusions, surgery, and death. People who are older, who are weak from illness, or who take other constipating medicines may be more likely to have serious constipation problems with LOTTRONEX.

To lower your chances of getting serious complications of constipation do the following:

- **If you are constipated,** do not start taking LOTTRONEX.
- **If you get constipated while taking LOTTRONEX,** stop taking it right away and call your doctor.
- **If your constipation does not get better after stopping LOTTRONEX,** call your doctor again.
- **If you stopped taking LOTTRONEX, do not start taking LOTTRONEX again** unless your doctor tells you to do so.

- 2. Ischemic colitis** (reduced blood flow to the bowel): About 3 out of every 1,000 women who take LOTTRONEX over a 6-month period may get a serious problem where blood flow to parts of the large bowel is reduced. This is called ischemic colitis. The chance of getting ischemic colitis when you take LOTTRONEX for more than 6 months is not known. **Ischemic colitis may lead to a hospital stay, and in rare cases, blood transfusions, surgery, and death.**

To lower your chances of getting serious complications of ischemic colitis, stop taking LOTTRONEX and call your doctor right away if you get:

- **new or worse pain in your stomach area (abdomen) or**
- **blood in your bowel movements.**

B. Is LOTTRONEX right for you?

LOTTRONEX may be right for you if all of these things are true about you:

- Your doctor has told you that your symptoms are due to IBS.
- Your IBS bowel problem is diarrhea.
- Your IBS has lasted for 6 months or longer.
- You tried other IBS treatments and they didn't give you the relief you need.
- Your IBS is severe.

You can tell if your IBS is severe if **at least 1** of the following is true for you:

- You have lots of painful stomach cramps or bloating.
- You often can't control the need to have a bowel movement, or you have "accidents" where your underwear gets dirty from diarrhea or bowel movements.
- You can't lead a normal home or work life because you need to be near a bathroom.

Enough testing has not been done to confirm LOTTRONEX works in men or children under age 18.

C. There is a special prescribing program for LOTTRONEX.

Only doctors who have signed up with the company that makes LOTTRONEX should write prescriptions for LOTTRONEX. As part of signing up, these doctors have said that they understand about IBS and the possible side effects of LOTTRONEX. They have agreed to use a special sticker on all prescriptions for LOTTRONEX, so the pharmacist will know that the doctors have signed up with the company.

You may be taught about LOTTRONEX by your doctor or healthcare provider under a doctor's direction. Your doctor will ask you to sign a Patient-Physician Agreement after you read this Medication Guide for the first time. Signing the Agreement means that you understand the benefits and risks of LOTTRONEX and that you have read and understand this Medication Guide.

2. What is LOTTRONEX?

LOTTRONEX is a medicine only for some women with severe chronic IBS whose:

- main problem is diarrhea and

- IBS symptoms have not been helped enough by other treatments.

LOTTRONEX does not cure IBS, and it may not help every person who takes it. For those who are helped, LOTTRONEX reduces lower stomach area (abdominal) pain and discomfort, the sudden need to have a bowel movement (bowel urgency), and diarrhea from IBS. If you stop taking LOTTRONEX, your IBS symptoms may return within 1 or 2 weeks.

3. Who should not take LOTTRONEX?

LOTTRONEX is not right for everyone. **Do not take LOTTRONEX if any of the following apply to you:**

- Your main IBS problem is constipation or you are constipated most of the time.
- You have had a serious problem from constipation.
- You have had serious bowel blockages.
- You have had blood flow problems to your bowels, such as ischemic colitis.
- You have had blood clots.
- You have had Crohn's disease, ulcerative colitis, or diverticulitis or severe liver disease.
- You do not understand this Medication Guide or the Patient-Physician Agreement, or you are not willing to follow them.
- You are allergic to LOTTRONEX or any of its ingredients. (See the list of ingredients at the end of this Medication Guide.)
- You are taking fluvoxamine (LUVOX[®])

If you are constipated now, do not start taking LOTTRONEX.

4. What should I talk about with my doctor before taking LOTTRONEX?

Talk with your doctor:

- about the possible benefits and risks of LOTTRONEX.
- about how much of a problem IBS is in your life and what treatments you have tried.
- about any other illnesses you have and medicines you take or plan to take. These include prescription and non-prescription medicines, supplements, and herbal remedies. Certain illnesses and medicines can increase your chance of getting serious side effects while taking LOTTRONEX. Other medicines may interact with how the body handles LOTTRONEX.
- if you are pregnant, planning to get pregnant, or breastfeeding.

5. How should I take LOTTRONEX?

- **Take LOTTRONEX exactly as your doctor prescribes it.** You can take LOTTRONEX with or without food.
- **Begin with 0.5 mg two times a day for 4 weeks** to see how LOTTRONEX affects you. You and your doctor may decide that you should keep taking this dose if you are doing well.
- **Check with your doctor 4 weeks after starting LOTTRONEX:**
 - >> If you try 0.5 mg two times a day for 4 weeks, it may not control your symptoms. If you do not get constipation or other side effects from LOTTRONEX, your doctor may increase your dose up to 1 mg two times a day.
 - >> If 1 mg two times a day does not work after 4 weeks, LOTTRONEX is not likely to help you. You should stop taking it and call your doctor.
- **If you miss a dose of LOTTRONEX**, just skip that dose. Do **not** take 2 doses the next time. Wait until the next time you are supposed to take it and then take your normal dose.
- **Follow the important instructions in the section “What is the most important information I should know about LOTTRONEX?”** about when you must stop taking the drug and when you should call your doctor.



- **If you see other doctors** about your IBS or side effects from LOTRONEX, let the doctor who prescribed LOTRONEX know.

6. What are the possible side effects of LOTRONEX?

Constipation is the most common side effect among women with IBS who take LOTRONEX. **Some patients have developed serious bowel side effects while taking LOTRONEX.** Read the section “**What is the most important information I should know about LOTRONEX?**” at the beginning of this Medication Guide for information about the serious side effects you may get with LOTRONEX.

This Medication Guide does not tell you about all the possible side effects of LOTRONEX. Your doctor or pharmacist can give you a more complete list.

7. General information about the safe and effective use of LOTRONEX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any questions or concerns about LOTRONEX, ask your doctor. Do not use LOTRONEX for a condition for which it was not prescribed. Do not share your medicine with other people. It may harm them.

Your doctor or pharmacist can give you more information about LOTRONEX that was written for healthcare professionals. You can also contact the company that makes LOTRONEX (toll free) at 1-888-825-5249 or at www.lotronex.com.

8. What are the ingredients of LOTRONEX?

Active Ingredient: alosetron hydrochloride

Inactive Ingredients: lactose (anhydrous), magnesium stearate, microcrystalline cellulose, and pregelatinized starch. The white film-coat for the 0.5-mg tablet contains hypromellose, titanium dioxide, and triacetin. The blue film-coat for the 1-mg tablet contains hypromellose, titanium dioxide, triacetin, and indigo carmine.

This Medication Guide has been approved by the US Food and Drug Administration.

Please consult the complete Prescribing Information.