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 CIC associated with LOTRONEX/valsoxeton hydrochloride and the requirements of the LOTRONEX REMS Program.
As a prescriber of LOTRONEX/valsoxeton 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/valsoxeton hydrochloride therapy.

Step 2: Educate Patients
Counsel patients on the risks associated with LOTRONEX/valsoxeton 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 1-844-861-3395.

- 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
- valsoxeton hydrochloride Prescribing Information

INDICATION: LOTRONEX/valsoxeton 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 biophysical 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 or 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/valsoxeton hydrochloride, the indication is restricted to those patients for whom the benefit-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of LOTRONEX/valsoxeton hydrochloride in men.

Privacy Policy
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This product may be covered by one or more US pending or issued patents.
LOTRONEX is a registered trademark of Prometheus Laboratories Inc., San Diego, CA.
INFORMATION FOR PATIENTS

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

Review the LOTRONEX 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.

LOTRONEX/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.

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

Download the:
LOTRONEX REMS Program Patient Education Sheet

INDICATION: LOTRONEX/alosetron 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), abnormal 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/alosetron 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/alosetron hydrochloride in men.
LOTRONEX REMS (Risk Evaluation and Mitigation Strategy) Program

LOTRONEX and its authorized generic alosertin hydrochloride are available by prescription as: LOTRONEX® (alosertin hydrochloride) Tablets.

What is the LOTRONEX 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 LOTRONEX 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:

- LOTRONEX® (alosertin hydrochloride) Tablets
- Alosertin Hydrochloride

INDICATION: LOTRONEX/alosertin hydrochloride is indicated only for women with severe diarrhea-predominant irritable bowel syndrome who have chronic irritable bowel syndrome symptoms (generally lasting 8 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/painful discomfort, frequent bowel urgency or fecal incontinence, disability or restriction of daily activities due to irritable bowel syndrome. Because of the frequent but serious gastrointestinal adverse events associated with LOTRONEX/alosertin 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/alosertin hydrochloride in men.
Medication Guide

LOTROLONE® (lotrolone) Tablets (clotrimazole hydrochloride)

Before using LOTROLONE for the first time, you should:

- Understand that LOTROLONE has serious risks for some people.
- Read and follow the directions in this Medication Guide.
- Carefully read the Medication Guide you get with each bottle of LOTROLONE. 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 LOTROLONE?

A. LOTROLONE is a medicine only for some women with severe chronic inflamed bowel syndrome (IBS) who have:

- more problem diarrhea and
- IBS symptoms to help relieve IBS symptoms.

B. In some patients, severe bowel side effects while taking LOTROLONE, Serious bowel (intestinal) side effects can happen suddenly, including the following:

1. Serious complications of constipation: About 1 out of every 1,000 women who take LOTROLONE may get severe 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 sick from illness, or who have other complicating medicines may be more likely to have severe complications of constipation.

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

- Do not start taking LOTROLONE. If you get constipated while taking LOTROLONE, stop taking it right away and call your doctor.

2. IBS symptoms may be worse while you take LOTROLONE: About 1 out of every 1,000 women who take LOTROLONE for 6 months or more may get a serious problem while blood flow to parts of the large bowel becomes reduced. This is called ischemic colitis. The chance of getting ischemic colitis when you take LOTROLONE for 6 months or more is unknown. 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 LOTROLONE and call your doctor right away if you get:

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

C. Is LOTROLONE right for you?

LOTROLONE 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.
- You have had IBS for 12 months or longer.
- You have had IBS symptoms for at least 6 months.
- You took other IBBS treatments and they did not give you the relief you needed.
- 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 had pain or stomach cramps or bloating.
You have had diarrhea or constipation, or you have had a change in your stool.
You have had blood in your stool.
You have had an normal blood or stool for bowel movements.
You have had a fever.
You have had a fever.
You have had a fever.
You have had a fever.

2. What is LOTROLONE?

LOTROLONE is a medicine only for some women with severe chronic IBS who have:

- more problem diarrhea and
- IBS symptoms to help relieve IBS symptoms.

LOTROLONE does not cure IBS and it may not help every person who takes it.

For those who are helped, LOTROLONE reduces lower stomach area pain and discomfort, the sudden need to have a bowel movement (diarrhea), urgency, and pain from IBS. If you stop taking LOTROLONE, your IBS symptoms may return within 1 to 2 weeks until you were before you started taking LOTROLONE.

LOTROLONE is not recommended for children.

3. Who should not take LOTROLONE?

LOTROLONE is not right for everyone. Do not take LOTROLONE 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 LOTROLONE.
- 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 Celiac disease, ulcerative colitis, diverticulitis, or severe liver disease.
- You do not understand this Medication Guide or you are not able to tolerate it.
- You are taking fluvoxamine (LUVOX).

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

Talk with your doctor about:
- the possible benefits and risks of LOTROLONE.
- about how much of a problem IBS is in your life and what treatments you have tried.
- about any other medicines you have and medicines you take or plan to take.

These include prescription and nonprescription medicines, supplements, and herbal remedies. Certain medicines and medicines can increase your chance of getting serious side effects while taking LOTROLONE. Other medicines may interact with the food handled by LOTROLONE.

Other allergies you have. See the end of the Medication Guide for a complete list of ingredients in LOTROLONE.

If you are pregnant, planning to get pregnant, or breastfeeding:

5. How should I take LOTROLONE?

- Take LOTROLONE exactly as your doctor prescribed. You can take LOTROLONE with or without food.
- Begin with 0.5 mg twice a day for 1 to 2 weeks to see how LOTROLONE helps you. Your doctor and your doctor may decide that you should keep taking the dose if you are doing well.
- Check with your doctor 2 weeks after starting LOTROLONE.
- If you need 0.5 mg twice a day for 1 weeks, it may or may not control your symptoms. If you still not get constipation or other side effects from LOTROLONE, your doctor may increase your dose up to 1 mg two times a day.
- If you have had a dose of LOTROLONE, take it again. Do not take 2 doses the next time. Wait until the next time you supposed to take it and then take your normal dose.
- Follow the important instructions in the "What is the most important information I should know about LOTROLONE?" section before you must stop taking the medicine and when you should call your doctor.

6. What are the possible side effects of LOTROLONE?

Constipation is the most common side effect among women who take LOTROLONE. Some patients have developed severe bowel side effects while taking LOTROLONE. Read the section "What is the most important information I should know about LOTROLONE?" before you start taking this medication. For information about the serious side effects, you may get with LOTROLONE.

This Medication Guide does not tell you about all the possible side effects of LOTROLONE. 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 LOTROLONE?

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

Keep LOTROLONE out of the reach of children.

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

Medicines are sometimes prescribed for purposes other than those listed in this Medication Guide. If you have any questions or concerns about LOTROLONE, ask your doctor. Do not take LOTROLONE for a condition for which it was not prescribed. Do not share your medicine with other people. It may harm them. You doctor should be consulted if you think you need more information about LOTROLONE, or if you think the medicine is not working for health reasons. We can also contact the company that makes LOTROLONE (Call them at 1-844-732-3521) or all www.lotrolone.com.

9. What are the ingredients of LOTROLONE?

Active ingredient: clotrimazole hydrochloride.

Inactive ingredients: lactose (anhydrous), magnesium stearate, microcrystalline cellulose, and pregelatinized starch. The white free-form for the 0.5 mg tablet contains hydroxypropylmethyl cellulose, titanium dioxide, lacquer, and lactose.

Manufactured for:

Sebela Laboratories Inc.

Distributed By:

Sebela Pharmaceuticals Inc.

555 8th Avenue, Montclair, NJ 07042

Toll Free 1-844-732-3521

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

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