

Bosentan REMS Program Website Pages

May 5, 2019

Version 6.0

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1. Public Pages

1.1 Coming Soon Page

COMING SOON!

Beginning **MM/DD/YYYY** bosentan is only available through the Bosentan REMS Program, and includes all brand and generic bosentan products. As of **MM/DD/YYYY** prescribers can verify whether their patient's pharmacy is authorized to dispense bosentan by visiting the ***Bosentan REMS Program Website***. Until **MM/DD/YYYY** patients will continue to have access to Tracleer through the Tracleer REMS Program and certified specialty pharmacies.

Prescribers that are certified in the Tracleer REMS Program will be automatically certified in the Bosentan REMS Program. Patients that are enrolled in the Tracleer REMS Program will be automatically enrolled in the Bosentan REMS Program. No further action is required for patients that are enrolled in the Tracleer REMS Program. Specialty pharmacies that are certified in the Tracleer REMS Program must complete certification in the Bosentan REMS Program.

Phone Number

1-866-359-2612

Fax Number

1-800-730-8231

Mailing Address

Bosentan REMS Program

PO BOX 29080

Phoenix, AZ 85038

1.2 Home Page

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A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks. The Bosentan REMS Program is a single shared REMS program for brand and generic approved bosentan medications for the treatment of pulmonary arterial hypertension (PAH). Due to the risks of hepatotoxicity and embryo-fetal toxicity, bosentan is only available through the Bosentan REMS Program.

Bosentan REMS Program Overview

- All healthcare providers must certify in the Bosentan REMS Program and comply with the Bosentan REMS Program requirements in order to prescribe a bosentan product
- All patients must be enrolled in the Bosentan REMS Program. Enrolled patients must comply with the Bosentan REMS Program requirements in order to receive bosentan:
 - Patients must agree to complete liver function tests, and pregnancy tests as appropriate for the patient's reproductive potential classification prior to receiving bosentan
 - All patients must agree to be counseled on the Bosentan REMS Program and the risks of treatment with bosentan
 - All patients must agree to be contacted about completing required monthly testing and counseling
- For all patients:
 - Prescribers must counsel all patients on the risk of hepatotoxicity associated with bosentan, the signs and symptoms of hepatotoxicity, and program requirements including the need to complete liver function testing and, as appropriate, pregnancy testing by reviewing the [Bosentan REMS Program Guide for Patients to each patient](#)
 - Prescribers must complete the [Bosentan REMS Program Patient Enrollment Form](#) with every bosentan patient and submit the form to the Bosentan REMS Program prior to initiating treatment
 - Counsel patients who fail to comply with program requirements
 - Prescribers must order and review liver function test results before bosentan treatment initiation
 - Prescribers must order and review monthly liver function test results
 - Prescribers must report all adverse events including those suggestive of hepatotoxicity to the Bosentan REMS Program
- For all female patients:
 - Prescribers must determine the reproductive potential status of every female before initiating bosentan treatment
 - Prescribers must report a change or misclassification in reproductive potential status by submitting a [Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#) to the Bosentan REMS Program within 10 business days of becoming aware of the change
 - Prescribers must report any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program
- For females of reproductive potential:
 - Prescribers must counsel patients about the risk of embryo-fetal toxicity and the need to use reliable contraception prior to initiating treatment, during bosentan treatment, and for one month after ending treatment
 - Prescribers must counsel the patient to immediately contact her healthcare provider if she misses a menstrual period or suspects pregnancy
 - Prescribers must order and review pregnancy tests prior to initiation of bosentan treatment, monthly during treatment, and for one month after ending treatment
- For pre-pubertal female patients:
 - Prescribers must counsel the patient and/or a parent/legal guardian about the risk of embryo-fetal toxicity
 - Prescribers must counsel the patient and/or a parent/legal guardian to immediately contact her healthcare provider if she begins to menstruate
 - Prescribers must evaluate patients age 8 years and older at least annually for any change in reproductive status and submit a [Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#) to the Bosentan REMS Program within 10 business days of becoming aware of the change
- Prescribers may report that the appropriate monthly tests and counseling, comprising liver function tests (for all patients), pregnancy tests for females of reproductive potential, and monthly counseling have been completed by reporting it to the Bosentan REMS Program. This information can be reported by one of the following methods:
 - Submitting a [Bosentan REMS Program Testing and Patient Counseling Reporting Form](#) by fax to the Bosentan REMS Program at 1-800-730-8231
 - Completing the [Bosentan REMS Program Testing and Patient Counseling Reporting Form](#) online at www.BosentanREMSProgram.com
 - Calling the Bosentan REMS Program at 1-866-359-2612

Note: Use of the [Bosentan REMS Program Testing and Patient Counseling Reporting Form](#) is voluntary.

- Prescribers must closely monitor transaminase levels and adjust monitoring and treatment with bosentan if increases are reported
- Prescribers must discontinue bosentan if liver aminotransferase elevations are accompanied by clinical symptoms of hepatotoxicity or increases in bilirubin $\geq 2 \times$ ULN
- Only inpatient, outpatient, and chain pharmacies certified in the Bosentan REMS Program can dispense bosentan

Materials for Prescribers

- [Bosentan REMS Program Prescriber Enrollment Form](#)
- [Bosentan REMS Program Prescriber Guide](#)
- [Bosentan REMS Program Patient Enrollment Form](#)
- [Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)
- [Bosentan REMS Program Testing and Patient Counseling Reporting Form](#)
- [Bosentan REMS Program Fact Sheet](#)

Start Prescriber Certification

Materials for Pharmacies

- [Bosentan REMS Program Outpatient Pharmacy Enrollment Form](#)
- [Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form](#)
- [Bosentan REMS Program Inpatient Pharmacy Enrollment Form](#)
- [Bosentan REMS Program Pharmacy Guide](#)
- [Bosentan REMS Program Fact Sheet](#)

Start Pharmacy Certification

Materials for Patients

- [Bosentan REMS Program Guide for Patients](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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1.3 Prescriber Landing Page

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Prescriber Certification

Prescriber's Role in the Bosentan REMS Program:

Expand all

1. READ

READ the Prescribing Information for bosentan and Medication Guide for the prescribed product and the **Bosentan REMS Program Prescriber Guide** to understand the risks of bosentan and to learn about the Bosentan REMS Program

- You must understand the risks of bosentan and become familiar with the Bosentan REMS Program

2. COMPLETE

COMPLETE a **Bosentan REMS Program Prescriber Enrollment Form**

- By signing the form, you attest to understanding the risks of bosentan and agree to comply with the requirements of the Bosentan REMS Program
- You can complete the **Bosentan REMS Program Prescriber Enrollment Form** [online](#) or download the form from the **Bosentan REMS Program Website** [here](#), and fax the form to the Bosentan REMS Program at 1-800-730-8231

3. DETERMINE

DETERMINE the reproductive potential for female patients

- You should identify female patients (captured on the **Bosentan REMS Program Patient Enrollment Form**) as one of the following categories:
 - Females of reproductive potential
 - Females of non-reproductive potential (choose one of the options below)
 - Pre-pubertal female of non-reproductive potential
 - Post-menopausal female of non-reproductive potential
 - Female with other medical reasons for permanent, irreversible infertility
- Expanded definitions are provided in the **Bosentan REMS Program Prescriber Guide**

4. EDUCATE & COUNSEL

EDUCATE & COUNSEL all patients about the risks of bosentan

- For all patients, you must:
 - Counsel all patients on the risk of hepatotoxicity associated with bosentan, the signs and symptoms of hepatotoxicity, and program requirements including the need to complete liver function testing and, as appropriate, pregnancy testing by reviewing and providing the patient the Medication Guide, and **Bosentan REMS Program Guide for Patients**
 - Complete the **Bosentan REMS Program Patient Enrollment Form** with every new bosentan patient and submit the form to the Bosentan REMS Program prior to initiating treatment
 - Educate patients about the Bosentan REMS Program
 - Order and review pretreatment liver function tests
 - Order and review monthly liver function tests
 - Notify the Bosentan REMS Program of all adverse events including those suggestive of hepatotoxicity
 - Notify the Bosentan REMS Program of any pregnancy and all available information during treatment with bosentan
- For females of reproductive potential, you must:
 - Counsel patients about the risk of embryo-fetal toxicity, the need to complete monthly pregnancy tests, and the need to use reliable contraception prior to initiating treatment, during bosentan treatment and for one month after ending treatment
 - Counsel the patient to immediately contact her healthcare provider if she misses a menstrual period or suspects pregnancy
 - Order and review pregnancy tests prior to initiation of bosentan treatment, monthly during treatment, and for one month after ending treatment
- For pre-pubertal females, you must:
 - Counsel the patient and/or a parent/legal guardian about the risk of embryo-fetal toxicity and the need to use reliable contraception
 - Counsel the patient and/or a parent/legal guardian to immediately contact her healthcare provider if she begins to menstruate
 - Evaluate patients age 8 years and older at least annually for any change in reproductive status and submit a **Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** to the Bosentan REMS Program within 10 business days of becoming aware of the change

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5. ENROLL

ENROLL all patients in the Bosentan REMS Program by ensuring patients complete the **Bosentan REMS Program Patient Enrollment Form**

- Confirm the patient has agreed to comply with program requirements and has signed the form where indicated
- Fax the completed form to the Bosentan REMS Program at 1-800-730-8231, or complete the form [here](#)
- Keep the original form with the patient's records

6. TEST

TEST each patient's liver function and pregnancy status of females of reproductive potential

- Order and review liver function tests for all patients:
 - Prior to initiating treatment
 - Monthly during treatment
- Order and review pregnancy tests for females of reproductive potential:
 - Prior to initiating treatment
 - Monthly during treatment
 - One month after ending bosentan treatment

7. REVIEW

REVIEW all required test results and monitor patients throughout treatment

- For all patients:
 - Order and review liver function tests each month during treatment with bosentan
 - You may, though you are not required to, confirm the completion of liver function tests and counseling each month by one of the following methods:
 - Submitting a **Bosentan REMS Program Testing and Patient Counseling Reporting Form** by fax to the Bosentan REMS Program at 1-800-730-8231
 - Completing the **Bosentan REMS Program Testing and Patient Counseling Reporting Form** [here](#)
 - Calling the Bosentan REMS Program at 1-866-359-2612
 - For changes in aminotransferase levels, adjust the monitoring and treatment with bosentan
 - Discontinue bosentan if aminotransferase elevations are accompanied by signs or symptoms of liver dysfunction or injury or increases in bilirubin $\geq 2 \times$ ULN
- For all females of reproductive potential:
 - Order and review pregnancy tests monthly during treatment with bosentan and for one month after ending treatment
 - You may, though you are not required to, confirm the completion of pregnancy tests and counseling each month by one of the following methods:
 - Submitting a **Bosentan REMS Program Testing and Patient Counseling Reporting Form** by fax to the Bosentan REMS Program at 1-800-730-8231
 - Completing the **Bosentan REMS Program Testing and Patient Counseling Reporting Form** online [here](#)
 - Calling the Bosentan REMS Program at 1-866-359-2612
 - Report any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program
 - Monitor patient's reproductive status during treatment with bosentan and report any change or misclassification in reproductive potential status by submitting a **Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** to the Bosentan REMS Program within 10 business days of becoming aware of the change
- For females of non-reproductive potential:
 - Monitor patient's reproductive status during treatment with bosentan and report any change or misclassification in reproductive potential status by submitting a **Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** to the Bosentan REMS Program within 10 business days of becoming aware of the change
 - For each patient who is 8 years of age or older, verify annually and report the reproductive status by completing and submitting the **Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form**

8. NOTIFY

NOTIFY the Bosentan REMS Program of all adverse events including those suggestive of hepatotoxicity

9. REPORT

REPORT any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program

[Start Prescriber Certification](#)

Materials for Prescribers

-  [Bosentan REMS Program Prescriber Enrollment Form](#)
-  [Bosentan REMS Program Prescriber Guide](#)
-  [Bosentan REMS Program Patient Enrollment Form](#)
-  [Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)
-  [Bosentan REMS Program Testing and Patient Counseling Reporting Form](#)
-  [Bosentan REMS Program Fact Sheet](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

1.4 Pharmacy Landing Page



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Bosentan REMS Program Pharmacy Types and Definitions

All outpatient, chain, and inpatient pharmacies must certify in the Bosentan REMS Program to purchase and dispense bosentan.

Pharmacy staff must enroll in the Bosentan REMS Program to obtain a Pre-dispense Authorization (PDA) or to perform an inpatient REMS requirements check from the REMS website. For more information on the pharmacy staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Pharmacies participating in the Bosentan REMS Program must determine their pharmacy type based on the definitions below:

Pharmacy Type	Definition
Outpatient Pharmacy	For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.
Chain Pharmacy	For the purposes of this REMS chain pharmacies are retail pharmacies with multiple locations that dispense bosentan for outpatient use and have a pharmacy headquarters that coordinates pharmacy enrollment in the Bosentan REMS Program.
Inpatient Pharmacy	For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.

To become certified, pharmacies must designate an authorized representative to complete enrollment. An authorized representative for a pharmacy may be, but is not limited to:

- Pharmacy Manager
- Staff Pharmacist
- Director of Pharmacy Services
- Corporate Executive overseeing Pharmacy Services

In general, an authorized representative for a pharmacy:

- Coordinates the activities required for the pharmacy and/or pharmacy staff in the Bosentan REMS Program
- Establishes and implements processes and procedures to ensure compliance with the safe use conditions of the Bosentan REMS Program
- Maintains documentation that all processes and procedures are in place and are being followed for the Bosentan REMS Program and provide upon request to the Bosentan Sponsors, or a third party acting on behalf of the Bosentan Sponsors
- Complies with audits by the Bosentan Sponsors, or a third party acting on behalf of the Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program

Note: Pharmacies must recertify in the Bosentan REMS Program if the pharmacy designates a new authorized representative.

Select your pharmacy type below for more information.

OUTPATIENT PHARMACY

CHAIN PHARMACY

INPATIENT PHARMACY

Materials for Pharmacies

- [Bosentan REMS Program Outpatient Pharmacy Enrollment Form](#)
- [Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form](#)
- [Bosentan REMS Program Inpatient Pharmacy Enrollment Form](#)
- [Bosentan REMS Program Pharmacy Guide](#)
- [Bosentan REMS Program Fact Sheet](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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Note: This page is available by selecting the 'Pharmacies' tab at the top of the screen and then selecting 'Pharmacy Certification' from the dropdown menu selection provided.

1.4.1 Pharmacy Landing Page: Outpatient Pharmacy

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Bosentan REMS Program Pharmacy Types and Definitions

All outpatient, chain, and inpatient pharmacies must certify in the Bosentan REMS Program to purchase and dispense bosentan.

Pharmacy staff must enroll in the Bosentan REMS Program to obtain a Pre-dispense Authorization (PDA) or to perform an inpatient REMS requirements check from the REMS website. For more information on the pharmacy staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Pharmacies participating in the Bosentan REMS Program must determine their pharmacy type based on the definitions below:

Pharmacy Type	Definition
Outpatient Pharmacy	For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.
Chain Pharmacy	For the purposes of this REMS chain pharmacies are retail pharmacies with multiple locations that dispense bosentan for outpatient use and have a pharmacy headquarters that coordinates pharmacy enrollment in the Bosentan REMS Program.
Inpatient Pharmacy	For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.

To become certified, pharmacies must designate an authorized representative to complete enrollment. An authorized representative for a pharmacy may be, but is not limited to:

- Pharmacy Manager
- Staff Pharmacist
- Director of Pharmacy Services
- Corporate Executive overseeing Pharmacy Services

In general, an authorized representative for a pharmacy:

- Coordinates the activities required for the pharmacy and/or pharmacy staff in the Bosentan REMS Program.
- Establishes and implements processes and procedures to ensure compliance with the safe use conditions of the Bosentan REMS Program.
- Maintains documentation that all processes and procedures are in place and are being followed for the Bosentan REMS Program and provide upon request to the Bosentan Sponsors, or a third party acting on behalf of the Bosentan Sponsors.
- Complies with audits by the Bosentan Sponsors, or a third party acting on behalf of the Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program.

Note: Pharmacies must recertify in the Bosentan REMS Program if the pharmacy designates a new authorized representative.

Select your pharmacy type below for more information.

OUTPATIENT PHARMACY

CHAIN PHARMACY

INPATIENT PHARMACY

The authorized representative for each outpatient pharmacy must complete the following steps in the Bosentan REMS Program:

Expand all

1. READ

READ the Prescribing Information for bosentan and Medication Guide and the **Bosentan REMS Program Pharmacy Guide** to understand the risks of bosentan and to learn about the Bosentan REMS Program

- The authorized representative for the pharmacy must understand the risks of bosentan and become familiar with the Bosentan REMS Program, prior to certifying their pharmacy

2. ENROLL

ENROLL the pharmacy by completing the **Bosentan REMS Program Outpatient Pharmacy Enrollment Form**

- By signing the form, the authorized representative attests to understanding the risks of bosentan and agrees to comply with the Bosentan REMS Program as described in the **Bosentan REMS Program Outpatient Pharmacy Enrollment Form**
- The authorized representative can complete the enrollment forms [online](#) or download the form [here](#) and fax the form to the Bosentan REMS Program at 1-800-730-8231
 - If your outpatient pharmacy supports electronic verification with the Bosentan REMS Program system, during the enrollment process your authorized representative will be instructed to verify the pre-dispense authorization (PDA) is operational using established telecommunication standards, and by running the standardized validation test transactions to validate the system enhancements

3. TRAIN

TRAIN all pharmacy staff who participate in dispensing bosentan on the Bosentan REMS Program requirements

- Prior to dispensing bosentan, the authorized representative must ensure that all pharmacy staff who participate in dispensing bosentan are educated on the risks associated with bosentan and the requirements of the Bosentan REMS Program as defined in the **Bosentan REMS Program Outpatient Pharmacy Enrollment Form**
- Any pharmacy employee may assume the role of a pharmacy staff member and associate with a certified outpatient pharmacy by accessing the **Bosentan REMS Program Website**
 - Pharmacy staff in outpatient pharmacies that do NOT support electronic communication verification with the Bosentan REMS Program system will be able to request a PDA

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4. DOCUMENT

DOCUMENT all staff training

- Certified pharmacies are subject to audit by Bosentan Sponsors, or a third party acting on behalf of Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program

5. VERIFY SAFE USE CONDITIONS

VERIFY SAFE USE CONDITIONS for each patient prior to dispensing bosentan

- Outpatient pharmacies must obtain a pre-dispense authorization (PDA) prior to dispensing bosentan to a patient
 - If your outpatient pharmacy supports electronic telecommunication verification with the Bosentan REMS Program system, your pharmacy must dispense bosentan to patients only after obtaining a PDA through your pharmacy management system
 - If your outpatient pharmacy does NOT support electronic telecommunication verification with the Bosentan REMS Program system, your pharmacy must dispense bosentan to patients only after obtaining a PDA by calling the Bosentan REMS Program Contact Center or accessing the **Bosentan REMS Program Website**
 - If a PDA is not issued, prior to dispensing bosentan the outpatient pharmacy may perform the corresponding activity to address the reasons that a PDA was not issued:
 - Certify the pharmacy in the Bosentan REMS Program
 - Contact the prescriber or the Bosentan REMS Program to notify the prescriber that certification is required in the Bosentan REMS Program before bosentan can be dispensed
 - Contact the prescriber or the Bosentan REMS Program to notify the prescriber that the patient must be enrolled in the Bosentan REMS Program before bosentan can be dispensed
 - If a PDA is not issued because required testing is not confirmed, the outpatient pharmacy can call the Bosentan REMS Program Contact Center at 1-866-359-2612 to confirm with the patient or the patient's prescriber that the testing has been completed before bosentan can be dispensed
 - If counseling is not confirmed in the Bosentan REMS Program, a PDA will be issued if all other safe use conditions are met. The pharmacy must call the Bosentan REMS Program Contact Center to complete the counseling requirement before bosentan is dispensed. The Contact Center will provide counseling guidelines to the pharmacy. The pharmacy is required to counsel the patient according to the guidelines from the Contact Center
 - The Contact Center agents will be available during normal business hours. The Contact Center agent will provide the counseling guidelines and document the counseling
 - An interactive voice response system will be available 24/7. The system will provide the counseling guidelines and document the counseling

6. DISPENSE

DISPENSE up to a 30-day supply, along with a copy of the Medication Guide for the bosentan product that is dispensed

- Up to a 90-day supply may be dispensed with a refill dispense exception authorized by the prescriber for extended travel outside of the United States of more than 30 days

7. NOT TRANSFER BOSENTAN

NOT TRANSFER BOSENTAN to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program

8. NOTIFY

NOTIFY the Bosentan REMS Program of all adverse events including those suggestive of hepatotoxicity

9. REPORT

REPORT any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program

[Start Pharmacy Certification](#)

Materials for Pharmacies

-  [Bosentan REMS Program Outpatient Pharmacy Enrollment Form](#)
-  [Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form](#)
-  [Bosentan REMS Program Inpatient Pharmacy Enrollment Form](#)
-  [Bosentan REMS Program Pharmacy Guide](#)
-  [Bosentan REMS Program Fact Sheet](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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Note: This page is available by selecting the pharmacies tab at the top of the screen and then selecting 'Pharmacy Certification' from the dropdown menu selection provided.

1.4.2 Pharmacy Landing Page: Chain Pharmacy

Prescribing Information | Medication Guides

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Pharmacies
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FAQs

Bosentan REMS

Pharmacy Certification
Pharmacy Staff Enrollment

Types and Definitions

All outpatient, chain, and inpatient pharmacies are required to enroll in the Bosentan REMS Program to purchase and dispense bosentan.

Pharmacy staff must enroll in the Bosentan REMS Program to obtain a Pre-dispense Authorization (PDA) or to perform an inpatient REMS requirements check from the REMS website. For more information on the pharmacy staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Pharmacies participating in the Bosentan REMS Program must determine their pharmacy type based on the definitions below:

Pharmacy Type	Definition
Outpatient Pharmacy	For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.
Chain Pharmacy	For the purposes of this REMS chain pharmacies are retail pharmacies with multiple locations that dispense bosentan for outpatient use and have a pharmacy headquarters that coordinates pharmacy enrollment in the Bosentan REMS Program.
Inpatient Pharmacy	For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.

To become certified, pharmacies must designate an authorized representative to complete enrollment. An authorized representative for a pharmacy may be, but is not limited to:

- Pharmacy Manager
- Staff Pharmacist
- Director of Pharmacy Services
- Corporate Executive overseeing Pharmacy Services

In general, an authorized representative for a pharmacy:

- Coordinates the activities required for the pharmacy and/or pharmacy staff in the Bosentan REMS Program.
- Establishes and implements processes and procedures to ensure compliance with the safe use conditions of the Bosentan REMS Program.
- Maintains documentation that all processes and procedures are in place and are being followed for the Bosentan REMS Program and provide upon request to the Bosentan Sponsors, or a third party acting on behalf of the Bosentan Sponsors.
- Complies with audits by the Bosentan Sponsors, or a third party acting on behalf of the Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program.

Note: Pharmacies must recertify in the Bosentan REMS Program if the pharmacy designates a new authorized representative.

Select your pharmacy type below for more information.

OUTPATIENT PHARMACY

CHAIN PHARMACY

INPATIENT PHARMACY

The authorized representative for the chain pharmacy must complete the following steps in the Bosentan REMS Program:

Expand all

1. READ

READ the Prescribing Information for bosentan and Medication Guide and the **Bosentan REMS Program Pharmacy Guide** to understand the risks of bosentan and to learn about the Bosentan REMS Program

- The authorized representative for the pharmacy must understand the risks of bosentan and become familiar with the Bosentan REMS Program, prior to certifying their pharmacy

2. ENROLL

ENROLL the chain pharmacy by completing the **Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form**

- By signing the form, the authorized representative attests to understanding the risks of bosentan and agrees to comply with the Bosentan REMS Program as described in the **Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form**
- The authorized representative can complete the enrollment forms [online](#) or download the form [here](#) and fax the form to the Bosentan REMS Program at 1-800-730-8231
- Ensure the pharmacy enables its pharmacy management system to support communication with the Bosentan REMS Program system, using established telecommunication standards, and runs the standardized validation test transactions to validate the system enhancements

3. TRAIN

TRAIN all pharmacy staff who participate in dispensing bosentan on the Bosentan REMS Program requirements

- Prior to dispensing bosentan, the authorized representative must ensure that all pharmacy staff who participate in dispensing bosentan are educated on the risks associated with bosentan and the requirements of the Bosentan REMS Program as defined in the **Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form**

4. DOCUMENT

DOCUMENT all staff training

- Once each dispensing location is trained, it is the authorized representative's responsibility to report confirmation of training to the Bosentan REMS Program online through www.BosentanREMSProgram.com, or by contacting the Bosentan REMS Program Contact Center at 1-866-359-2612 to obtain instructions on providing a list of trained pharmacy locations. Once the Bosentan REMS Program confirms the required dispensing information, the dispensing location will be authorized to purchase, receive, and dispense bosentan
- Certified pharmacies are subject to audit by Bosentan Sponsors or a third party designated by Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program

5. VERIFY SAFE USE CONDITIONS

VERIFY SAFE USE CONDITIONS for each patient prior to dispensing bosentan

- Chain pharmacies must dispense bosentan to patients only after obtaining a pre-dispense authorization (PDA) by processing the prescription including cash claims through their pharmacy management system.
 - If a PDA is not issued, prior to dispensing bosentan the pharmacy may perform the corresponding activity to address the reasons that a PDA was not issued:
 - Certify the pharmacy in the Bosentan REMS Program
 - Contact the prescriber or the Bosentan REMS Program to notify the prescriber that certification is required in the Bosentan REMS Program before bosentan can be dispensed
 - Contact the prescriber or the Bosentan REMS Program to notify the prescriber that the patient must be enrolled in the Bosentan REMS Program before bosentan can be dispensed
 - If a PDA is not issued because required testing is not confirmed, the outpatient pharmacy can call the Bosentan REMS Program Contact Center at 1-866-359-2612 to confirm with the patient or the patient's prescriber that the testing has been completed before bosentan can be dispensed
 - If counseling is not confirmed in the Bosentan REMS Program, a PDA will be issued if all other safe use conditions are met. The pharmacy must call the Bosentan REMS Program Contact Center to complete the counseling requirement before bosentan is dispensed. The Contact Center will provide counseling guidelines to the pharmacy. The pharmacy is required to counsel the patient according to the guidelines from the Contact Center
 - The Contact Center agents will be available during normal business hours. The Contact Center agent will provide the counseling guidelines and document the counseling
 - An interactive voice response system will be available 24/7. The system will provide the counseling guidelines and document the counseling

6. DISPENSE

DISPENSE up to a 30-day supply, along with a copy of the Medication Guide for the bosentan product that is dispensed

- Up to a 90-day supply may be dispensed with a refill dispense exception authorized by the prescriber for extended travel outside of the United States of more than 30 days

7. NOT TRANSFER BOSENTAN

NOT TRANSFER BOSENTAN to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program

8. NOTIFY

NOTIFY the Bosentan REMS Program of all adverse events including those suggestive of hepatotoxicity

9. REPORT

REPORT any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program

[Start Pharmacy Certification](#)

Materials for Pharmacies

-  [Bosentan REMS Program Outpatient Pharmacy Enrollment Form](#)
-  [Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form](#)
-  [Bosentan REMS Program Inpatient Pharmacy Enrollment Form](#)
-  [Bosentan REMS Program Pharmacy Guide](#)
-  [Bosentan REMS Program Fact Sheet](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Note: This page is available by selecting the pharmacies tab at the top of the screen and then selecting 'Pharmacy Certification' from the dropdown menu selection provided.

1.4.3 Pharmacy Landing Page: Inpatient Pharmacy



Prescribing Information | Medication Guides
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Prescribers

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Bosentan REMS

Pharmacy Certification

Pharmacy Staff Enrollment

Types and Definitions

All outpatient, chain, and inpatient pharmacies must enroll in the Bosentan REMS Program to purchase and dispense bosentan.

Pharmacy staff must enroll in the Bosentan REMS Program to obtain a Pre-dispense Authorization (PDA) or to perform an inpatient REMS requirements check from the REMS website. For more information on the pharmacy staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Pharmacies participating in the Bosentan REMS Program must determine their pharmacy type based on the definitions below:

Pharmacy Type	Definition
Outpatient Pharmacy	For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.
Chain Pharmacy	For the purposes of this REMS chain pharmacies are retail pharmacies with multiple locations that dispense bosentan for outpatient use and have a pharmacy headquarters that coordinates pharmacy enrollment in the Bosentan REMS Program.
Inpatient Pharmacy	For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.

To become certified, pharmacies must designate an authorized representative to complete enrollment. An authorized representative for a pharmacy may be, but is not limited to:

- Pharmacy Manager
- Staff Pharmacist
- Director of Pharmacy Services
- Corporate Executive overseeing Pharmacy Services

In general, an authorized representative for a pharmacy:

- Coordinates the activities required for the pharmacy and/or pharmacy staff in the Bosentan REMS Program.
- Establishes and implements processes and procedures to ensure compliance with the safe use conditions of the Bosentan REMS Program.
- Maintains documentation that all processes and procedures are in place and are being followed for the Bosentan REMS Program and provide upon request to the Bosentan Sponsors, or a third party acting on behalf of the Bosentan Sponsors.
- Complies with audits by the Bosentan Sponsors, or a third party acting on behalf of the Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program.

Note: Pharmacies must recertify in the Bosentan REMS Program if the pharmacy designates a new authorized representative.

Select your pharmacy type below for more information.

OUTPATIENT PHARMACY

CHAIN PHARMACY

INPATIENT PHARMACY

The authorized representative for each inpatient pharmacy must complete the following steps in the Bosentan REMS Program:

Expand all

1. READ

READ the Prescribing Information for bosentan and Medication Guide and the **Bosentan REMS Program Pharmacy Guide** to understand the risks of bosentan and to learn about the Bosentan REMS Program

- The authorized representative for the pharmacy must understand the risks of bosentan and become familiar with the Bosentan REMS Program, prior to certifying their pharmacy

2. ENROLL

ENROLL the pharmacy by completing the **Bosentan REMS Program Inpatient Pharmacy Enrollment Form**

- By signing the form, the authorized representative attests to understanding the risks of bosentan and agrees to comply with the Bosentan REMS Program as described in the **Bosentan REMS Program Inpatient Pharmacy Enrollment Form**
- The authorized representative can complete the enrollment forms [online](#) or download the form [here](#) and fax the form to the Bosentan REMS Program at 1-800-730-8231

3. TRAIN

TRAIN all dispensing staff on the Bosentan REMS Program

- Prior to dispensing bosentan, the authorized representative must ensure that all staff are appropriately trained on the Bosentan REMS Program procedures and materials as defined in the **Bosentan REMS Program Inpatient Pharmacy Enrollment Form**
- Any pharmacy employee may assume the role of a pharmacy staff member and associate with a certified inpatient pharmacy by accessing the **Bosentan REMS Program Website** to verify safe use conditions for each patient prior to dispensing bosentan

Bosentan_Website_Screen_Captures

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4. DOCUMENT

DOCUMENT all staff training

- Certified pharmacies are subject to audit by the Bosentan Sponsors or a third party designated by Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program

5. VERIFY SAFE USE CONDITIONS

VERIFY SAFE USE CONDITIONS for each patient prior to dispensing bosentan

- Dispense bosentan to patients only after calling the Bosentan REMS Program Contact Center or accessing the **Bosentan REMS Program Website** to verify the prescriber is certified
- Dispense bosentan to patients only after calling the Bosentan REMS Program Contact Center, accessing the **Bosentan REMS Program Website**, or accessing the patient's medical record to:
 - Verify the patient is under the supervision of a prescriber who is certified
 - Verify the patient is enrolled or will be enrolled prior to discharge
- Dispense to a patient only if he/she has been enrolled in the Bosentan REMS Program or if he/she will be enrolled prior to discharge from the healthcare facility
 - A patient who has not been enrolled by the certified prescriber will not have access to bosentan in the outpatient setting until enrollment has been completed

6. DISPENSE

DISPENSE no more than a 15-day supply of bosentan upon discharge

7. NOT TRANSFER BOSENTAN

NOT TRANSFER BOSENTAN to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program

8. NOTIFY

NOTIFY the Bosentan REMS Program of all adverse events including those suggestive of hepatotoxicity

9. REPORT

REPORT any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program

[Start Pharmacy Certification](#)

Materials for Pharmacies

-  [Bosentan REMS Program Outpatient Pharmacy Enrollment Form](#)
-  [Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form](#)
-  [Bosentan REMS Program Inpatient Pharmacy Enrollment Form](#)
-  [Bosentan REMS Program Pharmacy Guide](#)
-  [Bosentan REMS Program Fact Sheet](#)

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

Note: This page is available by selecting the pharmacies tab at the top of the screen and then selecting 'Pharmacy Certification' from the dropdown menu selection provided.

1.4.4 Pharmacy Landing Page: Pharmacy Staff

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username Password Sign in

Forgot Username? Forgot Password? Need an Account?

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Pharmacy Staff

Pharmacy Certification

Pharmacy Staff Enrollment

Steps for Pharmacy Staff Enrollment

Pharmacy staff may include pharmacists or other individuals who assist in dispensing medication in a pharmacy. If your pharmacy is certified to dispense bosentan, pharmacy staff can enroll in the Bosentan REMS Program to have access to the **Bosentan REMS Program Website**. Pharmacy staff can associate to one or more certified pharmacy locations in the Bosentan REMS Program through the **Bosentan REMS Program Website**. Pharmacy staff enroll by creating an online account.

For Outpatient Pharmacies that do not support electronic telecommunication verification: Pharmacy staff must enroll in the Bosentan REMS Program in order to obtain a pre-dispense authorization (PDA) and reverse a PDA through the **Bosentan REMS Program Website**.

For Inpatient Pharmacies: Pharmacy staff must enroll in the Bosentan REMS Program in order to check inpatient REMS requirements through the **Bosentan REMS Program Website**.

Pharmacy staff enrollment in the Bosentan REMS Program includes the following three steps:

1. **ASSOCIATE:** Associate to a Pharmacy
2. **ENROLL:** Complete the intake form
3. **ATTEST:** Complete and sign the pharmacy staff attestation

[Start Pharmacy Staff Enrollment](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

1.5 Patient Landing Page

Prescribing Information | Medication Guides

Bosentan
REMS Program

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[Prescribers](#) [Pharmacies](#) [Patients](#) [Pharmacy Lookup](#) [FAQs](#)

Patients

What is the Bosentan REMS (Risk Evaluation and Mitigation Strategy) Program?

The Bosentan REMS Program tells patients and healthcare providers about the **risks of liver damage and serious birth defects** when taking bosentan. This program is required by the Food and Drug Administration (FDA). All patients must enroll in the Bosentan REMS Program to receive bosentan.

How do I enroll in the Bosentan REMS Program?

You must complete the following steps to enroll in the Bosentan REMS Program:

Expand all

1. READ

READ the Medication Guide and the ***Bosentan REMS Program Guide for Patients***

2. ASK

ASK your healthcare provider any questions you have about taking bosentan and the Bosentan REMS Program

3. UNDERSTAND

MAKE SURE YOU UNDERSTAND

- The benefits and risks of bosentan
- How to enroll and take part in the Bosentan REMS Program

4. COMPLETE AND SIGN

COMPLETE AND SIGN the ***Bosentan REMS Program Patient Enrollment Form*** with your healthcare provider. Your healthcare provider will fill out most of the enrollment form for you. You must read and agree to the requirements, then sign to show you understand and will follow the rules of the program. Your healthcare provider will then send the form to the Bosentan REMS Program. A parent/legal guardian may sign the form for you. You do not need to set up an account on the ***Bosentan REMS Program Website***.

Materials for Patients

 ***Bosentan REMS Program Guide for Patients***

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

1.6 Prescribing Information for bosentan and Medication Guides



[Prescribing Information | Medication Guides](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

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FAQs

Prescribing Information for bosentan and Medication Guides

Brand Name Products

Trade Name	Generic Name	Company	Medication Guide	Prescribing Information

Generic Products

Trade Name	Generic Name	Company	Medication Guide	Prescribing Information

NOTE: The Bosentan Sponsors attest that the table above will only include products listed in the Product Name column for the Bosentan REMS Program on the REMS at FDA website.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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Note: The Bosentan Sponsors attest that the above table will only include products listed in the Product Name column for the Bosentan REMS Program on the REMS@FDA website.

1.7 Site Map

Bosentan
REMS Program

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Site Map

<p>Prescribers</p> <hr/> <p>Prescriber Home Page Prescriber FAQs Patient Enrollment Patient Management FAQs</p>	<p>General</p> <hr/> <p>Contact Us General FAQs Prescribing Information for bosentan Privacy Policy Transition FAQs Terms and Conditions Pharmacy Lookup</p>
<p>Pharmacies</p> <hr/> <p>Pharmacy Home Page Pharmacy Staff Home Page Pharmacy FAQs</p>	<p>Account</p> <hr/> <p>Forgot Password Forgot Username Need an Account</p>
<p>Patients</p> <hr/> <p>Patient Home Page</p>	

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

1.8 Contact Us

Bosentan
REMS Program

Prescribing Information | Medication Guides

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[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

Contact Us

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

Phone Number
[1-866-359-2612](tel:1-866-359-2612)

Fax Number
[1-800-730-8231](tel:1-800-730-8231)

Mailing Address
[Bosentan REMS Program](#)
[PO BOX 29080](#)
[Phoenix, AZ 85038](#)

Program Manufacturer

Company	Phone Number

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](tel:1-866-359-2612)

Note: The Bosentan Sponsors attest that the Program Manufacturer table above will only include companies listed in the Application Holder column for the Bosentan REMS Program on the REMS@FDA website.

1.9 Pharmacy Lookup

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username Password [Sign in](#)

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[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

Pharmacy Lookup

To search for a pharmacy, enter a zip code with or without a mile radius, or a city and state, or a pharmacy identifier below and press **Search**. Search results include contact information for pharmacies that are certified in the Bosentan REMS Program.

Pharmacy Information:

Please enter your zip code to find a certified pharmacy within miles of your location.

or

City and State

or

DEA or NPI or NCPDP

[Search](#)

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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1.10 Pharmacy Lookup Results

Bosentan
REMS Program

Prescribing Information | Medication Guides

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[Prescribers](#) [Pharmacies](#) [Patients](#) [Pharmacy Lookup](#) [FAQs](#)

Pharmacy Lookup

To search for a pharmacy, enter a zip code with or without a mile radius, or a city and state, or a pharmacy identifier below and press **Search**. Search results include contact information for pharmacies that are certified in the Bosentan REMS Program.

Pharmacy Information:

Please enter your zip code to find a certified pharmacy within miles of your location.

or

City and State

or

DEA or NPI or NCPDP

[Search](#)

Pharmacy Name	Pharmacy Address	Pharmacy Phone	Pharmacy Type
Uptown Drugs	5228 N Roxie Drive DURH	919-333-7325	Outpatient

Showing 1 to 1 of 1 entries 1 >> 10

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

1.11 Frequently Asked Questions

The screenshot shows the Bosentan REMS Program website. At the top, there is a navigation bar with the logo, a login section with 'Username' and 'Password' fields and a 'Sign in' button, and links for 'Prescribing Information | Medication Guides'. Below the navigation bar are tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The 'FAQs' tab is selected. The main content area is titled 'Frequently Asked Questions (FAQs)' and features a horizontal menu with categories: 'General', 'Prescriber', 'Pharmacy', 'Patient Management', and 'Transition'. The 'General' category is active. Below the menu, there is a list of five questions, each with a blue plus icon and the text '<Question>'. The first question is expanded, showing a blue minus icon and the text '<Answer>'. At the bottom of the content area, there is a purple text link: 'For additional information about the Bosentan REMS Program, please call 1-866-359-2612.' The footer contains links for 'Contact Us', 'Privacy Policy', 'Terms and Conditions', and 'Site Map'.

Note: The Bosentan Sponsors attest that the questions and answers on the FAQ screens will align with the FAQ document included in the submission.

2. Account Pages

2.1 Account Registration Page

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

Create an Account

For prescribers, pharmacies, and pharmacy staff only. To create your web account for the Bosentan REMS Program, please complete the fields below. The Username you specify must be unique within the Bosentan REMS Program Website.

First Name

Last Name

Email Address

Confirm Email Address

Phone Number

Username

Use Email Address as Username [Suggest Username](#)

Password

Confirm Password

I'm not a robot  [Privacy - Terms](#)

[Cancel](#) [Submit](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

2.2 Account Confirmation Page

Bosentan
REMS Program

Prescribing Information | Medication Guides

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Account Confirmation

 Your web account has been successfully activated. Please sign in to your account using the fields in the upper corner of this page.

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

2.3 Forgot Username

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

Forgot Username

Please enter your credentials in the spaces provided below. Your username will be sent to the email you registered with the Bosentan REMS Program.

First Name

Last Name

Email Address

[Submit](#)

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

2.4 Forgot Password

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

Forgot Password

Please enter your username and email address in the spaces provided below. Your username is the identification you established when creating your web account for the Bosentan REMS Program.

Username

Email Address

[Submit](#)

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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2.5 Change Username

Prescribing Information | Medication Guides

Username [My Dashboard](#)

[Change Username](#)
[Change Password](#)
[Edit Profile](#)
[Sign Out](#)

Prescribers Pharmacies Patients Ph FAQs

Change Username

To change your username, please provide your new username below. The information you provide for your username must be unique within the Bosentan REMS Program Website.

Username

Use Email Address as Username [Suggest Username](#)

[Cancel](#) [Save](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Contact Us | Privacy Policy | Terms and Conditions | Site Map

2.6 Change Password

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username  [My Dashboard](#)

[Change Username](#)
[Change Password](#)
[Edit Profile](#)
[Sign Out](#)

Prescribers Pharmacies Patients Ph FAQs

Change Password

To change your password, please complete the fields below.

Current Password	<input type="text"/>
New Password	<input type="text"/>
Confirm New Password	<input type="text"/>

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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2.7 Edit Prescriber Profile

Prescribing Information | Medication Guides

Username  My Dashboard

Change Username
Change Password
Edit Profile
Sign Out

Prescribers Pharmacies Patients Ph FAQs

My Profile Edit

My Information

First Name	<input type="text" value="John"/>	MI	<input type="text" value="S"/>
Last Name	<input type="text" value="Doe"/>		
Email	<input type="text" value="johndoe@email.com"/>		
Professional Designation	<input type="text" value="MD"/>		
Medical Specialty	<input type="text" value="Cardiology"/>		
Clinic / Practice Name (Optional)	<input type="text" value="Good Health Clinic"/>		
Address	<input type="text" value="1 Main Street"/>		
City	<input type="text" value="New York"/>		
State	<input type="text" value="New York"/>	Zip	<input type="text" value="10001"/>
Phone	<input type="text" value="555-555-5555"/>	Ext (Optional)	<input type="text" value="100"/>
Fax	<input type="text" value="555-555-0000"/>		
Preferred Method of Contact	<input type="text" value="Email"/>		

Prescriber Identifiers

DEA	<input type="text" value="AB23423412"/>
NPI	<input type="text" value="23423423423"/>

My Certification

Certification ID: **HCP123112312**

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Contact Us | Privacy Policy | Terms and Conditions | Site Map

2.8 Edit Authorized Representative Profile

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username  [My Dashboard](#)

[Change Username](#)
[Change Password](#)
[Edit Profile](#)
[Sign Out](#)

Prescribers Pharmacies Patients Ph [FAQs](#)

My Profile

[Edit](#)

My Information

First Name	<input type="text" value="John"/>
Last Name	<input type="text" value="Doe"/>
Email Address	<input type="text" value="email@email.com"/>
Credentials	<input type="text" value="PharmD"/>
Phone	<input type="text" value="555-555-5555"/>
Fax	<input type="text" value="555-555-0000"/>
Preferred Method of Contact	<input type="text" value="Email"/>

[Cancel](#) [Save](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

2.9 Edit Pharmacy Staff Profile

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username  [My Dashboard](#)

[Change Username](#)
[Change Password](#)
[Edit Profile](#)
[Sign Out](#)

Prescribers Pharmacies Patients Ph FAQs

My Profile

My Information

First Name	<input type="text" value="John"/>		
Last Name	<input type="text" value="Doe"/>		
Email Address	<input type="text" value="jDoe@gmail.com"/>		
Phone	<input type="text" value="555-555-5555"/>	Extension (Optional)	<input type="text" value="100"/>
Fax	<input type="text" value="555-555-3434"/>		
Preferred Method of Contact	<input type="text" value="Email"/> ▼		

My Enrollment

Enrollment ID: **HCP22200088**

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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3. Prescriber Online Certification

3.1 Prescriber Search with Results

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username 

Prescribers | Pharmacies | Patients | Pharmacy Lookup | FAQs

User Search

If you were transitioned to the Bosentan REMS Program, your data may already be populated in the Bosentan REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

Identifiers

NPI Number or DEA Number

First Name Last Name Certification ID (Optional)

Phone Fax Email

Search

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your enrollment process in the Bosentan REMS Program.

First Name	Last Name	Phone
John	Doe	555-555-5555

Showing 1 to 1 of 1 entries

1 >> 10 ▾

New User Submit

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

3.2 Prescriber Search with no Results

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username 

Prescribers | Pharmacies | Patients | Pharmacy Lookup | FAQs

User Search

If you were transitioned to the Bosentan REMS Program, your data may already be populated in the Bosentan REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

Identifiers

NPI Number DEA Number

or

First Name Last Name Certification ID (Optional)

Phone Fax Email

Search

No results found. Please try your search again or contact the Bosentan REMS Program for assistance. Alternatively, you may use the [New User](#) button below to begin your enrollment process in the Bosentan REMS Program

First Name	Last Name	Phone
No matching records found		

Showing 0 to 0 of 1 entries

1 >> 10 ▾

New User

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

3.3 Prescriber Intake Page

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username 

- Prescribers
- Pharmacies
- Patients
- Pharmacy Lookup
- FAQs

- 1 INTAKE**
- 2 ATTESTATION
- 3 CONFIRMATION

Prescriber Intake

To certify as a prescriber in the Bosentan REMS Program, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via your preferred method of contact. All fields listed below are required unless otherwise indicated.

Prescriber Information

First Name MI (Optional)

Last Name

Email

Confirm Email Address

Professional Designation

Medical Specialty

Clinic / Practice Name

Address

City

State Zip

Phone Ext (Optional)

Fax

Preferred Method of Contact

Prescriber Identifiers

DEA Number

NPI Number

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

3.4 Prescriber Attestation Page

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username:

Prescribers | Pharmacies | Patients | Pharmacy Lookup | FAQs

1 INTAKE | 2 ATTESTATION | 3 CONFIRMATION

Prescriber Attestation

To complete the prescriber certification for <First name last name> in the Bosentan REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Bosentan REMS Program at 1-800-730-8231 or mail it to the Bosentan REMS Program, P.O. Box 29080, Phoenix, AZ 85038.

As a prescriber, I attest to performing the following Bosentan REMS Program requirements:

1. I will review the Prescribing Information for bosentan
2. I will review the **Bosentan REMS Program Prescriber Guide**
3. I will enroll in the Bosentan REMS Program by completing the **Bosentan REMS Program Prescriber Enrollment Form** and submitting it to the Bosentan REMS Program
4. I will enroll each patient in the Bosentan REMS Program by performing the following:
 - a) Counsel the patient about the risk of hepatotoxicity associated with bosentan, the signs and symptoms of hepatotoxicity, and program requirements including the need to complete liver function testing and, as appropriate, pregnancy testing by reviewing and providing the **Bosentan REMS Program Guide for Patients**
 - b) Determine the reproductive potential status of each female patient as defined in the **Bosentan REMS Program Prescriber Guide**
 - c) For pre-pubertal females, counsel the patient and/or parent/legal guardian about (i) the risk of embryo-fetal toxicity, (ii) the need to immediately contact the prescriber if the patient begins to menstruate
 - d) For females of reproductive potential, counsel the patient about (i) the risk of embryo-fetal toxicity, (ii) the need to use reliable contraception as defined in the **Bosentan REMS Program Prescriber Guide** during treatment and for one month following treatment discontinuation, (iii) the need to immediately contact her prescriber if she misses a menstrual period or suspects she is pregnant, and (iv) her medical options in the event of unprotected sexual intercourse or known or suspected contraception failure
 - e) Complete the **Bosentan REMS Program Patient Enrollment Form** for each patient and provide a completed copy to the patient. Submit the completed form to the REMS Program
5. I will report all adverse events including those suggestive of hepatotoxicity to the Bosentan REMS Program
6. I will report any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program
7. I will perform the following on an ongoing basis for each female patient: a) Report a change or misclassification in the reproductive status of any female patient by completing the **Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** within 10 business days of becoming aware of the change
8. I will perform the following requirements on an ongoing basis for each patient:
 - a) Order and review liver function test results before bosentan treatment initiation and monthly during treatment
 - b) Counsel patients who fail to comply with program requirements
9. I will perform the following monitoring on an ongoing basis for each pre-pubertal female: a) Evaluate patients age 8 years and older at least annually for any change in reproductive status and complete the **Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** verifying their reproductive potential status
10. I will perform the following monitoring on an ongoing basis for each female patient of reproductive potential: a) Order and review pregnancy test results before bosentan treatment initiation, monthly during treatment, and for one month following treatment discontinuation

By checking the box, I signify my understanding of the risks of bosentan treatment and my obligations as a bosentan prescriber to educate my patients about the Bosentan REMS Program, monitor them appropriately, and report any adverse events, including hepatotoxicity and any pregnancies to the Bosentan REMS Program.

Signature

Signature Date

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Contact Us | Privacy Policy | Terms and Conditions | Site Map

3.5 Prescriber Confirmation Page

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username  [My Dashboard](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

1 INTAKE | **2** ATTESTATION | **3** CONFIRMATION

Prescriber Certification Confirmation

 You are now certified in the Bosentan REMS Program.

Below is your Bosentan REMS Program Certification ID. Please retain this information for your records.

Certification ID: [<Certification ID>](#)



If you would like to enroll patients now you can use [Enroll Patient](#). If you need to manage your patients you can use [Manage Your Patients](#).

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

4. Pharmacy Online Certification

4.1 Authorized Representative Role Selection Pages

4.1.1 Authorized Representative Role Selection



Prescribing Information | Medication Guides

Bosentan
REMS Program

Username Password Sign in

Forgot Username? Forgot Password? Need an Account?

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Authorized Representative Role Selection

Please select the option below that **best** describes your role and press **Continue**.

- Authorized Representative of an Outpatient Pharmacy** - For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies. An authorized representative of an outpatient pharmacy is responsible for ensuring certification of the pharmacy in the Bosentan REMS Program. The authorized representative is also responsible for coordinating the activities required for the pharmacy and pharmacy staff in the Bosentan REMS Program.
- Authorized Representative of a Chain Pharmacy Headquarters** - For the purposes of this REMS chain pharmacies are retail pharmacies with multiple locations that dispense bosentan for outpatient use and have a pharmacy headquarters that coordinates pharmacy enrollment in the Bosentan REMS Program. The authorized representative of a chain pharmacy headquarters is responsible for ensuring certification and training in the Bosentan REMS Program for a corporate pharmacy contracted to participate with a pharmacy network provider. The authorized representative is also responsible for reporting confirmation of pharmacy dispensing location training to the Bosentan REMS Program.
- Authorized Representative of an Inpatient Pharmacy** - For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons. An authorized representative of an inpatient pharmacy is responsible for ensuring certification of the pharmacy location, training of the pharmacy staff, and audit readiness.

Continue

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.1.2 Authorized Representative Role Selection: Outpatient Pharmacy

The screenshot displays the Bosentan REMS Program website interface. At the top, there is a navigation bar with the logo and a 'Sign in' button. Below the navigation bar, there are tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The main content area is titled 'Authorized Representative of an Outpatient Pharmacy' and contains a confirmation dialog box. The dialog box has a purple header and contains the following text:

Authorized Representative of an Outpatient Pharmacy
Based on the response selected, please confirm you are certifying for an Outpatient Pharmacy

For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies. An authorized representative of an outpatient pharmacy is responsible for ensuring certification of the pharmacy in the Bosentan REMS Program. The authorized representative is also responsible for coordinating the activities required for the pharmacy and pharmacy staff in the Bosentan REMS Program.

If the pharmacy you are certifying does not meet the definition of an outpatient pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

At the bottom of the dialog box, there are two buttons: 'Cancel' and 'Confirm'. Below the dialog box, there are radio buttons for selecting the role: 'Authorized Representative of an Outpatient Pharmacy' (selected) and 'Authorized Representative of an Inpatient Pharmacy'. A 'Continue' button is located at the bottom left of the main content area. At the bottom of the page, there is a footer with contact information and a link to call 1-866-359-2612.

4.1.3 Authorized Representative Role Selection: Chain Pharmacy Headquarters

The screenshot shows the Bosentan REMS Program website interface. At the top, there is a navigation bar with the logo and 'REMS Program' text. To the right, there are input fields for 'Username' and 'Password', and a 'Sign in' button. Below the navigation bar, there are tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The main content area is titled 'Authorized Representative' and contains a form with radio buttons for selecting a role. A modal dialog box is open, displaying the following text:

Authorized Representative of a Chain Pharmacy Headquarters
Based on the response selected, please confirm you are certifying for a Chain Pharmacy Headquarters

For the purposes of this REMS chain pharmacies are retail pharmacies with multiple locations that dispense bosentan for outpatient use and have a pharmacy headquarters that coordinates pharmacy enrollment in the Bosentan REMS Program. The authorized representative of a chain pharmacy headquarters is responsible for ensuring certification and training in the Bosentan REMS Program for a corporate pharmacy contracted to participate with a pharmacy network provider. The authorized representative is also responsible for reporting confirmation of pharmacy dispensing location training to the Bosentan REMS Program.

If the pharmacy you are certifying does not meet the definition of a chain pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

Buttons:

Below the dialog box, there are radio buttons for other roles:

- Authorized Representative of a Specialty Pharmacy** - For the purposes of this REMS specialty pharmacies include but are not limited to retail, specialty, and long-term care facilities. An authorized representative of a specialty pharmacy is responsible for ensuring certification of the pharmacy location, training of the pharmacy staff, and audit readiness.
- Authorized Representative of a Chain Pharmacy Headquarters** - For the purposes of this REMS chain pharmacies are retail pharmacies with multiple locations that dispense bosentan for outpatient use and have a pharmacy headquarters that coordinates pharmacy enrollment in the Bosentan REMS Program. The authorized representative of a chain pharmacy headquarters is responsible for ensuring certification and training in the Bosentan REMS Program for a corporate pharmacy contracted to participate with a pharmacy network provider. The authorized representative is also responsible for reporting confirmation of pharmacy dispensing location training to the Bosentan REMS Program.
- Authorized Representative of an Inpatient Pharmacy** - For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons. An authorized representative of an inpatient pharmacy is responsible for ensuring certification of the pharmacy location, training of the pharmacy staff, and audit readiness.

A 'Continue' button is located at the bottom of the form.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Footer: Contact Us | Privacy Policy | Terms and Conditions | Site Map

4.1.4 Authorized Representative Role Selection: Inpatient Pharmacy

The screenshot displays the Bosentan REMS Program website interface. At the top, there is a navigation bar with the logo and a 'Sign in' button. Below the navigation bar, there are tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The main content area is titled 'Authorized Representative of an Inpatient Pharmacy' and contains a confirmation dialog box. The dialog box has a purple header and contains the following text:

Authorized Representative of an Inpatient Pharmacy
Based on the response selected, please confirm you are certifying for an Inpatient Pharmacy

For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons. An authorized representative of an inpatient pharmacy is responsible for ensuring certification of the pharmacy location, training of the pharmacy staff, and audit readiness.

If the pharmacy you are certifying does not meet the definition of an inpatient pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

Below the text are two buttons: 'Cancel' and 'Confirm'. The 'Confirm' button is highlighted in purple. In the background, there are radio button options for different roles, with the 'Authorized Representative of an Inpatient Pharmacy' option selected. A 'Continue' button is also visible at the bottom of the dialog box.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Contact Us | Privacy Policy | Terms and Conditions | Site Map

4.2 Authorized Representative Search with Results

Bosentan
Prescribing Information | Medication Guides

Username

Prescribers
Pharmacies
Patients
Pharmacy Lookup
FAQs

User Search

To ensure that your information is available in the Bosentan REMS Program, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Zip Code

Identifiers

DEA Number
NPI Number
NCPDP Number

or

or

First Name

Last Name

Certification ID *(Optional)*

Phone *(Optional)*

Fax *(Optional)*

Email *(Optional)*

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your enrollment process in the Bosentan REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Pharmacy Phone	Pharmacy Type
Mary	More	ABC Pharmacy	4343 N. Scottsdale Road, AZ 85251	788-999-0000	Inpatient Pharmacy

Showing 1 to 1 of 1 entries 1 >>

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.3 Authorized Representative Search with no Results

Bosentan
Prescribing Information | Medication Guides

Username

Prescribers
Pharmacies
Patients
Pharmacy Lookup
FAQs

User Search

To ensure that your information is available in the Bosentan REMS Program, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Zip Code

and

Identifiers

DEA Number
NPI Number
NCPDP Number

or

or

First Name

Last Name

Certification ID (Optional)

Phone (Optional)

Fax (Optional)

Email (Optional)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your enrollment process in the Bosentan REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Pharmacy Phone	Pharmacy Type
Mary	More	ABC Pharmacy	4343 N. Scottsdale Road, AZ 85251	788-999-0000	Inpatient Pharmacy

Showing 1 to 1 of 1 entries 1 >>

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.4 Outpatient and Inpatient Pharmacy Authorized Representative Intake Page

Prescribing Information | Medication Guides

Username

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 CONFIRMATION

Authorized Representative Intake

To begin the process as an authorized representative in the Bosentan REMS Program, please complete the form below and press **Next**. All fields listed below are required unless otherwise indicated.

Authorized Representative Information

First Name	<input type="text"/>
Last Name	<input type="text"/>
Email Address	<input type="text"/>
Confirm Email Address	<input type="text"/>
Credentials	-- Please Select --
Phone	<input type="text"/>
Fax	<input type="text"/>
Preferred Method of Contact	-- Please Select --

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

4.5 Outpatient and Inpatient Pharmacy Authorized Representative Confirmation Page

The screenshot shows the Bosentan REMS Program website interface. At the top, there is a navigation bar with the Bosentan logo and 'REMS Program' text on the left, and 'Prescribing Information | Medication Guides', 'Username', and a 'My Dashboard' button on the right. Below this is a secondary navigation bar with tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The 'Pharmacies' tab is active. A progress indicator shows two steps: '1 INTAKE' and '2 CONFIRMATION', with the second step being the current page. The main content area is titled 'Confirmation' and contains a central message box. This box includes a green checkmark icon and the text 'You are now an authorized representative of the Bosentan REMS program.' A callout box explains that the Interactive Voice Response (IVR) unit is used by outpatient pharmacies only for updating patient testing and/or counseling. Below this, the 'IVR Access ID' is listed as '12341234'. Instructions follow, stating that users ready to certify their pharmacy should use the 'Certify Pharmacy' link, and those returning to the dashboard should use the 'My Dashboard' button. A final instruction says to close the browser if the session is complete. At the bottom of the main content area, there is a purple link for additional information: 'For additional information about the Bosentan REMS Program, please call 1-866-359-2612.' The footer contains links for 'Contact Us', 'Privacy Policy', 'Terms and Conditions', and 'Site Map'.

Prescribing Information | Medication Guides

Username [My Dashboard](#)

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 CONFIRMATION

Confirmation

You are now an authorized representative of the Bosentan REMS program.

The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.

IVR Access ID : **12341234**

If you are ready to certify your pharmacy now please use [Certify Pharmacy](#).

To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page.

If you have completed your session today, simply close your browser.

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

Contact Us | Privacy Policy | Terms and Conditions | Site Map

4.6 Outpatient Pharmacy Intake Page

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username 

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Pharmacy Intake

To certify your pharmacy, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the preferred method of contact you selected during your authorized representative intake. All f

Outpatient Pharmacy: For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.
Inpatient Pharmacy: For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.

Pharmacy Information

Pharmacy Name

Pharmacy Type 

Address

City

State Zip

Phone Fax

Pharmacy Identifiers

DEA

NPI

NCPDP

Can your pharmacy management system adjudicate claims online?

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.7 Inpatient Pharmacy Intake Page

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username 

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Pharmacy Intake

To certify your pharmacy, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the preferred method of contact you selected during your authorized representative intake. All f

Pharmacy Information

Pharmacy Name

Pharmacy Type 

Address

City

State Zip

Pharmacy Identifiers (at least one identifier required)

DEA

NPI

NCPDP

Outpatient Pharmacy: For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.

Inpatient Pharmacy: For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.8 Outpatient Pharmacy Attestation Page

Prescribing Information | Medication Guides

Username My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Pharmacy Attestation

To complete the certification for <Pharmacy Name> in the Bosentan REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Bosentan REMS Program at 1-800-730-8231 or mail it to the Bosentan REMS Program, P.O. Box 29060, Phoenix, AZ 85038.

As the authorized representative designated by my pharmacy to oversee the implementation and compliance with the Bosentan REMS Program, I <First_Name Last_Name> attest to understanding the Bosentan REMS Program requirements, and accept the responsibility to:

1. Complete and sign the **Bosentan REMS Program Outpatient Pharmacy Enrollment Form** on behalf of the pharmacy, and submit the form to the Bosentan REMS Program.
2. Review the **Bosentan REMS Program Pharmacy Guide**.
3. Ensure all relevant staff involved in the dispensing of bosentan are trained on the Bosentan REMS Program requirements as described in the **Bosentan REMS Program Pharmacy Guide** and maintain a record of the training.
4. Recertify in the Bosentan REMS Program if the pharmacy designates a new authorized representative.
5. Report all adverse events including those suggestive of hepatotoxicity to the Bosentan REMS Program.
6. Report any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program.
7. Maintain documentation that all processes and procedures are in place and are being followed for the Bosentan REMS Program and provide upon request to the Bosentan Sponsors or a third party acting on behalf of the Bosentan Sponsors.
8. Comply with audits by the Bosentan Sponsors or a third party acting on behalf of the Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program.
9. Put processes and procedures in place to ensure the following requirements are completed prior to dispensing bosentan:
 - a. Obtain a pre-dispense authorization.
10. Outpatient pharmacies that support electronic telecommunication verification with the Bosentan REMS Program system must:
 - a. Ensure the pharmacy enables its pharmacy management system to support communication with the Bosentan REMS Program system using established telecommunication standards, and runs the standardized validation test transactions to validate the system enhancements.
 - b. Dispense bosentan to patients only after obtaining a pre-dispense authorization by processing the prescription, including cash claims, through their pharmacy management system to electronically:
 - i. Verify the prescriber is certified and the patient is enrolled.
 - ii. Verify the patient has completed the liver function tests and each female of reproductive potential has completed the pregnancy test or the prescriber has authorized a refill for patients if testing could not be confirmed.
 - iii. Verify if patient has been counseled on the risk of hepatotoxicity and each female of reproductive potential has been counseled on the risk of embryo-fetal toxicity and the need to use reliable contraception.
 - c. If counseling was not completed, call the Bosentan REMS Program Contact Center to complete the counseling requirement before dispensing bosentan.
 - d. Dispense up to a 30-day supply of bosentan.
 - e. Provide the Medication Guide to the patient every time bosentan is dispensed.
 - f. Not transfer bosentan to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program.
11. Outpatient pharmacies that do NOT support electronic telecommunication verification with the Bosentan REMS Program system must:
 - a. Dispense bosentan to patients only after obtaining a pre-dispense authorization by calling the Bosentan REMS Program Contact Center or accessing the Bosentan REMS Program Website to:
 - i. Verify the prescriber is certified and the patient is enrolled.
 - ii. Verify the patient has completed the liver function tests and each female of reproductive potential has completed the pregnancy test or the prescriber has authorized a refill for patients if testing could not be confirmed.
 - iii. Verify if patient has been counseled on the risk of hepatotoxicity and each female of reproductive potential has been counseled on the risk of embryo-fetal toxicity and the need to use reliable contraception.
 - b. If counseling was not completed, call the Bosentan REMS Program Contact Center to complete the counseling requirement before dispensing bosentan.
 - c. Dispense up to a 30-day supply of bosentan.
 - d. Provide the Medication Guide to the patient every time bosentan is dispensed.
 - e. Not transfer bosentan to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program.

By checking the box, I signify my understanding of the risks of bosentan treatment, my obligations as a pharmacy certified in the Bosentan REMS Program as outlined above, and I agree to oversee the implementation and compliance with the Bosentan REMS Program requirements for this pharmacy.

Signature Signature Date

[Back](#) [Submit](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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Note: The following message will be displayed when user hover over the information icon after PDA: "A PDA is verification by the Bosentan REMS Program authorizing the pharmacy to dispense bosentan to an eligible patient."

4.9 Inpatient Pharmacy Attestation Page

Prescribing Information | Medication Guides

Username [My Dashboard](#)

[Prescribers](#) [Pharmacies](#) [Patients](#) [Pharmacy Lookup](#) [FAQs](#)

1 INTAKE **2 ATTESTATION** 3 CONFIRMATION

Pharmacy Attestation

To complete the certification for <Pharmacy Name> in the Bosentan REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Bosentan REMS Program at 1-800-730-8231 or mail it to the Bosentan REMS Program, P.O. Box 29080, Phoenix, AZ 85038.

As the authorized representative designated by my pharmacy to oversee the implementation and compliance with the Bosentan REMS Program, I <First_Name Last_Name> attest to understanding the Bosentan REMS Program requirements, and accept the responsibility to:

1. Complete and sign the **Bosentan REMS Program Inpatient Pharmacy Enrollment Form** on behalf of the pharmacy, and submit the form to the Bosentan REMS Program
2. Review the **Bosentan REMS Program Pharmacy Guide**
3. Ensure all relevant staff involved in the dispensing of bosentan are trained on the Bosentan REMS Program requirements as described in the **Bosentan REMS Program Pharmacy Guide** and maintain a record of the training
4. Recertify in the Bosentan REMS Program if the pharmacy designates a new authorized representative
5. Report all adverse events including those suggestive of hepatotoxicity to the Bosentan REMS Program
6. Report any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program
7. Maintain documentation that all processes and procedures are in place and are being followed for the Bosentan REMS Program and provide upon request to the Bosentan Sponsors or a third party acting on behalf of the Bosentan Sponsors
8. Comply with audits by the Bosentan Sponsors or a third party acting on behalf of the Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program
9. Put processes and procedures in place to ensure the following requirements are completed prior to dispensing bosentan:
 - a. Verify the patient is under the supervision and care of a prescriber who is certified
 - b. Verify the patient is enrolled or will be enrolled prior to discharge
 - c. Dispense no more than a 15-day supply of bosentan upon discharge
10. Verify the requirements by the following mechanisms, including but not limited to calling the Bosentan REMS Program Contact Center, accessing the Bosentan REMS Program Website, or by accessing the patient's medical record
11. Not transfer bosentan to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program

By checking the box, I signify my understanding of the risks of bosentan treatment, my obligations as a pharmacy certified in the Bosentan REMS Program as outlined above, and I agree to oversee the implementation and compliance with the Bosentan REMS Program requirements for this pharmacy.

Signature Signature Date

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For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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4.10 Pharmacy Certification Confirmation Page: Inpatient Pharmacies and Outpatient Pharmacies that do not Support Electronic Telecommunication Verification

The screenshot shows the Bosentan REMS Program website interface. At the top, there is a navigation bar with the Bosentan logo and 'REMS Program' on the left, and 'Prescribing Information | Medication Guides', 'Username', and 'My Dashboard' on the right. Below this is a menu with 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. A progress bar indicates three steps: 1 INTAKE, 2 ATTESTATION, and 3 CONFIRMATION. The main heading is 'Pharmacy Certification Confirmation'. The central content area features a green checkmark icon and the text 'Your pharmacy is now certified in the Bosentan REMS Program.' Below this, there is a callout box with the text: 'The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.' Underneath the callout, the 'IVR Access ID' is displayed as '12341234'. A printer icon is located below the ID. At the bottom of the main content area, it says 'To add additional pharmacies or manage your pharmacies, please use the My Dashboard button at the top of the page.' A purple link at the bottom of the page reads 'For additional information about the Bosentan REMS Program, please call 1-866-359-2612.' The footer contains links for 'Contact Us', 'Privacy Policy', 'Terms and Conditions', and 'Site Map'.

4.11 Chain Pharmacy Authorized Representative Intake Page

Prescribing Information | Medication Guides

Username 

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 CONFIRMATION

Authorized Representative Intake

To begin the process as an authorized representative in the Bosentan REMS Program, please complete the form below and press **Next**. All fields listed below are required unless otherwise indicated.

REMS Chain ID

Authorized Representative Information

First Name

Last Name

Email Address

Confirm Email Address

Credentials

Phone

Fax

Preferred Method of Contact

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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4.12 Chain Pharmacy Authorized Representative Confirmation Page

Prescribing Information | Medication Guides

Username [My Dashboard](#)

Prescribers | **Pharmacies** | Patients | Pharmacy Lookup | FAQs

1 INTAKE 2 CONFIRMATION

Confirmation

You are now an authorized representative of the Bosentan REMS Program.

The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.

IVR Access ID : 12341234

If you are ready to certify your chain headquarter pharmacy now please use [Certify Chain Headquarter Pharmacy](#).
If you have completed your session today, simply close your browser.

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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4.13 Chain Pharmacy Headquarters Intake Page

Prescribing Information | Medication Guides

Username 

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Chain Pharmacy Headquarters Intake

To certify your chain pharmacy headquarters, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the preferred method of contact you selected during your authorized representative intake. All fields listed below are required unless otherwise indicated.

Chain Pharmacy Headquarters Information

Pharmacy Name

Address

City

State Zip Code

Phone

Fax

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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4.14 Chain Pharmacy Headquarters Attestation Page

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Pharmacy Headquarters Attestation

To complete the certification for <Pharmacy Name> in the Bosentan REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Bosentan REMS Program at 1-866-359-2612. or mail it to the Bosentan REMS Program, P.O. Box 29080, Phoenix, AZ 85038.

I am the authorized representative designated by my pharmacy to coordinate the activities of the Bosentan REMS Program. I attest to understanding the Bosentan REMS Program requirements, and accept the responsibility to:

1. Complete and sign the **Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form** on behalf of the pharmacy, and submit the form to the Bosentan REMS Program
2. Review the **Bosentan REMS Program Pharmacy Guide**
3. Ensure all relevant staff involved in the dispensing of bosentan are trained on the Bosentan REMS Program requirements as described in the **Bosentan REMS Program Pharmacy Guide** and maintain a record of the training
4. Recertify in the Bosentan REMS Program if the pharmacy designates a new authorized representative
5. Report all adverse events including those suggestive of hepatotoxicity to the Bosentan REMS Program
6. Report any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program
7. Maintain documentation that all processes and procedures are in place and are being followed for the Bosentan REMS Program and provide upon request to the Bosentan Sponsors or a third party acting on behalf of the Bosentan Sponsors
8. Comply with audits by the Bosentan Sponsors or a third party acting on behalf of the Bosentan Sponsors to ensure that all processes and procedures are in place and are being followed for the Bosentan REMS Program
9. Put processes and procedures in place to ensure the following requirements are completed prior to dispensing bosentan:
 - a. Obtain a pre-dispense authorization
10. Ensure the pharmacy enables its pharmacy management system to support communication with the Bosentan REMS Program system using established telecommunication standards, and runs the standardized validation test transactions to validate the system enhancements
11. Dispense bosentan to patients only after obtaining a pre-dispense authorization by processing the prescription, including cash claims, through their pharmacy management system to electronically:
 - a. Verify the prescriber is certified and the patient is enrolled
 - b. Verify the patient has completed the liver function tests and each female of reproductive potential has completed the pregnancy test or the prescriber has authorized a refill for patients if testing could not be confirmed
 - c. Verify if patient has been counseled on the risk of hepatotoxicity and each female of reproductive potential has been counseled on the risk of embryo-fetal toxicity and the need to use reliable contraception
12. If counseling was not completed, call the Bosentan REMS Program Contact Center to complete the counseling requirement before dispensing bosentan
13. Dispense up to a 30-day supply of bosentan
14. Provide the patient the Medication Guide every time bosentan is dispensed
15. Not transfer bosentan to any pharmacy, practitioner or any healthcare setting not certified in the Bosentan REMS Program

By checking the box, I signify my understanding of the risks of bosentan treatment, my obligations as a pharmacy certified in the Bosentan REMS Program as outlined above, and I agree to oversee the implementation and compliance with the Bosentan REMS Program requirements for this pharmacy.

Signature

Signature Date

[Back](#) [Submit](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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Note: The following message will be displayed when user hover over the information icon after PDA: "A PDA is verification by the Bosentan REMS Program authorizing the pharmacy to dispense bosentan to an eligible patient."

4.15 Pharmacy Test Transactions Page: Chain Pharmacies and Outpatient Pharmacies that Support Electronic Telecommunication Verification

Bosentan
REMS Program

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[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

[1 INTAKE](#) | [2 ATTESTATION](#) | [3 CONFIRMATION](#)

Pharmacy Test Transactions

 **Thank you!** Your enrollment form was successfully submitted.

To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system.

- You will soon receive a communication via your preferred method of contact with instructions on how to submit test transactions to the Bosentan REMS Program. This will ensure that your pharmacy management system has been successfully configured to allow communication with the Bosentan REMS Program.
- To download the instructions now, please use the **Download Instructions** button below. After successful completion of the test transactions and validation of all required identifiers, you will be notified of your certification in the Bosentan REMS Program through your preferred method of contact.

 [Download Instructions](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.16 Chain Pharmacy Dispensing Location Intake Page

Prescribing Information | Medication Guides

Username 

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Chain Pharmacy Store Intake

To report training of your pharmacy dispensing location, please complete the form below and press **Next**. Once confirmed, you will receive a certification via the preferred method of contact you selected during your authorized representative intake. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Pharmacy Name

Address

City

State Zip

Phone Fax

Training Status

Pharmacy Identifiers

NCPDP Number

(Provide at least one)

DEA Number

NPI Number

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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4.17 Chain Pharmacy Dispensing Location Confirmation Page

The screenshot displays the Bosentan REMS Program interface. At the top, there is a dark blue header with the logo on the left and navigation links for 'Prescribing Information | Medication Guides', 'Username', and 'My Dashboard' on the right. Below the header is a light blue navigation bar with tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The main content area is titled 'Chain Pharmacy Dispensing Location Confirmation'. It features a green-bordered box containing a green checkmark icon and the text 'The pharmacy dispensing location has been successfully added.' Below this box, a message states: 'To add another pharmacy dispensing location, please use the **Add Pharmacy Dispensing Location** button below.' A purple button with the text 'Add Pharmacy Dispensing Location' is centered below the message. At the bottom of the main content area, there is a purple link: 'For additional information about the Bosentan REMS Program, please call 1-866-359-2612.' The footer is a dark grey bar with links for 'Contact Us', 'Privacy Policy', 'Terms and Conditions', and 'Site Map'.

4.18 Pharmacy Staff Search with Results

Bosentan
Prescribing Information | Medication Guide

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User Search

Your data may already be populated in the Bosentan REMS Program. Please complete the fields below and select the **Search** button. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Pharmacy Zip Code

Identifiers

DEA Number

NPI Number

NCPDP Number

Pharmacy Staff Information

First Name

Last Name

Phone (Optional)

Fax (Optional)

Email (Optional)

If the search results have returned your record, please highlight the row and select the **Submit** button to begin your enrollment process. If you do not see your record, you can either try your search again or the select the **New User** button to begin your enrollment process in the Bosentan REMS Program.

First Name	Last Name	Phone	Pharmacy Name	Pharmacy Address
John	Doe	555-555-5555	ABC Pharmacy	1234 W Palo Verde Lane Tempe AZ 85283

Showing 1 to 1 of 1 entries 1 >> 10 ▾

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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Bosentan_Website_Screen_Captures

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4.19 Pharmacy Staff Search with No Results

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REMS Program

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User Search

Your data may already be populated in the Bosentan REMS Program. Please complete the fields below and select the **Search** button. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Pharmacy Zip Code	Identifiers		
<input type="text"/>	DEA Number	NPI Number	NCPDP Number
	<input type="text"/>	<input type="text"/>	<input type="text"/>

Pharmacy Staff Information

First Name	Last Name	
<input type="text"/>	<input type="text"/>	
Phone (Optional)	Fax (Optional)	Email (Optional)
<input type="text"/>	<input type="text"/>	<input type="text"/>

[Search](#)

No results found. Please try your search again or contact the Bosentan REMS Program for assistance. You may also use the **New User** button below to begin your enrollment process in the Bosentan REMS Program.

First Name	Last Name	Phone	Pharmacy Name	Pharmacy Address
No matching records found				

Showing 1 to 1 of 1 entries 1 >> 10 ▼

[New User](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.19.1 Pharmacy Staff Pharmacy Search

Bosentan
Prescribing Information | Medication Guide

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FAQs

User Search

Your data may already be populated in the Bosentan REMS Program. Please complete the fields below and select the **Search** button. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Pharmacy Zip Code

Identifiers

DEA Number

NPI Number

NCPDP Number

and or or

Pharmacy Staff Information

First Name

Last Name

Phone *(Optional)*

Fax *(Optional)*

Email *(Optional)*

If the search results have returned your record, please highlight the row and select the **Submit** button to begin your enrollment process. If you do not see your record, you can either try your search again or the select the **New User** button to begin your enrollment process in the Bosentan REMS Program.

First Name	Last Name	Phone	Pharmacy Name	Pharmacy Address
John	Doe	555-555-5555	ABC Pharmacy	1234 W Palo Verde Lane Tempe AZ 85283

Showing 1 to 1 of 1 entries 1 >> 10 ▾

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.20 Pharmacy Staff Intake Page

Bosentan
REMS Program

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Prescribers Pharmacies Patients Support FAQs

1 INTAKE **2** ATTESTATION **3** CONFIRMATION

Pharmacy Staff Intake

To enroll as a pharmacy staff member in the Bosentan REMS Program, please complete the form below and select the **Next** button. Once enrolled, you will receive an enrollment confirmation via your preferred method of contact. All fields listed below are required unless otherwise indicated.

Pharmacy Staff Information

First Name

Last Name

Email Address

Email Address Confirmation

Phone

Extension (Optional)

Fax

Preferred Method of Contact

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.21 Pharmacy Staff Attestation Page

Bosentan
REMS Program

Prescribing Information | Medication Guide

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Prescribers Pharmacies Patients Support FAQs

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Pharmacy Staff Attestation

To complete pharmacy staff enrollment in the Bosentan REMS Program, please review the attestation section below to provide an acknowledgement along with signature and signature date.

As a pharmacy staff member:

1. I attest that I have been trained and will follow the requirements of the Bosentan REMS Program as outlined in the **Bosentan REMS Program Pharmacy Guide**
2. I understand I can access the **Bosentan REMS Program Website** to:
 - Check inpatient REMS requirements for a patient to receive bosentan (only applies to inpatient pharmacies)
 - Obtain a pre-dispense authorization (only applies to outpatient pharmacies that do NOT support electronic telecommunication verification)
 - Reverse a pre-dispense authorization (only applies to outpatient pharmacies that do NOT support electronic telecommunication verification)
 - Edit your profile information
 - Associate your profile to one or more pharmacies
 - Disassociate your profile from a pharmacy
3. I agree not to share my credentials for the **Bosentan REMS Program Website** or allow others to sign into the website using my credentials

As part of your enrollment, you must select the certified pharmacy location(s) where you fill and/or dispense bosentan. It is your responsibility to update this information as necessary.

By checking the box, I attest that I understand the requirements of the Bosentan REMS Program as indicated above, and I will follow the requirements of the Bosentan REMS Program.

Signature

Signature Date

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[Submit](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

4.22 Pharmacy Staff Confirmation Page

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[1 INTAKE](#) [2 ATTESTATION](#) [3 CONFIRMATION](#)

Pharmacy Staff Enrollment Confirmation

 You are now an enrolled pharmacy staff member in the Bosentan REMS Program.

Below is your Bosentan REMS Program information. The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR. this information for your records.

IVR Access ID  : 12341234



To add additional pharmacies or manage your pharmacies, please use the **My Dashboard** button at the top of the page.

[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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5. Patient Enrollment

5.1 Patient Intake Page: Initial Enrollment

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REMS Program

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1 INTAKE 2 ATTESTATION 3 REPRODUCTIVE CLASSIFICATION, TESTING, & COUNSELING 4 FINISH

Patient Intake

You must complete this form with your patient

To enroll your patient in the Bosentan REMS Program, please complete the form below with your patient and press **Next**. Once the patient enrollment is complete, you will receive an enrollment confirmation via your preferred method of contact. All fields listed below are required unless otherwise indicated.

Patient Information

First Name MI (Optional)

Last Name

Email (Optional)

Gender Date of Birth

Address

City

State Zip

Primary Phone

Alternate Phone (Optional)

Parent/Legal Guardian (Optional)

Relationship (Optional)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

5.2 Patient Attestation Page: Initial Enrollment

Bosentan
REMS Program

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Prescribers Pharmacies Patients Pharmacy Lookup FAQs

- 1 INTAKE 2 ATTESTATION 3 REPRODUCTIVE CLASSIFICATION, TESTING, & COUNSELING 4 FINISH

Patient Attestation

To complete patient enrollment in the Bosentan REMS Program, the patient or parent/legal guardian must review the attestation section below, attest to understanding the program requirements by checking the box and sign and date the form.

By signing below, I indicate that I have:

1. Received and has read the **Bosentan REMS Program Guide for Patients**
2. Received counseling from the healthcare professional regarding:
 - a. the risk of liver damage, the signs and symptoms of liver damage and, as appropriate, the risk of serious birth defects, and the need to use reliable contraception
 - b. the need to complete liver function testing and, as appropriate, pregnancy testing, as outlined in the **Bosentan REMS Program Guide for Patients**
 - c. the Bosentan REMS Program contacting you prior to each dispense of bosentan to confirm that liver function tests and, as appropriate, pregnancy test were completed and provide counseling
3. Completed and signed this **Bosentan REMS Program Patient Enrollment Form** with the healthcare professional

By checking the box, I attest that I understand the requirements of the Bosentan REMS Program as indicated on this form and in the **Bosentan REMS Program Guide for Patients**, and I will follow the requirements of the Bosentan REMS Program.

Patient/Parent/Legal Guardian Signature

Signature Date

Cancel

Next

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

5.3 Patient Reproductive Classification, Testing, and Counseling: Initial Enrollment

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

1 INTAKE 2 ATTESTATION 3 REPRODUCTIVE CLASSIFICATION, TESTING, & COUNSELING 4 FINISH

Patient Reproductive Classification, Testing, and Counseling

Please complete the form below to confirm the liver function and pregnancy tests (if applicable) and press **Next**. Completion of required tests and patient counseling must be confirmed with the Bosentan REMS Program for bosentan to be dispensed to your patient.

Liver Function Test

Liver function test has been completed Yes No

Patient Reproductive Classification

If your patient is female, select the correct patient category:

Patient Category Patient Sub-Category

If this patient is a female of reproductive potential, has a negative pregnancy test been completed prior to dispensing bosentan? Yes No

Acknowledgment of Patient Counseling

Patient has been counseled this month on the risks associated with bosentan treatment and the Bosentan REMS Program requirements

By checking the box above, you attest that this patient has been counseled this month on the risks of hepatotoxicity and embryo-fetal toxicity, as appropriate for the reproductive potential status as defined in the **Bosentan REMS Program Prescriber Guide**.

Prescriber Signature

By signing below, you attest that the patient indicated above meets the reproductive potential classification as defined in the **Bosentan REMS Program Prescriber Guide**, and that you agree to follow the requirements of the Bosentan REMS Program.

Signature Signature Date

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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5.4 Patient Confirmation Page: Initial Enrollment

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username  [My Dashboard](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

1 INTAKE | **2 ATTESTATION** | **3 REPRODUCTIVE CLASSIFICATION, TESTING, & COUNSELING** | **4 FINISH**

Patient Enrollment Confirmation

 Your patient is now enrolled in the Bosentan REMS Program.

Below is your Bosentan REMS Program Enrollment ID for your patient. Please retain this information for your records.

Enrollment ID: [<Enrollment ID>](#)



If you would like to enroll another patient please use [Enroll Patient](#).

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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6. Dashboard and Dashboard Actions

6.1 Prescriber Dashboard

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Prescriber Dashboard

The table below contains the patients you have treated with bosentan. If you do not find a patient, please use the **Enroll Patient** button to add the patient.

Enroll Patient

Q

First Name	MI	Last Name	DOB	Enrollment Status	Actions						
Giacomo	P	Gullizzoni	04/21/2007	Enrolled	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">Please Select</div> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">Go</div> </div> <div style="border: 1px solid #34495e; background-color: #2980b9; color: white; padding: 2px 5px; font-size: 0.8em; margin-top: 2px;"> Add Patient Tests & Counseling View Patient Profile Change Patient Reproductive Status Update Annual Verification Refill Dispense Exception </div>						
<p>Enrollment ID: PAT 989999 Gender: Female Patient Reproductive Classification: Female Non- Reproductive Potential, Pre-pubertal Female Relationship Status: Active</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr style="background-color: #f3f3f3;"> <th style="width: 33%;">Liver Test</th> <th style="width: 33%;">Pregnancy Test</th> <th style="width: 33%;">Monthly Counseling</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">11/21/2016</td> <td style="text-align: center;">N/A</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> </tbody> </table>						Liver Test	Pregnancy Test	Monthly Counseling	11/21/2016	N/A	<input checked="" type="checkbox"/>
Liver Test	Pregnancy Test	Monthly Counseling									
11/21/2016	N/A	<input checked="" type="checkbox"/>									
Marco	K	Botton	03/04/1948	Enrolled	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">Please Select</div> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">Go</div> </div>						

Showing 1 to 2 of 2 entries

1 »

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For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

[Contact Us](#)
[Privacy Policy](#)
[Terms and Conditions](#)
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6.2 Prescriber Dashboard: Edit Patient Profile

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

Patient Profile [Edit](#)

Patient Information

First Name	<input type="text" value="John"/>	MI (Optional)	<input type="text" value="T"/>
Last Name	<input type="text" value="Doe"/>		
Email (Optional)	<input type="text" value="johndoe@email.com"/>		
Gender	<input type="text" value="Male"/>	Date of Birth	<input type="text" value="01/01/1962"/>
Address	<input type="text" value="1 Main Street"/>		
City	<input type="text" value="New York"/>		
State	<input type="text" value="New York"/>	Zip	<input type="text" value="10001"/>
Primary Phone	<input type="text" value="555-555-0000"/>		
Alternate Phone (Optional)	<input type="text" value="555-555-5555"/>		
Parent/Legal Guardian (Optional)	<input type="text" value="Jane Doe"/>		
Relationship (Optional)	<input type="text" value="Mother"/>		

Patient Enrollment

Enrollment ID: **PAT123112312**

[Cancel](#) [Save](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.3 Prescriber Dashboard: Refill Dispense Exception – Required Testing Not Confirmed, Benefits Outweigh the Risk

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Refill Dispense Exception

A Refill Dispense Exception provides a prescriber to authorize a patient to receive up to a 30-day supply of bosentan without confirmed pregnancy and/or liver function testing, or up to a 90-day supply of bosentan for extended travel outside of the United States of more than 30 days.

Refill dispense exception reasons are below:

Required Testing Not Confirmed - Benefit Outweighs the Risk: By selecting this refill dispense exception you attest that testing has not been confirmed within the last month and that the benefits of receiving bosentan outweigh the risks of hepatotoxicity and embryo-fetal toxicity associated with bosentan.

Travel Outside of the United States for more than 30 Days: By selecting this refill dispense exception you attest to continue to counsel the patient about the risk of embryo-fetal toxicity and hepatotoxicity associated with bosentan, the signs and symptoms of hepatotoxicity, and program requirements including the need to complete liver function testing and, as appropriate, pregnancy testing monthly while traveling outside of the United States.

Patient Information

Name: **Jane Doe**

Date of Birth: **09/02/1997**

Authorization Number: **AUTH-1234-5678-B910**

Refill Dispense Exception:

By selecting the **Submit** button I attest that the benefits of receiving bosentan outweigh the risk of hepatotoxicity and embryo-fetal toxicity associated with bosentan. I understand the patient must complete appropriate testing before their next refill date.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.4 Prescriber Dashboard: Refill Dispense Exception – Travel Outside the United States for More Than 30 Days

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Refill Dispense Exception

A Refill Dispense Exception provides a prescriber to authorize a patient to receive up to a 30-day supply of bosentan without confirmed pregnancy and/or liver function testing, or up to a 90-day supply of bosentan for extended travel outside of the United States of more than 30 days.

Refill dispense exception reasons are below:

Required Testing Not Confirmed - Benefit Outweighs the Risk: By selecting this refill dispense exception you attest that testing has not been confirmed within the last month and that the benefits of receiving bosentan outweigh the risks of hepatotoxicity and embryo-fetal toxicity associated with bosentan.

Travel Outside of the United States for more than 30 Days: By selecting this refill dispense exception you attest to continue to counsel the patient about the risk of embryo-fetal toxicity and hepatotoxicity associated with bosentan, the signs and symptoms of hepatotoxicity, and program requirements including the need to complete liver function testing and, as appropriate, pregnancy testing monthly while traveling outside of the United States.

Patient Information

Name: **Jane Doe**

Date of Birth: **09/02/1997**

Authorization Number: **AUTH-1234-5678-B910**

Refill Dispense Exception:

By selecting the **Submit** button I attest to continue to counsel the patient about the risk of embryo-fetal toxicity and hepatotoxicity associated with bosentan, the signs and symptoms of hepatotoxicity, and program requirements including the need to complete liver function testing and, as appropriate, pregnancy testing monthly while traveling outside of the United States. Additionally, I understand the patient must complete testing before their next refill date.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.5 Prescriber Dashboard: Refill Dispense Exception – Confirmation Page

The screenshot displays the Bosentan REMS Program Prescriber Dashboard. At the top, there is a navigation bar with the Bosentan logo and 'REMS Program' on the left, and 'Prescribing Information | Medication Guides', 'Username', and 'My Dashboard' on the right. Below this is a horizontal menu with tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The main content area is titled 'Refill Dispense Exception' and contains several sections of text, including 'A Refill Dispense Exception...', 'Required Testing Not Co...', and 'Travel Outside of the Uni...'. A purple modal window is centered on the screen with the title 'Refill Dispense Exception Confirmation' and the message: 'The exception has been approved for one (1) dispense to occur within the next 45 days.' Below the message is a purple 'OK' button. Below the modal, there is a 'Patient Information' section with the following details: Name: Jane Doe, Date of Birth: 09/02/1997, Authorization Number: AUTH-1234-5678-B910, and Refill Dispense Exception: Travel Outside of the United States for more than 30 days. At the bottom of this section are 'Cancel' and 'Submit' buttons. A footer note states: 'For additional information about the Bosentan REMS Program, please call 1-866-359-2612.' The very bottom of the page has a dark grey bar with links for 'Contact Us', 'Privacy Policy', 'Terms and Conditions', and 'Site Map'.

Note: Popup messaging will be consistent with the results of the activity within this function.

6.6 Prescriber Dashboard: Change in Reproductive Potential Status & Pre-pubertal Annual Verification

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Patient Reproductive Status Change and Pre-pubertal Annual Verification

For an immediate reporting of changes to a patient's reproductive status, or to provide annual verification that a patient remains pre-pubertal, please update the Patient Reproductive Classification section, provide your signature and date, and select the **Submit** button.

Patient Information

Full Name: **Jane Doe**
Date of Birth: **07/01/2006**

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)

Females of Non-Reproductive Potential

- Pre-pubertal females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

Patient Reproductive Classification

Patient has had a change in reproductive status
Based on definitions of reproductive potential status, patient is:

Reproductive Status

Reason for change in classification:

Status Change Reason

Annual Verification of Pre-pubertal Status

Patient remains a pre-pubertal female age 8 years or older

Prescriber Signature

By checking the box, I attest that the patient's reproductive status as updated above is accurate, and that I will comply with the REMS requirements for my patient's reproductive potential status as defined in the **Bosentan REMS Program Prescriber Guide**.

Signature
Signature Date

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.7 Prescriber Dashboard: Patient Test and Counseling

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Patient Test and Counseling

Please complete the form below to confirm the liver function and pregnancy tests (if applicable) and press **Next**. Completion of required tests and patient counseling must be confirmed with the Bosentan REMS Program every month for bosentan to be dispensed to your patient.

Patient Information

Full Name: **Jane Doe**

Date of Birth: **09/02/1962**

Confirm Liver Function Test Completed

Complete this section to confirm the completion of a liver function test for your patient.

Monthly liver function test has been completed Date of Test

By checking the above box, I attest that a liver function test has been completed for the patient.

Confirm Pregnancy Test Completed

Complete this section to confirm the completion of a pregnancy test if your patient is a female of reproductive potential.

Monthly pregnancy test has been completed Date of Test

By checking the above box, I attest that a pregnancy test has been completed for the patient.

Acknowledgement of Patient Counseling

Patient has been counseled this month on the risks associated with bosentan treatment and the Bosentan REMS Program requirements.

By checking the box above, you attest that this patient has been counseled this month on the risks of hepatotoxicity and embryo-fetal toxicity as appropriate for the reproductive potential status.

Signature

By signing below, you signify that the appropriate test(s) and/or counseling indicated above have been completed for this patient.

Signature

Signature Date

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.8 Prescriber Dashboard: Patient Test and Counseling Confirmation

The screenshot displays the Bosentan REMS Program Prescriber Dashboard. A modal dialog box titled "Patient Testing and Counseling Confirmation" is centered on the screen. The dialog contains the following text and elements:

- Title:** Patient Testing and Counseling Confirmation
- Text:** You are confirming the following:
- List:**
 - Liver Test
 - Pregnancy Test
 - Counseling
- Text:** The patient must be counseled on the risks of hepatotoxicity and embryo-fetal toxicity as appropriate for the reproductive potential status.
- Buttons:** Cancel and Confirm

The background form, which is dimmed, includes the following sections:

- Header:** Bosentan REMS Program, Prescribing Information | Medication Guides, Username, My Dashboard
- Navigation:** Prescribers, Pharmacies, Patients, Pharmacy Lookup, FAQs
- Section:** Patient Test and Counseling
- Text:** Please complete the form below to confirm the completion of required tests and patient counseling must be confirmed with the Bose...
- Section:** Patient Information
 - Full Name: Jane Doe
 - Date of Birth: 09/02/1962
- Section:** Confirm Liver Function Test Completed
 - Complete this section to confirm the completion of a liver function test if your patient is a female of reproductive potential.
 - Monthly liver function test has been completed
 - By checking the above box, I attest that a...
- Section:** Confirm Pregnancy Test Completed
 - Complete this section to confirm the completion of a pregnancy test if your patient is a female of reproductive potential.
 - Monthly pregnancy test has been completed
 - Date of Test: MM/DD/YYYY
 - By checking the above box, I attest that a pregnancy test has been completed for the patient.
- Section:** Acknowledgement of Patient Counseling
 - Patient has been counseled this month on the risks associated with bosentan treatment and the Bosentan REMS Program requirements.
 - By checking the box above, you attest that this patient has been counseled this month on the risks of hepatotoxicity and embryo-fetal toxicity as appropriate for the reproductive potential status.
- Section:** Signature
 - By signing below, you signify that the appropriate test(s) and/or counseling indicated above have been completed for this patient.
 - Signature: Jane Smith
 - Signature Date: 11/20/2017
 - Buttons: Cancel, Next
- Footer:** For additional information about the Bosentan REMS Program, please call 1-866-359-2612. Contact Us | Privacy Policy | Terms and Conditions | Site Map

Note: Popup messaging will be consistent with the results of the activity within this function.

6.9 Pharmacy Dashboard: Inpatient Pharmacies

The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.

IVR Access ID : 12341234

Pharmacies | Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you need to add a new pharmacy to your list, please use the **Add Pharmacy** button. For patient actions, use the Actions list below.

Add Pharmacy

Pharmacy Name	Address	Pharmacy Type	Certification ID	Status	Actions
ABC Pharmacy	23565 N SCOTTSDALE RD, SCOTTSDALE, Arizona 85255	Inpatient	FAC100000000	Certified	-- Please Select -- -- Please Select -- Check Inpatient REMS Requirements View Pharmacy Profile

Showing 1 to 1 of 1 entries

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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Note: Refer to Screen 6.21 to view the Pharmacy Staff tab for all pharmacy types.

6.10 Pharmacy Dashboard: Outpatient Pharmacies that Do Not Support Electronic Telecommunication Verification

The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.

IVR Access ID : 12341234

Pharmacies | Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you need to add a new pharmacy to your list, please use the **Add Pharmacy** button. For patient actions, use the Actions list below.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Status	Actions
ABC Pharmacy	1234 West Pharmacy Lane Phoenix AZ 85008	Inpatient	FAC1000000000	Certified	Please Select Go
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Outpatient	FAC1000000001	Certified	View Pharmacy Profile Request Pre-dispense Authorization Reverse Pre-dispense Authorization

Showing 1 to 2 of 2 entries

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Contact Us | Privacy Policy | Terms and Conditions | Site Map

Note: Refer to Screen 6.21 to view the Pharmacy Staff tab for all pharmacy types.

6.11 Pharmacy Dashboard: Outpatient Pharmacies that Support Electronic Telecommunication Verification

Prescribing Information | Medication Guides

Username My Dashboard

The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.

IVR Access ID : 12341234

Pharmacies Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you need to add a new pharmacy to your list, please use the **Add Pharmacy** button. For patient actions, use the Actions list below.

Add Pharmacy Search

Pharmacy Name	Address	Pharmacy Type	Certification ID	Status	Actions
ABC Pharmacy	1234 West Pharmacy Lane Phoenix AZ 85008	Outpatient	FAC1000000000	Certified	Please Select Go
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Outpatient	FAC1000000001	Certified	Please Select Go View Pharmacy Profile

Showing 1 to 2 of 2 entries 1 > 10

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Contact Us | Privacy Policy | Terms and Conditions | Site Map

Note: Refer to Screen 6.21 to view the Pharmacy Staff tab for all pharmacy types.

6.12 Pharmacy Dashboard: Chain Pharmacy Headquarters

Prescribing Information | Medication Guides
Username

Pharmacies
Patients
Pharmacy Lookup
FAQs

The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.

IVR Access ID : **12341234**

Pharmacies
Pharmacy Staff

To add a store to the list below, use the **Add Pharmacy Dispensing Location** button. To certify a store in the list below as trained on all program requirements, select the store and use the **Certify Pharmacy Dispensing Location** button. For all other activities, use the Actions list for the store.

Add Pharmacy Dispensing Location
Certify Pharmacy Dispensing Location

Pharmacy Dispensing Location Name ▲	Address	Certification ID	Status	Actions
ABC Rx	234 Drug Avenue Phoenix AZ 85008	FAC1111000000	Certified	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px; margin-right: 5px;">Please Select ▼</div> <div style="background-color: #95a5a6; color: white; padding: 2px 5px; margin-right: 5px;">Go</div> </div> <div style="background-color: #2980b9; color: white; padding: 2px 5px; margin-right: 5px; text-decoration: none;">View Pharmacy Profile</div> <div style="border: 1px solid #ccc; padding: 2px; margin-left: 5px;">Please Select ▼</div> <div style="background-color: #95a5a6; color: white; padding: 2px 5px; margin-left: 5px;">Go</div>
XYZ Rx	123 West Pharmacy Lane Phoenix AZ 85008	FAC1000000123	Incomplete	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px; margin-right: 5px;">Please Select ▼</div> <div style="background-color: #95a5a6; color: white; padding: 2px 5px; margin-right: 5px;">Go</div> </div>

Showing 1 to 2 of 2 entries 1 > 10 ▼

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Contact Us | Privacy Policy | Terms and Conditions | Site Map

Note: Refer to Screen 6.21 to view the Pharmacy Staff tab for all pharmacy types.

6.13 Pharmacy Staff Dashboard: Inpatient Pharmacies

Prescribing Information | Medication Guides
Username

Pharmacies
Patients
Pharmacy Lookup
FAQs

The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.

IVR Access ID : **12341234**

The table below contains all of your associated pharmacies. If you need to associate yourself to a new pharmacy, please use the **Associate to Pharmacy** button. For patient actions, use the Actions list below.

Associate to Pharmacy

Pharmacy Name	Address	Pharmacy Type	Status	Actions
ABC Pharmacy	1234 West Pharmacy Lane Phoenix AZ 85008	Inpatient	Certified	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">Please Select</div> <div style="background-color: #95a5a6; color: white; padding: 2px 5px; margin-right: 5px;">Go</div> </div>
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Inpatient	Certified	<div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px 5px; margin-right: 5px;">Please Select</div> <div style="background-color: #95a5a6; color: white; padding: 2px 5px; margin-right: 5px;">Go</div> </div>

Showing 1 to 2 of 2 entries

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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6.14 Pharmacy Staff Dashboard: Outpatient Pharmacies that Do Not Support Electronic Telecommunication Verification

Prescribing Information | Medication Guides
Username My Dashboard
Bosentan
REMS Program

Pharmacies
Patients
Pharmacy Lookup
FAQs

The Interactive Voice Response (IVR) unit is used by outpatient pharmacies only. Use this number to update patient testing and/or counseling through the IVR.

IVR Access ID : **12341234**

The table below contains all of your associated pharmacies. If you need to associate yourself to a new pharmacy, please use the **Associate to Pharmacy** button. For patient actions, use the Actions list below.

Associate to Pharmacy

Pharmacy Name	Address	Pharmacy Type	Certification Status	Actions
ABC Pharmacy	1234 West Pharmacy Lane Phoenix AZ 85008	Inpatient	Certified	<div style="border: 1px solid #ccc; padding: 2px;"> Please Select <input style="border: none; padding: 0 5px;" type="button" value="Go"/> </div> <ul style="list-style-type: none"> <li style="background-color: #2c3e50; color: white; padding: 2px; margin-bottom: 2px;">Request Pre-dispense Authorization <li style="padding: 2px; margin-bottom: 2px;">Reverse Pre-dispense Authorization <li style="padding: 2px;">Disassociate from Pharmacy
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Outpatient	Certified	

Showing 1 to 2 of 2 entries 1 » 10 ▾

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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6.15 Pharmacy Staff Dashboard: Associate to a Pharmacy – Search Results

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Associate to Pharmacy

To identify your certified pharmacy, please complete the fields below and select **Search**. All fields are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Pharmacy Zip Code	Identifiers		
<input type="text"/>	DEA Number	NPI Number	NCPDP Number
	<input type="text"/>	<input type="text"/>	<input type="text"/>

and or or

Search

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Bosentan REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Phone
ABC Pharmacy	1234 W Palo Verde Lane Tempe AZ 85283	555-555-5555

Showing 1 to 1 of 1 entries

1 >> 10 ▾

Cancel

Submit

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.16 Pharmacy Staff Dashboard: Disassociate from a Pharmacy

The screenshot shows the Bosentan REMS Program Pharmacy Staff Dashboard. At the top, there is a navigation bar with the logo and 'REMS Program' text, and links for 'Prescribing Information | Medication Guides', 'Username', and 'My Dashboard'. Below this is a secondary navigation bar with tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The main content area is titled 'My Dashboard' and contains a table of pharmacies. A modal dialog box titled 'Disassociate from Pharmacy' is overlaid on the table, with the text: 'Please select the **Confirm** button to remove this pharmacy from the list of pharmacies on your dashboard.' The dialog has 'Cancel' and 'Confirm' buttons. The table below the dialog shows two entries: 'ABC Pharmacy' and 'XYZ Pharmacy' with details like address, location, and certification status. At the bottom of the dashboard, there is a footer with contact information and a footer bar with links for 'Contact Us', 'Privacy Policy', 'Terms and Conditions', and 'Site Map'.

Prescribing Information | Medication Guides

Username My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

My Dashboard

The table below contains all of the pharmacies associated with your dashboard. For patient actions, use the **Associate to Pharmacy** button.

Pharmacy Name	Address	Location	Certification	Actions
ABC Pharmacy				Please Select <input type="button" value="Go"/>
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Outpatient	Certified	Please Select <input type="button" value="Go"/>

Showing 1 to 2 of 2 entries 1 » 10 ▾

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

Contact Us | Privacy Policy | Terms and Conditions | Site Map

6.17 Pharmacy Dashboard: Edit Pharmacy Profile – Inpatient Pharmacy

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

My Inpatient Pharmacy

Edit

My Information

Pharmacy Name

Pharmacy Type

Address

City

State Zip

Phone Fax

Email

Pharmacy Identifiers (at least one identifier required)

DEA Number

NPI Number

NCPDP Number

My Certification

Certification ID: **FAC123112312**

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.18 Pharmacy Dashboard: Edit Pharmacy Profile – Outpatient Pharmacy

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

My Outpatient Pharmacy [Edit](#)

My Information

Pharmacy Name	Pharmacy A		
Pharmacy Type	Outpatient Pharmacy		
Address	123 Main Street		
City	New York		
State	New York	Zip Code	10001
Phone	555-555-5555	Fax	555-555-0000
Email	john.doe@website.com		

Pharmacy Identifiers

DEA Number	AB23423423
NPI Number	123234234234
NCPDP Number	234234234

Can your pharmacy management system adjudicate claims online?

My Certification

Certification ID: **FAC123112312**

[Cancel](#) [Save](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

6.19 Pharmacy Dashboard: Edit Pharmacy Profile – Chain Pharmacy Headquarters

Prescribing Information | Medication Guides

Username 

Prescribers | **Pharmacies** | Patients | Pharmacy Lookup | FAQs

My Chain Pharmacy Headquarters Edit

My Information

Chain ID	123456		
Pharmacy Name	<input type="text" value="Pharmacy AAA"/>		
Pharmacy Type	Chain Pharmacy		
Address	<input type="text" value="4343 North Scottsdale Road"/>		
City	<input type="text" value="Scottsdale"/>		
State	<input type="text" value="AZ"/>	Zip	<input type="text" value="85251"/>
Phone	<input type="text" value="602-123-3456"/>	Fax	<input type="text" value="602-123-3434"/>

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

6.20 Pharmacy Dashboard: Edit Pharmacy Profile – Chain Pharmacy Dispensing Location

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

My Dispensing Location

My Information

Chain ID 123456

Dispensing Location Name

Pharmacy Type Chain Store

Address

Address Line 2

City

State Zip

Phone Fax

Pharmacy Identifiers (at least one identifier required)

NCPDP Number

DEA Number

NPI Number

My Training

Training Status Incomplete

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.21 Authorized Representative Pharmacy Dashboard: View Pharmacy Staff

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

My Dashboard

Pharmacies **Pharmacy Staff**

This table below contains all of the pharmacy staff members that are currently associated to your pharmacy. 

First Name	Last Name	Pharmacy Name	Pharmacy Address	Enrollment ID	Status	Actions
Mary	Brown	ABC Pharmacy	1234 W Palo Verde Lane Tempe AZ 85283	FAC1000000023	Enrolled	Please Select  <input type="button" value="Go"/>
Terry	White	ABC Pharmacy	1234 W Palo Verde Lane Tempe AZ 85283	FAC1000000000	Enrolled	Please Select  <input type="button" value="Go"/> <input type="button" value="Remove Pharmacy Staff"/>

Showing 1 to 2 of 2 entries 1 » 10 ▾

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.22 Authorized Representative Pharmacy Dashboard: Remove Pharmacy Staff

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and select the **Submit** button.

Pharmacy Staff Information

Staff Member: **Jane Doe**

Pharmacy Name: **ABC Pharmacy**

Enrollment ID: **HCP123456789**

By selecting this box I am removing this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Bosentan REMS Program.

[Cancel](#) [Submit](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.23 Pharmacy Dashboard: Check Inpatient REMS Requirements - Rx Information Entry

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

[Prescribers](#) | [Pharmacies](#) | [Patients](#) | [Pharmacy Lookup](#) | [FAQs](#)

Check Inpatient REMS Requirements

To determine if the safe use conditions have been met for your patient to receive bosentan, please complete the information below and select **Submit**. The results of the inpatient REMS requirements check will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth Zip Code

Prescription Information (Optional)

Date of Fill

Manufacturer

NDC Number

Days Supply Quantity

Prescriber Identifier (at least one is required)

Prescriber DEA Number

Prescriber NPI Number

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.24 Pharmacy Dashboard: Check Inpatient REMS Requirements – Confirmed (Patient Enrolled and Patient not Enrolled)

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Inpatient REMS Requirements Check Results

Patient Name: **Jane Doe**
DOB: **09/14/1962**
Prescriber Name: **Jane Smith**

Inpatient REMS Requirements Check Results - Confirmed

 This patient is eligible to receive bosentan

As a reminder, prior to discharge this patient must be enrolled in the Bosentan REMS Program and under the supervision and care of a certified prescriber.



[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

Note: The patient enrollment reminder language will only be displayed if the patient is not enrolled and the prescriber is certified in the Bosentan REMS Program.

6.25 Pharmacy Dashboard: Check Inpatient REMS Requirements – Rejected

Bosentan
REMS Program

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Inpatient REMS Requirements Check Results

Patient Name: **Jane Doe**
DOB: **09/14/1962**
Prescriber Name: **Jane Smith**

Inpatient REMS Requirements Check Results - Rejected

 The patient is not enrolled and the prescriber is not certified in the Bosentan REMS Program

Do not dispense bosentan to this patient!
This patient's prescriber must be certified in the Bosentan REMS Program prior to dispensing bosentan to this patient.



[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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6.26 Pharmacy Dashboard: Pre-dispense Authorization – Rx Information Entry

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Pre-dispense Authorization

To determine if the pharmacy is eligible to dispense bosentan to an eligible patient, please complete the pre-dispense authorization information below and select the appropriate response for each question. All fields listed below are required.

A PDA is verification by the Bosentan REMS Program authorizing the pharmacy to dispense bosentan to an eligible patient. Chain and Outpatient pharmacies must obtain a PDA from the Bosentan REMS Program for each dispensing that verifies the following safe use conditions are met for the patient:

- Patient is enrolled in the Bosentan REMS Program
- Prescriber is certified in the Bosentan REMS Program
- Current completed liver function test for the patient is confirmed
- If the patient is a female of reproductive potential, a current completed pregnancy test for the patient is confirmed
- Current hepatotoxicity counseling for the patient is confirmed
- Current embryo-fetal toxicity counseling for each female of reproductive potential is confirmed

in, please complete the pre-dispense authorization information after the information is submitted.

Patient Info

Date of Birth MM/DD/YYYY Zip Code

Pre-dispense Authorization Request

Date of Fill MM/DD/YYYY

Manufacturer

NDC Number

Days Supply Quantity

Prescriber Information (at least one identifier is required)

Prescriber DEA Number (Optional)

Prescriber NPI Number

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.27 Pharmacy Dashboard: Pre-dispense Authorization Result – Authorized with Counseling Confirmed

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Pre-dispense Authorization Result

 The patient is eligible to receive bosentan.

Patient Name: **Jane Doe**

Patient DOB: **09/02/1962**

Patient ID #: **PAT123456789**

Authorization Number: **AUTH-1234-5678-8910**



For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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6.28 Pharmacy Dashboard: Pre-dispense Authorization Result – Authorized with Counseling Not Confirmed

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Pre-dispense Authorization Result

 This patient is eligible to receive bosentan.
NOTE: Patient counseling is not confirmed. A pharmacist or patient can call 1-866-359-2612 for counseling guidelines

Patient Name: **Jane Doe**
Patient DOB: **09/02/1962**
Patient ID #: **PAT123456789**
Authorization Number: **[AUTH-1234-5678-8910](#)**



[For additional information about the Bosentan REMS Program, please call 1-866-359-2612.](#)

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6.29 Pharmacy Dashboard: Pre-dispense Authorization Result – Rejected

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Pre-dispense Authorization Result

 Do not dispense bosentan to this patient.

Name: **Jane Doe**
DOB: **09/02/1962**
Patient ID #: **PAT123456789**

 <Reject Reason>



For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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6.30 Pharmacy Dashboard: Reverse Pre-dispense Authorization – Search

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Pharmacy Reverse Pre-dispense Authorization

To reverse a pre-dispense authorization for a bosentan prescription that was not dispensed to a patient, enter the authorization number and select **Search**. This will reverse the pre-dispense authorization but does not reverse the prescription with the payer.

Authorization Number

[Forgot the authorization number? Look it up here](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.31 Pharmacy Dashboard: Reverse Pre-dispense Authorization – Search Results

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Pharmacy Reverse Pre-dispense Authorization

To reverse a pre-dispense authorization, enter the authorization number and select **Search**. This will reverse the pre-dispense authorization but does not reverse the prescription with the payer.

Authorization Number Search

Forgot the authorization number? Look it up [here](#)

Select the row and **Submit** to reverse the pre-dispense authorization.

Authorization Number	Patient First Name	Patient Last Name	Patient DOB	Date Processed
AUTH-1234-5678-B910	Randy	Botton	09/02/1997	10/01/2016 10:45 AM

Showing 1 to 1 of 1 entries 1 >> 10 ▾

Cancel Submit

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.32 Pharmacy Dashboard: Reverse Pre-dispense Authorization – Forgot Authorization Number

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Pharmacy Reverse Pre-dispense Authorization

Below is a list of all bosentan pre-dispense authorizations obtained by the pharmacy. Select the row and **Submit** to reverse the pre-dispense authorization. This will reverse the pre-dispense authorization but does not reverse the prescription with the payer.

Authorization Number	Patient First Name	Patient Last Name	Patient DOB	Date Processed
AUTH-1234-5678-B910	Randy	Botton	09/02/1997	10/01/2016 10:45 AM
AUTH-4444-5678-B910	John	Doe	09/02/1997	10/01/2016 10:45 AM

Showing 1 to 2 of 2 entries

1 >> 10 ▾

[Cancel](#) [Submit](#)

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

6.33 Pharmacy Dashboard: Reverse Pre-dispense Authorization – Verification

The screenshot shows the Bosentan REMS Program Pharmacy Dashboard. At the top, there is a navigation bar with the Bosentan logo and 'REMS Program' on the left, and 'Prescribing Information | Medication Guides', 'Username', and 'My Dashboard' on the right. Below this is a secondary navigation bar with tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The main content area is titled 'Pharmacy Reverse Pre-dispense Authorization'. It contains a text box for 'Authorization Number' and a 'Search' button. A modal dialog titled 'Pre-dispense Authorization Reversal' is open, displaying the instruction: 'Select **Confirm** to reverse the pre-dispense authorization or **Cancel** to return to the pre-dispense authorization results.' Below the instruction are 'Cancel' and 'Confirm' buttons. Below the modal, there is a table with the following data:

Authorization Number	Patient First Name	Patient Last Name	Patient DOB	Date Processed
AUTH-1234-5678-B910	Randy	Botton	09/02/1997	10/01/2016 10:45 AM

Below the table, it says 'Showing 1 to 1 of 1 entries' and a pagination control showing '1' and '10'. At the bottom of the main content area, there are 'Cancel' and 'Submit' buttons. A footer note reads: 'For additional information about the Bosentan REMS Program, please call 1-866-359-2612.' The bottom of the page has a dark footer with links for 'Contact Us', 'Privacy Policy', 'Terms and Conditions', and 'Site Map'.

6.34 Pharmacy Dashboard: Reverse Pre-dispense Authorization – Confirmation

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Pharmacy Pre-dispense Authorization Reversal Confirmation

The pre-dispense authorization has been reversed. The product can be returned to stock.

 Pre-dispense Authorization Reversed

Patient Name: **Jane Doe**

Patient DOB: **09/02/1962**

Authorization Number: **AUTH-1234-5678-B910**



For additional information about the Bosentan REMS Program, please call 1-866-359-2612.