

Rx Prescriber Information

What is my role in the LOTRONEX REMS Program?

Healthcare professionals are expected to complete the LOTRONEX REMS Program Prescriber Training and return the LOTRONEX REMS Program Completion of Training Form (online or paper) in order to prescribe LOTRONEX or its authorized generic.

Step 1: Complete the LOTRONEX REMS Program Prescriber Training

You should become familiar with the risks of IC and CoC associated with LOTRONEX/alose tron hydrochloride and the requirements of the LOTRONEX REMS Program.

As a prescriber of LOTRONEX/alose tron hydrochloride, you should comply with the LOTRONEX REMS Program by reviewing a [LOTRONEX REMS Program Prescriber Education Slide Deck](#). Then complete a Prescriber [Completion of LOTRONEX REMS Program Training Form](#) to document that you have trained on the benefits and risks of LOTRONEX/alose tron hydrochloride therapy.

Step 2: Educate Patients

Counsel patients on the risks associated with LOTRONEX/alose tron hydrochloride and provide the LOTRONEX REMS Program Patient Education Sheet.

Program Resources and Education Materials

The LOTRONEX REMS Program provides the resources and educational materials you and your patients need to understand your roles and responsibilities in the program.

There are two ways to obtain program materials:

1. VIEW, PRINT, OR SAVE ON YOUR COMPUTER –You can view, print, or save the materials to your computer. Select items from the list below.
2. BY PHONE – you can order materials by calling the LOTRONEX REMS Program Coordinating Center at 1-844-851-3395.

- [REMS letter Healthcare Providers](#)
- [LOTRONEX REMS Program Prescriber Education Slide Deck](#)
- [LOTRONEX REMS Program Safety Information Fact Sheet for Prescribers](#)
- [LOTRONEX REMS Program Patient Education Sheet](#)
- [LOTRONEX REMS Program Professional Societies Letter](#)
- [LOTRONEX Prescribing Information](#)
- [alose tron hydrochloride Prescribing Information](#)

INDICATION: LOTRONEX/alose tron hydrochloride is indicated only for women with severe diarrhea-predominant irritable bowel syndrome who have: chronic irritable bowel syndrome 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 irritable bowel syndrome 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 irritable bowel syndrome. Because of infrequent but serious gastrointestinal adverse events associated with LOTRONEX/alose tron hydrochloride, 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/alose tron hydrochloride in men.



645 Hembree Parkway, Suite I
Roswell, Georgia 30076
Toll Free 1-844-732-3521

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Patient Information

INFORMATION FOR PATIENTS

I take LOTRONEX or alosetron hydrochloride tablets, what do I need to know about the LOTRONEX REMS Program?

Review the [LOTROX REMS Program Patient Education Sheet](#) with your Health Care Provider.

Important safety Information about LOTRONEX/alosetron hydrochloride:

Serious bowel (intestine) side effects can happen suddenly including

- Serious complications of constipation
- Ischemic colitis (reduced blood flow to the bowel)

These complications may lead to hospital stay, and in rare cases blood transfusions, surgery, or death.

Stop taking LOTRONEX/alosetron hydrochloride and call your doctor right away if you get:

- Constipated while taking LOTRONEX/alosetron hydrochloride
- New or worse pain in your stomach area (abdomen)
- Blood in your bowel movements

Do not start taking LOTRONEX/alosetron hydrochloride again until your doctor tells you to do so.

LOTROX/alosetron hydrochloride is:

A medicine only for some women with severe chronic irritable bowel syndrome (IBS) whose main problem is diarrhea and IBS symptoms have not been helped enough by other treatments.

LOTROX/alosetron hydrochloride does not cure IBS, and it may not help every person who takes it. For those who are helped, LOTROX/alosetron hydrochloride 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 LOTROX/alosetron hydrochloride, your IBS symptoms may return within 1 or 2 weeks to what they were before you started LOTROX/alosetron hydrochloride.

Download the:

[LOTROX REMS Program Patient Education Sheet](#)



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LOTTRONEX REMS (Risk Evaluation and Mitigation Strategy) Program

LOTTRONEX and its authorized generic alosetron hydrochloride are available by prescription as:
LOTTRONEX® (alose tron hydrochloride) Tablets.

What is the LOTTRONEX REMS Program?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh the risks. The purpose of the LOTTRONEX REMS Program is to inform prescribers about the risks of:
Serious Gastrointestinal Adverse Reactions, including ischemic colitis and serious complications of constipation, which have resulted in hospitalization and, rarely, blood transfusion, surgery, and death.

Click below for complete prescribing information, including Boxed Warning and Medication Guide:

- [LOTTRONEX® \(alose tron hydrochloride\) Tablets](#)
- [Alose tron hydrochloride](#)

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Medication Guide

LOTROXEX® (LOW-trah-nex) Tablets (alosecron hydrochloride)

Before using LOTROXEX for the first time, you should:

- Understand that LOTROXEX has serious risks for some people.
- Read and follow the directions in this Medication Guide.

Carefully read the Medication Guide you get with each refill for LOTROXEX. There may be new information. This Medication Guide does not take the place of talking with your doctor.

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

A. LOTROXEX is a medicine only for some women with severe chronic irritable bowel syndrome (IBS) whose:

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

B. Some patients have developed serious bowel side effects while taking LOTROXEX. Serious bowel (intestine) side effects can happen suddenly, including the following.

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 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 complications of constipation with LOTROXEX.

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

- If you are constipated, do not start taking LOTROXEX.
- If you get constipated while taking LOTROXEX, stop taking it right away and call your doctor.
- If your constipation does not get better after stopping LOTROXEX, call your doctor again.
- If you stopped taking LOTROXEX, do not start taking LOTROXEX 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 LOTROXEX 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 LOTROXEX 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 LOTROXEX and call your doctor right away if you get:

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

C. Is LOTROXEX right for you?

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 lasted for 6 months or longer.
- You tried other IBS treatments and they did not 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 cannot control the need to have a bowel movement, or you have "accidents" where your underwear gets dirty from diarrhea or bowel movements.
- You cannot lead a normal home or work life because you need to be near a bathroom.

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

2. What is 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.

LOTROXEX does not cure IBS, and it may not help every person who takes it. For those who are helped, LOTROXEX 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 LOTROXEX, your IBS symptoms may return within 1 or 2 weeks to what they were before you started taking LOTROXEX.

LOTROXEX is not recommended for children.

3. Who should not take LOTROXEX?

LOTROXEX is not right for everyone. Do not take LOTROXEX 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. If you are constipated now, do not start taking LOTROXEX.
- 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, diverticulitis, or severe liver disease.
- You do not understand this Medication Guide or you are not willing to follow it.
- You are taking fluvoxamine (LUVOX®).

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

Talk with your doctor:

- about the possible benefits and risks of LOTROXEX.
- 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 LOTROXEX. Other medicines may interact with how the body handles LOTROXEX.
- about any allergies that you have. See the end of the Medication Guide for a complete list of ingredients in LOTROXEX.
- if you are pregnant, planning to get pregnant, or breastfeeding.

5. How should I take LOTROXEX?

- Take LOTROXEX exactly as your doctor prescribes it. You can take LOTROXEX with or without food.
- Begin with 0.5 mg two times a day for 4 weeks to see how LOTROXEX 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 LOTROXEX:
 - 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 LOTROXEX, 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, LOTROXEX is not likely to help you. You should stop taking it and call your doctor.
- If you miss a dose of LOTROXEX, 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 LOTROXEX?" about when you must stop taking the medicine and when you should call your doctor.
- If you see other doctors about your IBS or side effects from LOTROXEX, tell the doctor who prescribed LOTROXEX.

6. What are the possible side effects of LOTROXEX?

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

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

7. How should I store LOTROXEX?

- Store LOTROXEX between 59°F to 86°F (15°C to 30°C).
- Protect LOTROXEX from light and getting wet (moisture).

Keep LOTROXEX and all medicines out of the reach of children.

8. General information about the safe and effective use of LOTROXEX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any questions or concerns about LOTROXEX, ask your doctor. Do not use LOTROXEX 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 LOTROXEX that was written for healthcare professionals. You can also contact the company that makes LOTROXEX (toll free) at 1-844-732-3521 or at www.lotronex.com.

9. What are the ingredients of LOTROXEX?

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.

Manufactured for:
Sebela Ireland Ltd.

Distributed By:
Sebela Pharmaceuticals Inc.
645 Hembree Parkway, Suite I
Roswell, Georgia 30076

Toll Free 1-844-732-3521

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

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