

Alosetron REMS Program

Risk Evaluation and Mitigation Strategy

Web Mockups

V20

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1. FOOTER

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

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2. HOME PAGE



For Patients

For Prescribers

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 and objectives of the Alosetron REMS Program are to mitigate the risks of ischemic colitis (IC) and serious complications of constipation (CoC) associated with alosetron hydrochloride (hereinafter, referred to as alosetron) by:

- Informing prescribers of alosetron about:
 - the serious risks of IC and serious CoC associated with alosetron
 - the importance of understanding that alosetron should only be used in severely affected diarrhea-predominant irritable bowel syndrome patients for whom the benefits exceed the risks
 - the importance of counseling patients about the risks of IC and serious CoC
- Informing patients about the risks of IC and CoC and actions to take should they experience early warning signs and symptoms of these risks.

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),
- had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and
- not responded adequately to conventional therapy.

3. PATIENT



For Patients

For Prescribers

Patient Role in the Alosetron REMS Program

Only patients who are counseled on the safe use of alosetron by their prescriber should be prescribed alosetron. Patients will be counseled on the Alosetron REMS Program by trained prescribers. Patients will have the opportunity to discuss any questions or concerns they have with their prescriber. The prescriber will provide and review the Alosetron REMS Program Patient Education Sheet with the patient at the beginning of treatment. Please use the links below to review the Alosetron REMS Program Patient Education Sheet and Medication Guide.

 [Alosetron REMS Program Patient Education Sheet](#)

Medication Guide

 [Alosetron Medication Guide \(Company Name\)](#)



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NOTE: The Alosetron REMS Sponsors attest the Medication Guides on the website will only include companies for the Alosetron REMS Program on the REMS at FDA website.

4. PRESCRIBERS



For Patients

For Prescribers

Prescriber Role in the Alosetron REMS Program

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

Prescribers should comply with the following requirements of the Alosetron REMS Program:

- Review the Alosetron REMS Program Prescriber Education Slide Deck
- Fill out and submit the Prescriber Completion of Alosetron REMS Program Training Form.

Prescriber Training

Prescribers should train in the Alosetron REMS Program prior to prescribing alosetron.

To train in the Alosetron REMS Program via web:

1. Review the Alosetron REMS Program Prescriber Education Slide Deck located in the Resources section below.
2. Press **Next** to begin the completion of training process.

To train in the Alosetron REMS Program via fax:

1. Review the Alosetron REMS Program Prescriber Education Slide Deck located in the Resources section below.
2. Complete the Prescriber Completion of Alosetron REMS Program Training Form located in the Resources section below.
3. Fax the completed Prescriber Completion of Alosetron REMS Program Training Form to the Alosetron REMS Program at 1-800-535-6805.

Resources



[Prescriber Completion of Alosetron REMS Program Training Form](#)



[Alosetron REMS Program Patient Education Sheet](#)



[Alosetron REMS Program Prescriber Education Slide Deck](#)



[Alosetron REMS Program Safety Information Fact Sheet for Prescribers](#)



[REMS Letter to Healthcare Providers](#)

Prescribing Information and Medication Guide



[Alosetron Prescribing Information \(Company Name\)](#)



[Alosetron Medication Guide \(Company Name\)](#)



Next

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5. PRESCRIBER AGREEMENT



For Patients

For Prescribers

The Alosetron REMS Program – Prescriber Completion of Training

Thank you for completing the Alosetron REMS Program training. As a confirmation that you independently reviewed the program training materials, please press the **Complete Training** button and provide your details on the following form.

[Complete Training](#)

6. PRESCRIBER ONLINE TRAINING FORM



For Patients

For Prescribers

Please complete the fields below and press **Submit** to complete training in the Alosetron REMS Program. All fields below are required unless otherwise indicated.

Prescriber Information

First Name	<input type="text"/>
Last Name	<input type="text"/>
Specialty	<input type="text" value="-- Please Select --"/>
National Provider Identifier (NPI)	<input type="text"/>
Office Name	<input type="text"/>
Address 1	<input type="text"/>
Address 2	<input type="text"/> (Optional)
City	<input type="text"/>
State	<input type="text" value="-- Please Select --"/>
Zip Code	<input type="text"/>
Phone	<input type="text"/>
Fax	<input type="text"/>
Email	<input type="text"/>
Correspondence Confirmation Preference	<input type="radio"/> Email <input type="radio"/> Fax

Your signature and date are required to complete your training. 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.

<input type="text" value="Signature (First and Last Name as typed above)"/>	<input type="text" value="Date MM/DD/YYYY"/>	<input type="checkbox"/> I'm not a robot	
---	--	--	--

Submit

7. PRESCRIBER ONLINE TRAINING FORM – OTHER SPECIALTY SELECTED



For Patients

For Prescribers

Please complete the fields below and press **Submit** to complete training in the Alosetron REMS Program. All fields below are required unless otherwise indicated.

Prescriber Information

First Name	<input type="text"/>
Last Name	<input type="text"/>
Specialty	Other <input type="text"/>
	<input type="text" value="-- Please Specify --"/>
National Provider Identifier (NPI)	<input type="text"/>
Office Name	<input type="text"/>
Address 1	<input type="text"/>
Address 2	<input type="text"/> (Optional)
City	<input type="text"/>
State	<input type="text" value="-- Please Select --"/>
Zip Code	<input type="text"/>
Phone	<input type="text"/>
Fax	<input type="text"/>
Email	<input type="text"/>
Correspondence Confirmation Preference	<input type="radio"/> Email <input type="radio"/> Fax

Your signature and date are required to complete your training. 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.

<input type="text" value="Signature (First and Last Name as typed above)"/>	<input type="text" value="Date MM/DD/YYYY"/>	<input type="checkbox"/> I'm not a robot	 reCAPTCHA Privacy - Terms
			<input type="submit" value="Submit"/>

8. PRESCRIBER TRAINING CONFIRMATION



For Patients

For Prescribers

Congratulations!

You have successfully trained in the Alosetron REMS Program!

Below is your Alosetron REMS Program Training Confirmation. Please note, you will receive acknowledgement of completion of training via your correspondence confirmation preference. Please retain this information for your records.

Training Confirmation: <Confirmation ID>

9. RESOURCES



For Patients

For Prescribers

Resources

Prescriber

-  [Alosetron REMS Program Prescriber Education Slide Deck](#)
-  [Prescriber Completion of Alosetron REMS Program Training Form](#)
-  [Alosetron REMS Program Patient Education Sheet](#)
-  [Alosetron REMS Program Safety Information Fact Sheet for Prescribers](#)
-  [REMS Letter to Healthcare Providers](#)

Prescribing Information and Medication Guide

-  [Alosetron Prescribing Information \(Company Name\)](#)
-  [Alosetron Medication Guide \(Company Name\)](#)



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10. CONTACT US



For Patients

For Prescribers

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