

GET HELP GOING WHERE YOU WANT TO GO



Multisymptom relief
for some women with
severe, chronic
diarrhea-predominant
IBS who have not
responded adequately
to other therapy


LOTRONEX[®]
(alosectron HCl) 0.5 & 1 MG
TABLETS

Before using LOTRONEX for the first time, you should:

- Understand that LOTRONEX has serious risks for some people
- Read and follow the directions in the Medication Guide on pages 17 to 19
- Sign a Patient-Physician Agreement with your doctor



INTRODUCTION

Your symptoms of severe, chronic diarrhea-predominant IBS (D-IBS) have affected your home or work life. You've tried other medications, and they didn't give you the relief you need. So, your doctor has suggested LOTRONEX, a medication available only by prescription that may help multiple symptoms of D-IBS.

It is very important to understand the side effects associated with LOTRONEX. Before taking LOTRONEX, you and your doctor will discuss other treatments you have tried, as well as the benefits and risks of LOTRONEX. This brochure and the Medication Guide on pages 17 to 19 will provide you with information that will help you make an educated decision about using LOTRONEX.

Be sure to talk to your doctor to see if LOTRONEX is right for you.

Please read the important safety information in the Medication Guide on pages 17 to 19 before using LOTRONEX.



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ARE YOU INFORMED?

What is LOTRONEX?

LOTRONEX is a medicine prescribed only for some women with severe, chronic IBS whose major symptom is diarrhea and who have not been helped enough by other treatments. LOTRONEX does not cure D-IBS, and it may not help every person who takes it. LOTRONEX may reduce pain or discomfort in the lower stomach area, the sudden need to have a bowel movement (bowel urgency), and diarrhea from IBS. If you stop taking LOTRONEX, your D-IBS symptoms may return within 1 or 2 weeks.

Because of infrequent but serious bowel side effects associated with LOTRONEX, its use is restricted to those patients for whom the benefits outweigh the risks.

Available by prescription in 2 strengths



0.5 mg 1 mg

Pills shown actual size.

How may LOTRONEX help you?

LOTRONEX provides relief from symptoms that interfere with daily activities.

- Patients with severe, chronic D-IBS taking LOTRONEX reported*:
 - Less interference with work and social activities
 - Less difficulty sleeping
 - Less tiredness
 - Fewer eating problems
- However, these patients did not report differences in emotional and mental distress and physical and sexual activity

*These results were reported by patients taking LOTRONEX during a 12-week study.

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For more information call 888-423-5227
or visit www.LOTRONEX.com.

ARE YOU A CANDIDATE FOR TREATMENT?

Is LOTRONEX right for me?

LOTRONEX may be right for you if all of the following are true for you:

- Your doctor has told you that your symptoms are due to D-IBS. Some common symptoms of D-IBS are:
 - Frequent abdominal pain and discomfort
 - Loose, watery stool
 - Frequent bowel movements
 - Urgency, or the sudden need for a bowel movement
- Your IBS bowel problem is diarrhea
- Your symptoms have lasted for 6 months or longer
- You tried other IBS treatments, and they didn't give you the relief you needed
- Your D-IBS is severe



What is severe D-IBS?

You can tell if your D-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 LOTRONEX works in men or children under age 18.

Please read the important safety information in the Medication Guide on pages 17 to 19 before using LOTRONEX.


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ARE YOU KNOWLEDGEABLE?

Who should not take LOTRONEX?

LOTRONEX is not right for everyone. **Do not take LOTRONEX 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, diverticulitis, or severe liver disease
- You do not understand the Medication Guide or the Patient-Physician Agreement, or you are not willing to follow them
- You are allergic to LOTRONEX or any of its ingredients (see the list of active/inactive ingredients within the Medication Guide)
- You are taking Luvox® (fluvoxamine maleate) or generic fluvoxamine maleate

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

Luvox is a registered trademark of Solvay Pharmaceuticals.

What is the most important information I should know about LOTRONEX?

LOTRONEX is a medicine only for some women with severe, chronic IBS whose main problem is diarrhea and whose IBS symptoms have not been helped enough by other treatments.

There is a special prescribing program for LOTRONEX.

Some patients have developed serious bowel side effects while taking LOTRONEX.

Please read the important safety information in the Medication Guide on pages 17 to 19 before using LOTRONEX.



ARE YOU KNOWLEDGEABLE?

(CONT)

What is the most important information I should know about LOTRONEX?

Serious bowel side effects can happen suddenly, and include the following:

Serious complications of constipation:

About 1 out of every 1,000 women who take LOTRONEX may experience serious complications of constipation. These complications **may lead to a hospital stay, and in rare cases, blood transfusions, surgery, and death.** Women who are older, who are weak from illness, or who take other constipating medicines, may be more likely to have serious constipation problems with LOTRONEX.

To lower your chances of experiencing serious complications of constipation:

- Do not start taking LOTRONEX **if you are already constipated**
- **If you become constipated while taking LOTRONEX,** stop taking it right away and call your doctor
- **If your constipation does not improve after stopping LOTRONEX,** call your doctor again
- **If you've stopped taking LOTRONEX, do not start taking LOTRONEX again** unless your doctor tells you to do so

Ischemic colitis (reduced blood flow to the bowel): About 3 out of every 1,000 women who take LOTRONEX over a 6-month period experience 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 LOTRONEX for more than 6 months is unknown.

Ischemic colitis may lead to a hospital stay, and in rare cases, blood transfusions, surgery, and death.

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

- **New or worse pain in your lower stomach area, or**
- **Blood in your bowel movements**

Please read the important safety information in the Medication Guide on pages 17 to 19 before using LOTRONEX.


LOTRONEX[®]
(alosetron HCl) 0.5 & 1 MG
TABLETS

ARE YOU KNOWLEDGEABLE?

(CONT)

The Prescribing Program for LOTRONEX™.

Only doctors who have signed up in the Prescribing Program for LOTRONEX (PPL) should write prescriptions for LOTRONEX. As part of signing up, these doctors have said that they understand about IBS and the possible side effects of LOTRONEX. They also agree to use a special sticker on **all** prescriptions for LOTRONEX, so the pharmacist will know the doctors have signed up in the PPL.

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

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.** For more information on the serious side effects you may experience from taking LOTRONEX, review the section **“What is the most important information I should know about LOTRONEX?”** within the Medication Guide.

The Medication Guide does not provide you with all the possible side effects of LOTRONEX. Please consult your doctor or pharmacist for a more complete list.



Please read the important safety information in the Medication Guide on pages 17 to 19 before using LOTRONEX.


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or visit www.LOTRONEX.com.

ARE YOU READY?

How should I take LOTRONEX?

Take LOTRONEX exactly as your doctor prescribes it. You can take LOTRONEX with or without food:

- **Begin with 0.5 mg, two times a day, for 4 weeks** to see how LOTRONEX 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 LOTRONEX:

- If you try 0.5 mg, two times a day, for 4 weeks and it does not control your symptoms, and you do not get constipation or other side effects from LOTRONEX, then 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, you should stop taking LOTRONEX and call your doctor
- **If you miss a dose of LOTRONEX**, 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 LOTRONEX?”** about when you must stop taking the drug and when you should call your doctor

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

What should I talk about with my doctor before using LOTRONEX?

- The possible risks and benefits of LOTRONEX
- The treatments you have already tried
- The degree of interference in daily activities caused by your D-IBS
- Other illnesses you have and medicines you take or plan to take, including prescription and nonprescription medicines, supplements, and herbal remedies. This is important because:
 - Some illnesses and medicines may increase your chance of experiencing serious side effects while taking LOTRONEX
 - LOTRONEX should be used with caution if you have mild or moderate liver disease
 - Other medicines may interfere with how the body handles LOTRONEX
 - If you are pregnant, planning to get pregnant, or breast-feeding

Please read the important safety information in the Medication Guide on pages 17 to 19 before using LOTRONEX.



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ARE YOU READY?

(CONT)

General information about the use of LOTRONEX.

Medicines are sometimes prescribed for purposes other than those listed in the 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. LOTRONEX may be harmful to others.

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 888-423-5227 or visit www.LOTRONEX.com.



MEDICATION GUIDE
LOTRONEX® (LOW-trah-nex) Tablets
(alose tron hydrochloride)

Before using LOTRONEX for the first time, you should:

- Understand that LOTRONEX has serious risks for some people.
- Read and follow the directions in this Medication Guide.
- Sign a Patient-Physician Agreement with your doctor.

Read this Medication Guide carefully before you sign the Patient-Physician Agreement. You must sign the Patient-Physician Agreement before you start LOTRONEX. Read the Medication Guide you get with each refill for LOTRONEX. 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 LOTRONEX?

LOTRONEX 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 LOTRONEX. 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 LOTRONEX 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 constipation problems with LOTRONEX.

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

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

LOTRONEX 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.

LOTRONEX® (alosetron hydrochloride) Tablets (cont)

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 LOTRONEX works in men or children under age 18.

C. There is a special prescribing program for LOTRONEX.

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

You may be taught about LOTRONEX 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 LOTRONEX and that you have read and understand this Medication Guide.

2. What is LOTRONEX?

LOTRONEX 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.

LOTRONEX does not cure IBS, and it may not help every person who takes it. For those who are helped, LOTRONEX 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, your IBS symptoms may return within 1 or 2 weeks.

3. Who should not take LOTRONEX?

LOTRONEX is not right for everyone. **Do not take LOTRONEX 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, 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 LOTRONEX 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 LOTRONEX.

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

Talk with your doctor:

- about the possible benefits and risks of LOTRONEX.
- 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

LOTRONEX. Other medicines may interact with how the body handles LOTRONEX.

- if you are pregnant, planning to get pregnant, or breastfeeding.

5. How should I take LOTRONEX?

- **Take LOTRONEX exactly as your doctor prescribes it.** You can take LOTRONEX with or without food.
- **Begin with 0.5 mg two times a day for 4 weeks** to see how LOTRONEX 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 LOTRONEX:**
 - ▷ 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 LOTRONEX, 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, LOTRONEX is not likely to help you. You should stop taking it and call your doctor.
- **If you miss a dose of LOTRONEX**, 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 LOTRONEX?”** 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 888-423-5227 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.



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