Alosetron REMS Program

Risk Evaluation and Mitigation Strategy

Web Mockups
V10
Footer is included on every web page. To reduce the length of the document, the screenshot is included once.

Please consult the Prescribing Information and Important Safety Information.

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Alosetron REMS (Risk Evaluation and Mitigation Strategy)

What is the Alosetron REMS Program?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product. The FDA has determined that a REMS is necessary for alosetron to ensure the benefits of the drug outweigh the risk of serious gastrointestinal (GI) adverse reactions.

The Alosetron REMS Program was implemented to help reduce the risks of a serious GI adverse event.

The goals of the Alosetron REMS Program are:

- To mitigate the risk of ischemic colitis (IC) and serious complications of constipation (CoC) associated with alosetron hydrochloride (hereinafter, referred to as alosetron) by ensuring that alosetron is used in only severely affected patients in whom the benefits exceed the risks.
- To ensure that the risk of IC and serious CoC with the use of alosetron are communicated to patients, pharmacists, and prescribers.

The key elements of the Alosetron REMS Program are:

- Only prescribers who have enrolled in the Alosetron REMS Program, based on their understanding of the benefits and risks, can prescribe alosetron.
- Pharmacists may only dispense alosetron from prescriptions with a sticker1 and written by prescribers participating in the Alosetron REMS Program.

Alosetron is indicated ONLY for women with severe diarrhea-predominant IBS who have:

- Chronic irritable bowel syndrome symptoms (generally lasting for 6 months or longer).
- Anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and
- Not responded adequately to conventional therapy.

1 In the alternative, a prescription for alosetron may be dispensed in the presence of a Prescribing Program for LOTRONEX™ sticker, if generic substitution of alosetron is permitted pursuant to state substitution laws.
Patient Role in the Alosetron REMS Program

The Alosetron Medication Guide is provided to enhance patient awareness and understanding of the potential serious risks associated with the use of alosetron. The Alosetron Medication Guide includes critical information that every patient and caregiver should know about alosetron. Please use the links below to review the Medication Guide and Important Safety Information for alosetron.

- [Medication Guide](#)
- [Important Safety Information](#)

The Patient Follow-Up Survey for the Alosetron REMS Program will help the supplier of alosetron hydrochloride learn more about alosetron. Everyone who takes alosetron is invited to voluntarily sign up. If you sign up you will get questions in the mail or by email about how you are doing on alosetron. You do not have to sign up if you do not wish to, but signing up will help us learn more about alosetron. The Survey is being done by the generic supplier of alosetron hydrochloride. The Survey results will be shared with the U.S. Food and Drug Administration (FDA) to help all patients; however, your identity and individual responses will be kept confidential. If you are taking alosetron and want to participate, please use the link below to download, print and complete the Patient Follow-up Survey Pre-Enrollment Form and return it to the program by fax or mail as indicated on the form.

- [Patient Follow-up Survey Pre-Enrollment Form](#)
- [Enrollment Form](#)
Prescriber Role in the Alosetron REMS Program

Only prescribers who enroll in the Alosetron REMS Program, based on their understanding of the benefits and risks, can prescribe alosetron. The Alosetron REMS Program facilitates patient safety. The program requires patients, prescribers, and pharmacists to understand the appropriate use of alosetron and its potential risks, as well as potential adverse events and how to handle them.

Prescribers need to comply with the following requirements of the Alosetron REMS Program:

- Complete enrollment in the Alosetron REMS Program.
- Review and provide Medication Guide to the patient.
- Have the patient complete the Patient Acknowledgment Form. Place the original in the patient's medical record and give a copy to the patient.
- Provide patient with a written prescription with affixed Alosetron REMS sticker.

Prescriber Enrollment

Prescribers must enroll in the Alosetron REMS Program prior to prescribing alosetron.

To enroll in the Alosetron REMS Program via web:
1. Review the Prescriber Education Slide Deck located in the Resources section below.
2. Press Next to begin the enrollment process.

To enroll in the Alosetron REMS Program via fax:
1. Review the Prescriber Education Slide Deck located in the Resources section below.
2. Complete the Prescriber Enrollment Form located in the Resources section below.
3. Fax the completed Prescriber Enrollment Form to the Alosetron REMS Program at 1-800-535-6805.

Resources

- Prescriber Enrollment Form
- Medication Guide
- Patient Acknowledgment Form
- Important Safety Information
- Prescribing Information
- Prescriber Education Slide Deck
PRESCRIBER AGREEMENT

The A洛setron REMS Program - Prescriber Enrollment

To begin the enrollment process, please read the attestation statements below.

I understand and agree to the following:

- I have read and understand the complete Prescribing Information and other enrollment materials for the A洛setron REMS Program. I understand the risks associated with its use and will follow the requirements of the A洛setron REMS Program described below. I understand the importance of reporting all cases of ischemic colitis and serious complications of constipation to the A洛setron REMS Program at 1-844-267-8675.
- I understand that A洛setron is approved only for women with severe, diarrhea-predominant irritable bowel syndrome who have:
  - chronic irritable bowel syndrome symptoms (generally lasting for 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
- I understand that if I prescribe A洛setron for my patient(s), I must be able to perform the following:
  - diagnose and manage irritable bowel syndrome, ischemic colitis, constipation, and complications of constipation or refer patients to a specialist as needed
  - ensure that all patients under my care are educated by me or a healthcare provider in my practice about the benefits and risks of the drug
- I agree to provide each of my patients with a copy of the A洛setron Medication Guide at initiation of A洛setron treatment.
- I agree to review the content of the Medication Guide and encourage the patient to read it and ask questions.
- I agree to have each patient sign the A洛setron Patient Acknowledgement Form. The original signed form must be placed in the patient’s medical record, and a copy given to the patient.
- I agree to inform my patients about the A洛setron Patient Follow-Up Survey, encourage them to participate and provide them with an A洛setron Patient Follow-Up Survey Pre-Enrollment Form.
- I agree to affix A洛setron REMS stickers to written prescriptions for A洛setron (i.e., the original and all subsequent prescriptions). A洛setron REMS stickers will be provided as part of the A洛setron REMS Program. Refills are permitted to be written on prescriptions.
- I agree to ensure that all prescriptions for A洛setron are written and not transmitted by telephone, facsimile, or computer.

To continue enrollment, please press the I Agree button.
Please complete the fields below and press Submit to complete enrollment in the Alosetron REMS Program. All fields below are required unless otherwise indicated.

**Enrolling Prescriber**

First Name

Last Name

National Provider Identifier (NPI)

**Prescriber Office Address**

Office Name

Address 1

Address 2 (Optional)

City

State

Zip Code

Phone

Fax

Email

Correspondence Confirmation Preference

Signature (First and Last Name as typed above) Date MM/DD/YYYY Submit

Your signature and date are required to complete your enrollment. Please type your exact first and last name along with today's date in the spaces provided below. This will serve as your electronic signature and will certify that you have read and agreed to the terms provided for the program.
Congratulations!

You have successfully enrolled in the Alosetron REMS Program!

Below is your Alosetron REMS Program Enrollment ID. Please note, you will receive an enrollment confirmation via your correspondence confirmation preference. Please retain this information for your records. You will also receive additional enrollment materials via postal mail in the next 7 to 10 days.

Enrollment ID: <Enrollment ID>

PHARMACISTS

Pharmacist Role in the Alosetron REMS Program

As a pharmacist you play an important role in the Alosetron REMS Program. Please read the complete Prescribing Information below, which includes the Medication Guide. To become familiar with the requirements of the program, please also review the Pharmacists Education Slide Deck below.

Pharmacists Education Slide Deck
Pharmacist Letter
Prescribing Information
Medication Guide

Pharmacists need to comply with the following requirements of the Alosetron REMS Program:

- Dispense only prescriptions that have an Alosetron REMS sticker.
- Never fill telephone, facsimile, or computer generated prescriptions.
- Refills are permitted on written prescriptions.
- Dispense the Medication Guide with each prescription.

\(^1\) In the alternative, a prescription for alosetron may be dispensed in the presence of a Prescribing Program for LOTRONEX\textsuperscript{TM} sticker, if generic substitution of alosetron is permitted pursuant to state substitution laws.
IMPORTANT SAFETY INFORMATION

Important Safety Information

WARNING: SERIOUS GASTROINTESTINAL ADVERSE REACTIONS

See full prescribing information for complete boxed warning.

Infrequent but serious gastrointestinal adverse reactions have been reported with the use of alosetron. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization and, rarely, blood transfusion, surgery, and death.

- Only prescribers who have enrolled in the Alosetron REMS Program can prescribe alosetron. (5.3)
- Alosetron is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have not responded adequately to conventional therapy. (1)
- Discontinue alosetron immediately in patients who develop constipation or symptoms of ischemic colitis. Do not resume alosetron in patients who develop ischemic colitis. (2.1, 5.1, 5.2)

Alosetron is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have chronic IBS symptoms (generally lasting 6 months or longer), had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and who have not responded adequately to conventional therapy. Diarrhea-predominant IBS 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 IBS.

Alosetron should not be initiated in patients with constipation. Alosetron is contraindicated in patients with a history of chronic or severe constipation or sequelae from constipation; intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; ischemic colitis; impaired intestinal circulation, thrombophlebitis, or hypercoagulable state; Crohn's disease or ulcerative colitis, diverticulitis; severe hepatic impairment, inability to understand or comply with the Patient Acknowledgement Form, and concomitant use of fluoxetine.

Please see the Full Prescribing Information for alosetron for all information including boxed warnings, and the Medication Guide for important safety information.

If you have any questions or require additional information or further copies of all the Alosetron REMS Program documents, please visit either the Alosetron REMS Program website or call the Alosetron REMS Program at 1-844-267-8675.

Promptly report suspected adverse events directly to the Alosetron REMS Program at 1-844-267-8675. You also may report adverse event information to the FDA MedWatch Reporting System by telephone at (800) FDA-1088 or by mail using Form 3500, available at www.fda.gov/medwatch.
RESOURCES

Resources

Patient
- Patient Follow-up Survey Pre-Enrollment Form

Prescriber
- Prescribing Information
- Medication Guide
- Prescriber Education Slide Deck
- Prescriber Enrollment Form
- Patient Acknowledgement Form
- Patient Follow-up Survey Pre-Enrollment Form

Pharmacist
- Prescribing Information
- Medication Guide
- Pharmacist Education Slide Deck
- Pharmacist Letter
Contact Us

If you have any questions or require additional information, please contact the Alosetron REMS Program utilizing the information provided below.

**Phone Number**
1-844-267-8675

**Fax Number**
1-800-535-6805

**Mailing Address**
Alosetron REMS Program
PO BOX 29292
PHOENIX AZ 85038-9292