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RISK EVALUATION AND MITIGATION STRATEGY (REMS) Bosentan REMS

A. Single Shared System for Bosentan

I. Goals

The goal of the Bosentan REMS Program is to mitigate the risk of hepatotoxicity and embryo-fetal toxicity associated with bosentan by:

- Ensuring prescribers are educated on the following:
 - the risks of hepatotoxicity and embryo-fetal toxicity
- Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Bosentan REMS Program
 - monitoring patients at baseline and monthly
- Ensuring that pharmacies are educated on the following:
 - the risks of hepatotoxicity and embryo-fetal toxicity
- Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing bosentan
- Ensuring that patients are informed about:
 - the risks of hepatotoxicity and embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

II. Elements to Assure Safe Use

1. Healthcare providers who prescribe bosentan must be certified

- a. To become certified to prescribe bosentan, prescribers must:
 - i. Review the Prescribing Information for bosentan
 - ii. Review the *Bosentan REMS Program Prescriber Guide*
 - iii. Enroll in the Bosentan REMS Program by completing the *Bosentan REMS Program Prescriber Enrollment Form* and submitting it to the Bosentan REMS Program

- b. As a condition of certification, prescribers must:
- i. Enroll each patient in the Bosentan REMS Program by performing the following:
 - 1) 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*
 - 2) Determine the reproductive potential status of each female patient as defined in the *Bosentan REMS Program Prescriber Guide*
 - 3) 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
 - 4) 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
 - 5) 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
 - ii. Report all adverse events including those suggestive of hepatotoxicity to the Bosentan REMS Program
 - iii. Report any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program
 - iv. 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
 - v. Perform the following requirements on an ongoing basis for each patient:
 - 1) Order and review liver function test results before bosentan treatment initiation and monthly during treatment

- 2) Counsel patients who fail to comply with program requirements
- vi. Perform the following monitoring on an ongoing basis for each pre-pubertal female:
 - 1) 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
 - vii. Perform the following monitoring on an ongoing basis for each female patient of reproductive potential:
 - 1) Order and review pregnancy test results before bosentan treatment initiation, monthly during treatment, and for one month following treatment discontinuation
- c. Bosentan Sponsors must:
- i. Ensure that healthcare providers who prescribe bosentan are certified, in accordance with the requirements described above
 - ii. Provide all the following mechanisms for healthcare providers to complete the certification process for the Bosentan REMS Program: online, mail, fax
 - iii. Ensure that healthcare providers are notified when they have been certified by the Bosentan REMS Program
 - iv. Maintain a validated, secure database of healthcare providers who are certified to prescribe bosentan in the Bosentan REMS Program. The database must link the prescribers' information and date of certification to their enrolled patients' information and update it accordingly
 - v. Ensure that healthcare providers meet the REMS requirements and decertify healthcare providers who do not maintain compliance with REMS requirements
 - vi. Ensure that certified prescribers are provided access to the database of certified pharmacies and enrolled patients
 - vii. Provide the *Bosentan REMS Program Prescriber Enrollment Form*, *Bosentan REMS Program Prescriber Guide*, *Bosentan REMS Program Fact Sheet*, *Bosentan REMS Program Patient Enrollment Form*, *Bosentan REMS Program Guide for Patients*, and *Bosentan REMS Program Testing and Patient Counseling Reporting Form* to healthcare providers who (1) attempt to prescribe bosentan and are not yet certified, or (2) inquire about how to become certified

The following materials are part of the REMS and are appended:

- *Bosentan REMS Program Prescriber Guide*
- *Bosentan REMS Program Prescriber Enrollment Form*
- *Bosentan REMS Program Guide for Patients*
- *Bosentan REMS Program Patient Enrollment Form*
- *Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form*
- *Bosentan REMS Program Fact Sheet*
- *Bosentan REMS Program Testing and Patient Counseling Reporting Form*
- *Bosentan REMS Program Website* (www.BosentanREMSProgram.com)

2. Pharmacies that dispense bosentan must be certified

- a. To become certified to dispense bosentan, pharmacies must:
 - i. Designate an authorized representative to complete the certification process by submitting the appropriate completed form on behalf of the pharmacy:
 - 1) *Bosentan REMS Program Outpatient Pharmacy Enrollment Form*¹
 - 2) *Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form*²
 - 3) *Bosentan REMS Program Inpatient Pharmacy Enrollment Form*³
 - ii. Ensure that the authorized representative oversees the implementation of and compliance with the Bosentan REMS Program requirements by the following:
 - 1) Review the *Bosentan REMS Program Pharmacy Guide*

¹ For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.

² 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.

³ For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.

- 2) 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
- b. As a condition of certification:
- i. Pharmacies must recertify in the Bosentan REMS Program if the pharmacy designates a new authorized representative
 - ii. Report all adverse events including those suggestive of hepatotoxicity to the Bosentan REMS Program
 - iii. Report any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program
 - iv. 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
 - v. 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
 - vi. Outpatient Pharmacies:
 - 1) Put processes and procedures in place to ensure the following requirements are completed prior to dispensing bosentan
 - a) Obtain a pre-dispense authorization from the Bosentan REMS Program by accessing the *Bosentan REMS Program Website*, calling the Bosentan REMS Program Contact Center, or enabling the pharmacy management system to support communication with the Bosentan REMS Program
 - 2) 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 pre-dispense authorization by processing prescriptions, 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 the 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) Not transfer bosentan to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program
- 3) 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 the 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) Not transfer bosentan to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program

vii. Inpatient Pharmacies:

- 1) 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) Verify the patient has completed the liver function tests and each female of reproductive potential has completed the pregnancy test
 - d) Verify if the 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
 - e) Dispense no more than a 15-day supply of bosentan upon discharge
- 2) 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 records
- 3) Not transfer bosentan to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program

c. Bosentan Sponsors must:

- i. Ensure that pharmacies that dispense bosentan are certified, in accordance with the requirements described above
- ii. Provide all the following mechanisms for pharmacies to complete certification for the Bosentan REMS Program: online, mail, fax
- iii. Ensure that pharmacies are notified when they have been certified by the Bosentan REMS Program
- iv. Ensure that certified pharmacies are provided access to the database of certified prescribers and enrolled patients
- v. Verify every 2 years that the authorized representative's name and contact information correspond to those of the current designated authorized

representative for the certified pharmacy. If different, the pharmacy must be required to recertify with a new authorized representative

The following materials are part of the REMS and are appended:

- *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*

3. Bosentan must be dispensed with evidence or other documentation of safe use conditions

- a. To become enrolled in the Bosentan REMS Program, the patient and/or parent/legal guardian must sign a *Bosentan REMS Program Patient Enrollment Form* indicating that he/she has:
 - i. Received and has read the *Bosentan REMS Program Guide for Patients*
 - ii. Received counseling from the prescriber regarding:
 - 1) the risk of hepatotoxicity, the signs and symptoms of hepatotoxicity and, as appropriate, the risk of embryo-fetal toxicity and the need to use reliable contraception
 - 2) the need to complete liver function testing and, as appropriate, pregnancy testing as outlined in the *Bosentan REMS Program Guide for Patients*
 - 3) the Bosentan REMS Program contacting him/her prior to each dispense of bosentan to confirm that liver function tests and, as appropriate, pregnancy test were completed and provide counseling
- b. Bosentan Sponsors must:
 - i. Provide all the following mechanisms for the certified prescribers to be able to submit the completed *Bosentan REMS Program Patient Enrollment Form* to the Bosentan REMS Program: online, mail, fax
 - ii. Ensure that the certified outpatient pharmacy is able to verify bosentan is dispensed to patients only if there is evidence or other documentation that they have met the following requirements:
 - 1) Prescriber is certified
 - 2) Patient is enrolled

- 3) Patient has completed the liver function tests and each female of reproductive potential has completed the pregnancy test
 - 4) 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
- iii. Before each outpatient dispensing, ensure the Bosentan REMS Program Contact Center:
- 1) Confirms and documents each patient has completed the liver function tests and each female of reproductive potential has completed the pregnancy test. If unable to obtain confirmation from the patient that the testing was completed, or if the patient cannot be reached, obtain confirmation from the patient's prescriber
 - 2) If the patient's prescriber cannot confirm that the required testing was completed, the Bosentan REMS Program Contact Center will:
 - a) Remind the prescriber of his/her obligation to order and review monthly liver function tests and pregnancy tests (for females of reproductive potential)
 - b) Ask the prescriber whether or not he/she authorizes the refill of bosentan. The patient is eligible to receive a 30-day supply of bosentan only if the prescriber authorizes the refill
 - c) Document the prescriber's decision to authorize the refill in the Bosentan REMS Program system and notify to the dispensing pharmacy of the authorization
 - 3) Counsels the patient on the risk of hepatotoxicity, the signs and symptoms of hepatotoxicity and, as appropriate, the risk of embryo-fetal toxicity and need to use reliable contraception
- iv. Ensure the certified outpatient pharmacies receive authorization from the Bosentan REMS Program before each dispensing of bosentan
- v. Provide all the following mechanisms for outpatient pharmacies to obtain a pre-dispense authorization via accessing the Bosentan REMS Program Website, calling the Bosentan REMS Program Contact Center, or by using the REMS Pharmacy Network
- vi. Provide all the following mechanisms for certified inpatient pharmacies to verify prescriber certification and patient enrollment: accessing the Bosentan REMS Program Website or calling the Bosentan REMS Program Contact Center

- vii. Ensure that the certified pharmacies complete the verifications required under [Section A.II.2](#) for patients prior to dispensing
- viii. Ensure that the Bosentan REMS Program Contact Center updates the Bosentan REMS Program system with a patient's change in reproductive status within one business day of receipt of a completed *Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form*

B. Implementation System

1. Bosentan Sponsors must ensure that Bosentan is only distributed to certified pharmacies by:
 - a. Ensuring that wholesalers/distributors who distribute bosentan comply with the program requirements for wholesalers/distributors. The wholesalers/distributor must:
 - i. Put processes and procedures in place to verify, prior to distributing bosentan, that the pharmacy is certified
 - ii. Train all relevant staff on the Bosentan REMS Program requirements
 - iii. Comply with audits 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. In addition, wholesalers/distributors must maintain appropriate documentation and make it available for audits
 - iv. Provide complete, unblended and unblocked distribution data, including information on shipment to pharmacies to the Bosentan Sponsors to verify compliance with the Bosentan REMS Program
 - b. Ensuring that wholesalers/distributors maintain distribution records of all shipments of bosentan and provide the data to the Bosentan Sponsors
2. Bosentan Sponsors must monitor distribution data to ensure all the processes and procedures are in place and functioning to support the requirements of the Bosentan REMS Program
3. Bosentan Sponsors must audit the wholesalers/distributors within 180 calendar days after the wholesaler/distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the Bosentan REMS Program. Corrective action must be instituted by Bosentan Sponsors if noncompliance is identified
4. Bosentan Sponsors must maintain a validated, secure database of pharmacies who are certified to dispense bosentan in the Bosentan REMS Program

5. Bosentan Sponsors must maintain records of bosentan distribution and dispensing, certified prescribers, certified pharmacies, wholesalers/distributors, and enrolled patients to meet REMS requirements
6. Bosentan Sponsors must maintain a Bosentan REMS Program Contact Center (1-866-359-2612) and *Bosentan REMS Program Website*. The *Bosentan REMS Program Website* must include the capability to complete prescriber and pharmacy certification online, the capability to enroll and manage patients online, the capability to verify prescriber certification and patient enrollment online, the option to print the Prescribing Information, and Bosentan REMS Program materials. Bosentan product websites must include a prominent REMS-specific link to the *Bosentan REMS Program Website*. The *Bosentan REMS Program Website* must not link back to the product websites
7. Bosentan Sponsors must ensure that within 30 calendar days of REMS approval the *Bosentan REMS Program Website* is fully operational and the REMS materials listed in or appended to the Bosentan REMS Program document are available through the *Bosentan REMS Program Website* or by calling the Bosentan REMS Program Contact Center
8. Bosentan Sponsors must monitor on an ongoing basis the certified pharmacies to ensure the requirements of the Bosentan REMS Program are being met. Bosentan Sponsors must institute corrective action if noncompliance is identified and decertify pharmacies that do not maintain compliance with the REMS requirements
9. Bosentan Sponsors must maintain an ongoing annual audit plan that involves wholesalers/distributors and pharmacies
10. Bosentan Sponsors must audit 10 pharmacies or one percent (1%), whichever is greater, of the certified pharmacies within 180 calendar days after the pharmacy places its first order of bosentan to ensure that all processes and procedures are in place and functioning to support the requirements of the Bosentan REMS Program. The certified pharmacies must also be included in Bosentan Sponsors ongoing annual audit plan. Bosentan Sponsors must institute corrective action if noncompliance is identified
11. Bosentan Sponsors must take reasonable steps to improve implementation of and compliance with the requirements in the Bosentan REMS Program based on monitoring and evaluation of the Bosentan REMS Program

C. Timetable for Submission of Assessments

Bosentan NDA Sponsors must submit REMS assessments to the FDA annually from the date of the initial approval of the Bosentan REMS Program (MM/DD/YYYY).

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each annual assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. The Bosentan NDA Sponsors must submit each assessment so that it will be received by FDA on or before the due date.

Bosentan

REMS Program

Prescriber Guide

The Bosentan **R**isk **E**valuation and **M**itigation **S**trategy (REMS) Program is a single shared program for brand and generic bosentan medication 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.

This guide contains important information for prescribers about the risks of Bosentan, including hepatotoxicity and embryo-fetal toxicity, and includes:

- Bosentan REMS Program Overview
- Overview of Enrollment Requirements for Prescribers
- Bosentan Liver Function Treatment Results and Monitoring Recommendations
- Prescriber's Role in the Bosentan REMS Program: Step by Step
- Contraception Options for Females of Reproductive Potential

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About Bosentan

Tracleer® is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1):

- in adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%).
- in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Bosentan is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1):

- in adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%).

Risk of Hepatotoxicity

Bosentan may cause liver damage. Liver function monitoring of all patients is essential prior to initiation of treatment and monthly thereafter. It is important to adhere strictly to the monthly monitoring schedule for the duration of treatment.

Changes in aminotransferases may occur early or late in treatment. There have been rare postmarketing reports of liver failure and unexplained hepatic cirrhosis in a setting of close monitoring; the contribution of bosentan could not be excluded.

Elevations in aminotransferases require close attention. If elevated aminotransferase levels are seen, changes in monitoring and treatment must be initiated. See the Bosentan Liver Function Test Results and Monitoring Recommendations table on [Page 9](#) for treatment and monitoring recommendations for liver enzyme elevations. Use of bosentan should generally be avoided in patients with elevated aminotransferases ($>3 \times$ ULN) **at baseline** because monitoring for hepatotoxicity may be more difficult.

Risk of Embryo-fetal Toxicity

Bosentan is contraindicated in females who are or may become pregnant and may cause fetal harm when administered to a pregnant woman. Animal studies have shown that bosentan is likely to cause major birth defects when administered during pregnancy. If bosentan is used during pregnancy, apprise the patient of the potential hazard to a fetus. To prevent pregnancy, females of reproductive potential must use reliable contraception prior to beginning treatment with bosentan, during treatment, and for one month after ending bosentan treatment. Patients must not become pregnant while taking bosentan.

What is the Bosentan REMS Program?

Due to the risks of hepatotoxicity and embryo-fetal toxicity, bosentan is only available through a single shared system required and approved by the Food and Drug Administration (FDA), called the Bosentan REMS Program. The Bosentan REMS Program is a shared program including all brand and generic bosentan products.

The goal of the Bosentan Risk Evaluation and Mitigation Strategy (REMS) Program is to mitigate the risk of hepatotoxicity and embryo-fetal toxicity associated with bosentan by:

- Ensuring prescribers are educated on the following:
 - the risks of hepatotoxicity and embryo-fetal toxicity
- Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Bosentan REMS Program
 - monitoring patients at baseline and monthly
- Ensuring that pharmacies are educated on the following:
 - the risks of hepatotoxicity and embryo-fetal toxicity
- Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing bosentan
- Ensuring that patients are informed about:
 - the risks of hepatotoxicity and embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

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 and providing 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 tests results before bosentan treatment initiation
 - Prescribers must order and review monthly liver function tests
 - 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 as defined on [Page 7](#) of this guide
 - 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 older¹ 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 ≥ 2 x ULN, referenced on [Page 9](#)
 - Only inpatient, outpatient and chain pharmacies certified in the Bosentan REMS Program can dispense bosentan

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
 - For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (pre-menarchal)
- **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**

¹ Clinical threshold for evaluating onset of puberty.

Overview of Enrollment Requirements for Prescribers

Requirement	All Patients	Females of Reproductive Potential	Females of Non-Reproductive Potential	
			Pre-pubertal	Post-menopausal or other medical reasons for permanent, irreversible infertility
Prescriber enrolls the patient into the Bosentan REMS Program	X			
Prescriber counsels the patient using the <i>Bosentan REMS Program Guide for Patients</i> , particularly on the risks of hepatotoxicity and embryo-fetal toxicity and the need to use reliable contraception	X*			
Prescriber must order and review liver function tests prior to initiation of treatment and monthly during treatment	X			
Prescriber must order and review pregnancy tests prior to initiation of treatment, monthly during treatment, and for one month after ending treatment		X		
Prescriber must verify reproductive status annually in patients 8 years of age or older by completing the <i>Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i>			X	
Prescriber must complete the <i>Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i> upon becoming aware of any change or misclassification in reproductive potential status within 10 business days of awareness		X	X	X

*For pre-pubertal female patients and/or a parent/legal guardian: Counsel only about the risks of hepatotoxicity, embryo-fetal toxicity and the need to immediately contact the prescriber if the patient begins to menstruate.

Tracleer® and Bosentan Liver Function Test Results and Monitoring Recommendations

The tables below provide recommendations on managing patients taking Tracleer (Adult and Pediatric patients) and bosentan (Patients > 12 years) with elevated liver function test results. Elevated monthly liver function test results do not preclude treatment with Tracleer or bosentan.

- Table 1: Dosage Adjustment and Monitoring for **Tracleer**
- Table 2: Dosage Adjustment and Monitoring for **Bosentan**

Table 1. Dosage Adjustment and Monitoring for Patients Taking Tracleer who Develop Aminotransferase Elevations >3 x ULN

ALT/AST level	Treatment and monitoring recommendations
>3 to ≤5 x ULN	<p>Confirm by another aminotransferase test: if confirmed:</p> <ul style="list-style-type: none"> ▪ <u>in adults and pediatric patients >12 years and >40 kg</u>, reduce the daily dose to 62.5mg twice daily or interrupt treatment, and monitor aminotransferase levels at least every 2 weeks. If the aminotransferase levels return to pretreatment values, treatment may continue or be reintroduced at 62.5 mg twice daily, with reassessment of aminotransferase levels within 3 days. ▪ <u>in all other pediatric patients*</u>, interrupt treatment with no prior dose reduction. If the aminotransferase levels return to pretreatment values, reintroduce at the dose used prior to treatment interruption, with reassessment of aminotransferase levels within 3 days.
>5 to ≤8 x ULN	<p>Confirm by another aminotransferase test; if confirmed, stop treatment and monitor aminotransferase levels at least every 2 weeks. Once the aminotransferase levels return to pretreatment values,</p> <ul style="list-style-type: none"> ▪ <u>in adults and pediatric patients >12 years and >40 kg</u>, consider reintroduction of treatment at 62.5 mg twice daily, with reassessment of aminotransferase levels within 3 days. ▪ <u>in all other pediatric patients*</u>, consider reintroduction at the dose used prior to treatment interruption, with reassessment of aminotransferase levels within 3 days.
>8 x ULN	<p>Stop treatment permanently. There is no experience with reintroduction of Tracleer in these circumstances.</p>

*Use of bosentan in pediatric patients ≤ 12 years of age is exclusive to Tracleer.

Discontinue Tracleer if aminotransferase elevations are accompanied by signs or symptoms of liver dysfunction or injury, or increases in bilirubin of ≥2 x ULN.

Table 2. Dosage Adjustment and Monitoring for Patients >12 years Taking bosentan who Develop Aminotransferase Elevations >3 x ULN

ALT/AST levels	Treatment and monitoring recommendations
> 3 and ≤ 5 x ULN	<p>Confirm by another aminotransferase test; if confirmed,</p> <ul style="list-style-type: none"> • <u>in patients >12 years and >40 kg</u>, reduce the daily dose to 62.5 mg twice daily or interrupt treatment, and monitor aminotransferase levels at least every 2 weeks. If the aminotransferase levels return to pretreatment values, treatment may continue or be reintroduced at 62.5 mg twice daily, with reassessment of aminotransferase levels within 3 days. • <u>in patients > 12 years and <40 kg</u>, interrupt treatment with no prior dose reduction. If the aminotransferase levels return to pretreatment values, reintroduce at the dose used prior to treatment interruption, with reassessment of aminotransferase levels within 3 days.
> 5 and ≤ 8 x ULN	<p>Confirm by another aminotransferase test; if confirmed, stop treatment and monitor aminotransferase levels at least every 2 weeks. Once the aminotransferase levels return to pretreatment values,</p> <ul style="list-style-type: none"> • <u>in patients >12 years</u>, consider reintroduction of the treatment of 62.5 mg twice daily, with reassessment of aminotransferase levels within 3 days.
> 8 x ULN	<p>Stop treatment permanently. There is no experience with reintroduction of bosentan in these circumstances.</p>

Discontinue bosentan if aminotransferase elevations are accompanied by signs or symptoms of liver dysfunction or injury, or increases in bilirubin of ≥ 2 x ULN.

What is a Refill Dispense Exception?

The Bosentan REMS Program allows prescribers to apply clinical judgment and authorize continued dispensing of bosentan to enrolled patients when a patient's testing could not be confirmed in a given month or for extended travel outside of the United States. In order for a pharmacy to dispense to a patient, the prescriber must authorize a refill dispense exception.

A refill dispense exception allows a prescriber to authorize a patient to receive up to a 30-day supply of bosentan without confirmed pregnancy and/or liver function testing. The refill dispense exception also allows the prescriber to authorize up to a 90-day supply of bosentan for extended travel outside of the United States of more than 30 days.

In order for a patient to be eligible to receive a refill dispense exception due to testing not being confirmed in a given month:

- The patient must be enrolled in the Bosentan REMS Program
- The patient must have confirmed testing on file for the previous month
- The prescriber must attest that the benefits of receiving bosentan outweigh the risks of hepatotoxicity and embryo-fetal toxicity associated with bosentan

In order for a patient to be eligible to receive a refill dispense exception for extended travel outside of the United States:

- The patient must be enrolled in the Bosentan REMS Program
- The patient must have confirmed testing on file for the previous month
- The patient must be traveling outside of the United States for more than 30 days
- The prescriber must attest that the benefits of receiving bosentan outweigh the risks of hepatotoxicity and embryo-fetal toxicity associated with bosentan
- The prescriber must 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
 - Test confirmation is not required to be provided to the Bosentan REMS Program while the patient is traveling outside of the United States

Only certified prescribers can authorize a refill dispense exception by:

- Calling the Bosentan REMS Program Contact Center at 1-866-359-2612
- Documenting the refill dispense exception authorization through the ***Bosentan REMS Program Website***

Prescriber's Role in the Bosentan REMS Program: Step by Step

Prescribers must complete the following steps in the Bosentan REMS Program:

1. **READ** the Prescribing Information for bosentan and Medication Guide for the prescribed product and this 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** 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 paper copies from the *Bosentan REMS Program Website* at www.BosentanREMSProgram.com, and fax the form to the Bosentan REMS Program at 1-800-730-8231
3. **DETERMINE** the reproductive potential status for female patients
 - You should identify female patients (captured on the *Bosentan REMS Program Patient Enrollment Form*) as one of the following categories:
 - **Female of Reproductive Potential**
 - **Female 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 section above: "[Bosentan REMS Program Overview](#)"
4. **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 *Bosentan REMS Program Guide for Patients* to each patient
 - 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
 - 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
 - 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

5. 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 online at **www.BosentanREMSProgram.com**
- Keep the original form with the patient’s records

6. 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 all required test results and monitor patients throughout treatment

- **For all patients:**
 - Order and review liver function tests each month during treatment with bosentan
 - Prescribers may, though 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*** online at **www.BosentanREMSProgram.com**
 - 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 at **www.BosentanREMSProgram.com**
 - 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*** to the Bosentan REMS Program within 10 business days of becoming aware of the change

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

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

All Bosentan REMS Program forms can be completed online or downloaded from the website at **www.BosentanREMSProgram.com**. Hard copies can be faxed to the program at 1-800-730-8231. Other information about the Bosentan REMS Program can be found on the ***Bosentan REMS Program Website***. The Bosentan REMS Program Contact Center can be reached at 1-866-359-2612.

Important Information for Prescribers of Females of Reproductive Potential Taking Bosentan

- Educate and counsel females of reproductive potential about medical options in the event of unprotected sex or known or suspected contraceptive failure
- Remind the patient to report missing a period or any other reason for suspected pregnancy during treatment to you immediately
- If pregnancy is suspected for any reason, a pregnancy test must be performed
- The prescriber must notify the Bosentan REMS Program at 1-866-359-2612 of any pregnancies that occur during treatment or within one month of ending bosentan treatment

Contraception for Females of Reproductive Potential

All females of reproductive potential must use reliable contraception during treatment with bosentan and for one month after ending bosentan treatment. Patients should also have monthly contraceptive counseling with either the prescriber or another designated healthcare provider trained in contraceptive counseling. Please refer to the table below for a complete list of acceptable contraceptive methods. A similar table can be found in the ***Bosentan REMS Program Guide for Patients*** and should be used to discuss acceptable birth control options with patients. The patient should be instructed to select one of the options listed below.

Option 1 One method from this list:	Option 2 One method from this list:	Option 3 One method from this list:	Option 4 One method from this list:
Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNg 20 IUS: progesterone IUS) Tubal sterilization	Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant	Diaphragm with spermicide Cervical cap with spermicide	Partner's vasectomy
	PLUS One method from this list:	PLUS One method from this list:	PLUS One method from this list:
	Male condom Diaphragm with spermicide Cervical cap with spermicide	Male condom	Male condom Diaphragm with spermicide Cervical cap with spermicide Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant

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You can reach the Bosentan REMS Program Contact Center by calling toll free 1-866-359-2612. For more information about the Bosentan REMS Program, please visit **www.BosentanREMSProgram.com**.

Please see the Prescribing Information for bosentan, including complete Boxed Warning for hepatotoxicity and embryo-fetal toxicity, and the Medication Guide for each approved bosentan product, which can be found at **www.BosentanREMSProgram.com**.

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.

Instructions

For immediate certification, please go to www.BosentanREMSProgram.com.

To submit this form via fax or mail, please complete all required fields below and fax to 1-800-730-8231 or mail to the Bosentan REMS Program, P.O. Box 29080, Phoenix, AZ 85038. You will receive a confirmation via the contact preference you list below.

If you have questions, require additional information, or need additional copies of Bosentan REMS Program documents, please visit the program website at www.BosentanREMSProgram.com, or call the Bosentan REMS Program at 1-866-359-2612.

Prescriber Responsibilities

Specifically, you attest to the following:

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 this **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: 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: 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: Order and review pregnancy test results before bosentan treatment initiation, monthly during treatment, and for one month following treatment discontinuation

Prescriber Information (All fields required unless otherwise indicated)

First Name:	MI (opt):	Last Name:
Email Address:		Professional Designation: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> PA <input type="checkbox"/> NP
NPI#:	DEA#:	Medical Specialty: <input type="checkbox"/> Cardiology <input type="checkbox"/> Pulmonology <input type="checkbox"/> Rheumatology <input type="checkbox"/> General/Family Practice <input type="checkbox"/> Other
Clinic/Practice Name:		
Address:		City:
State:	Zip:	Preferred method of contact: <input type="checkbox"/> Fax <input type="checkbox"/> Email
Phone:	Ext (opt):	Fax:

Prescriber Signature

By signing below, you signify your understanding of the risks of bosentan treatment and your obligations as a bosentan prescriber to educate your 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:

Date:

Bosentan

REMS Program

Guide for Patients

Information to help you during your treatment with bosentan

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What is bosentan?

Bosentan is a prescription medicine used to treat people with certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the vessels of the lungs.

Bosentan can improve your ability to exercise and can slow the worsening of your physical condition and symptoms. Bosentan lowers high blood pressure in your lungs and lets your heart pump more efficiently.

What are the serious risks of bosentan?

Bosentan can cause **liver damage** and, if taken during pregnancy, can cause **serious birth defects**.

All patients - liver function must be monitored:

- Before you start taking bosentan,
- Every month while taking bosentan, and
- Any time your healthcare provider orders testing

Female patients - pregnancy must be avoided:

- Before you start taking bosentan,
- While taking bosentan, and
- For one month after you end bosentan treatment

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:

1. Read this ***Bosentan REMS Program Guide for Patients*** and the Medication Guide which comes with your medicine
2. Ask your healthcare provider any questions you have about taking bosentan and the Bosentan REMS Program
3. 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 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

What are the Bosentan REMS Program requirements for me?

- Participate in the Bosentan REMS Program for as long as you are taking the medication, and for one month after ending bosentan treatment
- Be counseled on the requirements of the Bosentan REMS Program and the risk of liver damage
- Go for any other liver tests your healthcare provider orders for you. Your healthcare provider will monitor your liver function monthly and may adjust or stop your treatment if there are signs of liver damage
- Tell your healthcare provider if you have had liver problems, including liver problems while on other medicines
- Call your healthcare provider right away if you have any of these symptoms of liver problems while you are on bosentan:
 - Nausea, vomiting, fever, unusual tiredness, stomach area (abdominal) pain, or yellowing of the skin or the whites of your eyes (jaundice)
- Read the Medication Guide and the ***Bosentan REMS Program Guide for Patients***
- Complete a liver function test before beginning treatment, and monthly thereafter until ending bosentan treatment
- Be contacted by the Bosentan REMS Program before receiving bosentan to provide confirmation that a current liver function test was completed and you were counseled on the risks of bosentan and your requirements in the Bosentan REMS Program
- Complete and sign the ***Bosentan REMS Program Patient Enrollment Form*** with your healthcare provider

Females who can get pregnant have additional requirements in the program

You are considered a female who can get pregnant if you:

- Have entered puberty, even if you have not started your period, and
 - Have a uterus, and
 - Have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had your ovaries removed)
- Be counseled before your first prescription and each month thereafter on the need to use reliable birth control during bosentan treatment, and for one month after ending bosentan treatment
 - Complete a pregnancy test before beginning treatment with bosentan, monthly during bosentan treatment, and for one month after ending bosentan treatment
 - Be contacted by the Bosentan REMS Program before receiving bosentan to provide confirmation that a pregnancy test was completed before beginning treatment, monthly during treatment, and for one month after ending bosentan treatment
 - Be counseled on the requirements of the Bosentan REMS Program and the risk of serious birth defects
 - Notify your healthcare provider immediately if you miss a menstrual period or suspect that you are pregnant
 - Be contacted by a Bosentan REMS Program representative if you become pregnant while on bosentan or within one month after ending bosentan treatment
 - A pre-pubertal female and/or her parent/legal guardian must immediately contact their healthcare provider if she has a menstrual period

What are my birth control options?

Your healthcare provider will talk with you about your birth control options before you start bosentan. Ask your healthcare provider if you have any questions. Tell your healthcare provider if you want to change your birth control.

You must choose one of the four options listed below. More than one birth control method might be needed every time you have sex.

Acceptable birth control options

Option 1 One method from this list:	or	Option 2 One method from this list:	or	Option 3 One method from this list:	or	Option 4 One method from this list:
Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNg 20 IUS: progesterone IUS) Tubal sterilization		Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant		Diaphragm with spermicide Cervical cap with spermicide PLUS One Method from this list: Male condom		Partner's vasectomy PLUS One Method from this list: Male condom Diaphragm with spermicide Cervical cap with spermicide Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant

How will I receive bosentan?

Bosentan is available only through certified pharmacies in the Bosentan REMS Program. A certified pharmacy is a pharmacy that is authorized by the Bosentan REMS Program to provide bosentan to you.

- Each month, before you receive bosentan, you will be contacted by the Bosentan REMS Program to confirm that you have completed your testing and to talk to you about the benefits and risks of bosentan. If your healthcare provider has already notified the Bosentan REMS Program that you have completed your testing, you will not receive a phone call from the Bosentan REMS Program that month
- Read the Medication Guide each time you receive it. Important information may have been added or changed

For a list of certified pharmacies, please call the Bosentan REMS Program at 1-866-359-2612 or visit www.BosentanREMSProgram.com.

Your steps to treatment with bosentan

Use this helpful checklist to get started with bosentan and to stay on track during your treatment.

BEFORE YOU START TREATMENT: All Patients

- Review the *Bosentan REMS Program Guide for Patients*
- Make sure you understand the risks and benefits of taking bosentan
- Tell your healthcare provider if you have had liver problems, including liver problems while taking other medicines
- Go for your liver function test
- Go for your pregnancy test (for females who can get pregnant)
- Enroll in the Bosentan REMS Program

EVERY MONTH: All Patients

- Read the Medication Guide that comes with every prescription
- Complete the monthly liver function tests ordered by your healthcare provider
- Fill your prescription at a certified pharmacy
- A healthcare provider from the Bosentan REMS Program will call you every month to ask if you had your liver function tests and were counseled on the risk of liver damage before you can receive your bosentan. **If your healthcare provider has already notified the Bosentan REMS Program that you have completed your testing and counseling, you will not receive a phone call from the Bosentan REMS Program that month.** The refill may not be ready on time if you have not had your liver tests and counseling
- Tell your healthcare provider right away if you have any of these symptoms of liver problems while taking bosentan: nausea, vomiting, fever, unusual tiredness, stomach area (abdominal) pain, or yellowing of the skin or the whites of your eyes (jaundice)

EVERY MONTH: Female Patients who can get pregnant

- Use the reliable birth control method(s) agreed upon with your healthcare provider during treatment and for one month after you stop taking bosentan

- Complete the monthly pregnancy test ordered by your healthcare provider
- A healthcare provider from the Bosentan REMS Program will call you every month to ask if you had a pregnancy test and were counseled on the risk of birth defects before you can receive your bosentan. **If your healthcare provider has already notified the Bosentan REMS Program that you have completed your testing and counseling, you will not receive a phone call from the Bosentan REMS Program that month.** The refill may not be ready on time if you have not had your pregnancy test and counseling
- Do not get pregnant. Tell your healthcare provider right away if you:
 - Had unprotected sex
 - Think that your birth control failed
 - Miss a menstrual period
 - Think you are pregnant

Bosentan

REMS Program

You can reach the Bosentan REMS Program by calling toll free at 1-866-359-2612.

For more information about the Bosentan REMS Program, please visit **www.BosentanREMSProgram.com**.

Instructions

For **immediate patient enrollment**, please go to www.BosentanREMSProgram.com. The patient must complete this form with the prescriber. The form may be completed using this paper copy or online.

To submit this form via fax or mail, please complete all required fields below and fax to 1-800-730-8231 or mail to the Bosentan REMS Program, P.O. Box 29080, Phoenix, AZ 85038.

If you have questions, require additional information, or need additional copies of Bosentan REMS Program documents, please visit the program website at www.BosentanREMSProgram.com, or call the Bosentan REMS Program at 1-866-359-2612.

Patient Agreement and Signature

To become enrolled in the Bosentan REMS Program, a patient and/or parent/legal guardian is indicating that he/she has:

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

Patient Information (All fields required unless otherwise indicated)

First Name:	MI (opt):	Last Name:	Gender:
Date of Birth (MM/DD/YYYY):	Email Address (opt):		
Primary Phone #:	Alternate Phone # (opt):		
Address:	City:		
State:	Zip:		
Legal Guardian (opt):	Relationship (opt):		

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

Patient/Parent/Legal Guardian Signature:

Date:

Patient Reproductive Classification and Acknowledgement of Counseling (To be completed by the prescriber)

For this patient, have you reviewed their current liver function tests? Yes No

If your patient is FEMALE, select the correct female patient category (please see definitions of these terms in the **Bosentan REMS Program Prescriber Guide**):

Female of Reproductive Potential

Female of Non-Reproductive Potential

If this patient is a female of reproductive potential, has a negative pregnancy test been completed prior to prescribing bosentan?

Yes No

Please specify:

Pre-pubertal Female Post-menopausal Female

Female with other medical reasons for permanent, irreversible infertility

For this patient, have you provided counseling on the risks associated with bosentan treatment and the Bosentan REMS Program requirements? Yes No

Prescriber Information (All fields required unless otherwise indicated)

First Name:	MI (opt):	Last Name:
NPI# or DEA#:	City:	
Address:	Zip:	
State:	Ext (opt):	Fax:
Phone:		

Prescriber Signature

By signing below, you attest that the patient indicated on this form 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.

Prescriber Signature:

Date:

Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form

NOTE: THIS FORM SHOULD NOT BE USED TOGETHER WITH THE BOSENTAN REMS PROGRAM PATIENT ENROLLMENT FORM. USE IT ONLY TO REPORT A CHANGE IN REPRODUCTIVE POTENTIAL STATUS OR FOR PRE-PUBERTAL ANNUAL VERIFICATION.

Fax this form to the Bosentan REMS Program at 1-800-730-8231.

Instructions

For **immediate** reporting of changes to a patient's reproductive status, or to provide annual verification that a patient remains pre-pubertal, please go to www.BosentanREMSProgram.com.

The patient's prescriber must use this form to:

1. Report a change or misclassification in reproductive potential status of any female patient within 10 business days of becoming aware of the change
2. Complete the annual verification of the reproductive potential status for patients age 8 years and older

If you have questions, require additional information, or need additional copies of Bosentan REMS Program documents, please visit the program website at www.BosentanREMSProgram.com, or call the Bosentan REMS Program at 1-866-359-2612.

Patient Information (All fields required unless otherwise indicated)

First Name:	MI (opt):	Last Name:	Phone:
Date of Birth (MM/DD/YYYY):		Email Address (opt):	
Address:		City:	
State:	Zip:		

Prescriber Information (All fields required unless otherwise indicated)

First Name:	MI (opt):	Last Name:
NPI# or DEA#:		
Phone:	Fax:	Email Address:

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

Select (by checking the appropriate box) the most appropriate reason for submitting this form

Patient has had a change in reproductive status

Based on definitions of reproductive potential status, patient is (choose one):

- Female of reproductive potential
- Female of non-reproductive potential – Patient is pre-pubertal
- Female of non-reproductive potential – Patient is post-menopausal
- Female of non-reproductive potential – Other medical reasons for permanent, irreversible infertility

Reason for change in classification (choose one):

- Physiological transition
- Medical/surgical (please specify): _____
- Other (please specify): _____

Annual verification of pre-pubertal status

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

Prescriber Signature

By signing below, I attest that the patient's reproductive status as noted above is accurate, and that I will comply with the REMS requirements for my patient's reproductive potential status as defined in the Definitions section above, and the **Bosentan REMS Program Prescriber Guide**

Prescriber
Signature

Date

BACKGROUND

The single shared Bosentan REMS Program was approved by the Food and Drug Administration (FDA) for all bosentan products. In the Bosentan REMS Program:

Patients must be enrolled in the Bosentan REMS Program. Prescribers must complete the *Bosentan REMS Program Patient Enrollment Form* for each patient.

Prescribers must be certified in the Bosentan REMS Program.

Pharmacies must be certified in the Bosentan REMS Program.

Prescriptions require a Pre-dispense Authorization (PDA) from the Bosentan REMS Program before a certified outpatient pharmacy can dispense bosentan. A PDA is verification sent to outpatient and chain pharmacies by the Bosentan REMS Program, authorizing the pharmacy to dispense bosentan to an eligible patient.

STAKEHOLDER

BOSENTAN REMS PROGRAM REQUIREMENTS

OUTPATIENT
PHARMACIES¹

- Designate an authorized representative to oversee the implementation of and compliance with the Bosentan REMS Program
- To become certified, the authorized representative must:
 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:
 - Obtain a pre-dispense authorization
 10. Outpatient pharmacies that support electronic telecommunication verification with the Bosentan REMS Program system must:
 - 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
 - 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:
 - Verify the prescriber is certified and the patient is enrolled
 - 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
 - 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
 - If counseling was not completed, call the Bosentan REMS Program Contact Center to complete the counseling requirement before dispensing bosentan
 - Dispense up to a 30-day supply of bosentan
 - Provide the Medication Guide to the patient every time bosentan is dispensed
 - 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:
 - 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*

	<p>to:</p> <ul style="list-style-type: none"> • Verify the prescriber is certified and the patient is enrolled • 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 • 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 <ul style="list-style-type: none"> ○ If counseling was not completed, call the Bosentan REMS Program Contact Center to complete the counseling requirement before dispensing bosentan ○ Dispense up to a 30-day supply of bosentan ○ Provide the patient the Medication Guide every time bosentan is dispensed ○ Not transfer bosentan to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program
<p>CHAIN PHARMACIESⁱⁱ</p>	<ul style="list-style-type: none"> • Designate an authorized representative to oversee the implementation of and compliance with the Bosentan REMS Program • To become certified the authorized representative must: <ol style="list-style-type: none"> 1. Complete and sign the <i>Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form</i> on behalf of the pharmacy, and submit the form to the Bosentan REMS Program 2. Comply with requirements #2 through #10 in the Outpatient Pharmacies section above 3. Once the <i>Bosentan REMS Program Chain Pharmacy Headquarters Enrollment Form</i> has been processed, the authorized representative will receive instructions on submitting test transactions to the Bosentan REMS Program to ensure that the pharmacy management system has been successfully configured/updated to communicate with the Bosentan REMS Program 4. After successful completion of the test transactions, the authorized representative will receive a pharmacy certification confirmation. Upon receipt, the chain pharmacy headquarters is certified and dispensing locations are now eligible to complete their training 5. Once each dispensing location is trained, the authorized representative must report confirmation of training to the Bosentan REMS Program online through www.BosentanREMSProgram.com, or by calling 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
<p>INPATIENT PHARMACIESⁱⁱⁱ</p>	<ul style="list-style-type: none"> • Designate an authorized representative to oversee the implementation of and compliance with the Bosentan REMS Program • To become certified the authorized representative must: <ol style="list-style-type: none"> 1. Complete and sign the <i>Bosentan REMS Program Inpatient Pharmacy Enrollment Form</i> on behalf of the pharmacy, and submit the form to the Bosentan REMS Program 2. Review the <i>Bosentan REMS Program Pharmacy Guide</i> 3. Ensure that all pharmacy staff involved in the dispensing of bosentan are trained on the Bosentan REMS Program requirements as described in the <i>Bosentan REMS Program Pharmacy Guide</i> 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: <ul style="list-style-type: none"> ○ Verify the patient is under the supervision and care of a prescriber who is certified ○ Verify the patient is enrolled or will be enrolled prior to discharge ○ 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 <i>Bosentan REMS Program Website</i>, or by accessing the patient's medical records 11. Not transfer bosentan to any pharmacy, practitioner, or any healthcare setting not certified in the

	Bosentan REMS Program
<p>PRESCRIBERS</p>	<ul style="list-style-type: none"> • To become certified to prescribe bosentan, each prescriber must: <ol style="list-style-type: none"> 1. Review the Prescribing Information for bosentan 2. Review the <i>Bosentan REMS Program Prescriber Guide</i> 3. Enroll in the Bosentan REMS Program by completing the <i>Bosentan REMS Program Prescriber Enrollment Form</i> and submitting it to the Bosentan REMS Program 4. Enroll each patient in the Bosentan REMS Program by performing the following: <ul style="list-style-type: none"> ○ 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 <i>Bosentan REMS Program Guide for Patients</i> ○ Determine the reproductive potential status of each female patient as defined in the <i>Bosentan REMS Program Prescriber Guide</i> ○ 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 ○ 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 <i>Bosentan REMS Program Prescriber Guide</i> 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 ○ Complete the <i>Bosentan REMS Program Patient Enrollment Form</i> for each patient and provide a completed copy to the patient. Submit the completed form to the Bosentan REMS Program 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. Perform the following on an ongoing basis for each female patient: Report a change or misclassification in the reproductive status of any female patient by completing the <i>Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i> within 10 business days of becoming aware of the change 8. Perform the following requirements on an ongoing basis for each patient: <ul style="list-style-type: none"> ○ Order and review liver function test results before bosentan treatment initiation and monthly during treatment ○ Counsel patients who fail to comply with program requirements 9. Perform the following monitoring on an ongoing basis for each pre-pubertal female: Evaluate patients age 8 years and older at least annually for any change in reproductive status and complete the <i>Bosentan REMS Program Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i> verifying their reproductive potential status 10. Perform the following monitoring on an ongoing basis for each female patient of reproductive potential: Order and review pregnancy test results before bosentan treatment initiation, monthly during treatment, and for one month following treatment discontinuation
<p>PATIENTS/PARENTS/LEGAL GUARDIANS</p>	<ul style="list-style-type: none"> • Each patient and/or parent/legal guardian must complete and sign the <i>Bosentan REMS Program Patient Enrollment Form</i> with the prescriber to indicate that he/she has: <ol style="list-style-type: none"> 1. Received and has read the <i>Bosentan REMS Program Guide for Patients</i> 2. Received counseling from the prescriber regarding: <ul style="list-style-type: none"> ○ 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 ○ the need to complete liver function testing and, as appropriate, pregnancy testing, as outlined in the <i>Bosentan REMS Program Guide for Patients</i> ○ contact by the Bosentan REMS Program prior to each dispense of bosentan to obtain confirmation that liver function tests and, as appropriate, pregnancy test were completed and provide counseling

BOSENTAN REMS PROGRAM PDA SCENARIOS FOR PHARMACIES	PDA ISSUED*
Pharmacy is certified, prescriber is certified, patient is enrolled, patient has completed the required test(s), and current appropriate counseling is confirmed	
Patient liver function test is not on file, but later confirmed to have taken place If patient does not have a current completed liver function test confirmed with the Bosentan REMS Program, a PDA will not be issued. The pharmacy can contact the Bosentan REMS Program to notify the patient or patient's prescriber that a liver function test is required. The Bosentan REMS Program Contact Center will update completion of testing for the patient.	
Pregnancy test for a female of reproductive potential is not on file, but later confirmed to have taken place If patient does not have a current completed pregnancy test confirmed with the Bosentan REMS Program, a PDA will not be issued. The pharmacy can contact the Bosentan REMS Program to notify the patient or patient's prescriber that a pregnancy test is required. The Bosentan REMS Program Contact Center will update completion of testing for the patient.	
Confirmation of counseling is not on file If all safe use conditions are met but the patient does not have current appropriate counseling confirmed with the Bosentan REMS Program, a PDA will be issued by the Bosentan REMS Program, with a message instructing the pharmacist or patient to call the Bosentan REMS Program Contact Center to complete the counseling requirement.	
Pharmacy is not certified If a pharmacy is not certified in the Bosentan REMS Program, a PDA will not be issued.	
Prescriber is not certified If a prescriber is not certified in the Bosentan REMS Program, a PDA will not be issued.	
Patient is not enrolled If a patient is not enrolled in the Bosentan REMS Program, a PDA will not be issued.	
Patient liver function test is not confirmed If a patient does not have a current completed liver function test confirmed with the Bosentan REMS Program, a PDA will not be issued.	
Pregnancy test for females of reproductive potential is not confirmed If a female of reproductive potential does not have a current pregnancy test confirmed with the Bosentan REMS Program, a PDA will not be issued.	

*A green checkmark indicates approval to dispense bosentan to the patient. A red "X" indicates safe use conditions have not been met and bosentan should not be dispensed to the patient.

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

ⁱⁱ 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.

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

Instructions for Prescribers

This optional form may be used to confirm the completion of both liver function and pregnancy tests on a single form. Completion of required tests and patient counseling must be confirmed with the Bosentan REMS Program for bosentan to be dispensed to your patient.

- This form may be completed online at www.BosentanREMSProgram.com or by calling the Bosentan REMS Program Contact Center at 1-866-359-2612
- Your patient will not receive a call from the Bosentan REMS Program during a given month if you have already confirmed completion of tests and counseling for that month
- If this form is not submitted, your patient will receive a call from the Bosentan REMS Program each month during treatment to confirm completion of required tests and counseling on the risks associated with treatment with bosentan

To submit this form via fax, please complete all required fields below and fax to 1-800-730-8231. You will receive a confirmation via the contact preference you identified when you completed the **Bosentan REMS Program Prescriber Enrollment Form**.

Use this form to:

1. Report that a patient has been counseled on the risk of hepatotoxicity
2. Report pretreatment and monthly liver function test completion for a patient in the Bosentan REMS Program
3. Report that a female of reproductive potential (as defined in the **Bosentan REMS Program Prescriber Guide**) has been counseled on the risk of embryo-fetal toxicity and the need to use reliable contraception
4. Report pretreatment and monthly pregnancy test completion for a female of reproductive potential in the Bosentan REMS Program

If you have questions, require additional information, or need additional copies of Bosentan REMS Program documents, please visit the program website at www.BosentanREMSProgram.com, or call the Bosentan REMS Program at 1-866-359-2612.

Prescriber Information (All fields required)

First Name:	Last Name:	NPI# or DEA#:
Phone:	Fax:	Email Address:

Patient Information (All fields required)

First Name:	Last Name:	
Date of Birth (MM/DD/YYYY):	Zip Code:	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female
Is this patient a Female of Reproductive Potential? (as defined in the Bosentan REMS Program Prescriber Guide) <input type="checkbox"/> Yes <input type="checkbox"/> No		

Confirm Liver Function Test Completed

Complete this section to confirm the completion of a liver function test for all patients:

Monthly liver function test has been completed
By checking the above box, you attest that a liver function test has been completed for the patient indicated on this form

Date of Test (MM/DD/YYYY) _____

Confirm Pregnancy Test Completed

Complete this section to confirm the completion of a pregnancy test only for a patient who is a female of reproductive potential:

Monthly pregnancy test has been completed
By checking the above box, you attest that a pregnancy test has been completed for the patient indicated on this form

Date of Test (MM/DD/YYYY) _____

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

Signature:	Date:
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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

Important Program Updates

[Prescribing Information](#) | [Medication Guides](#)

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

Prescribers | Pharmacies | Patients | Pharmacy Lookup | FAQs

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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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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1.4.2 Pharmacy Landing Page: Chain Pharmacy

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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**

Bosentan_Website_Screen_Captures

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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

Bosentan
REMS Program

Sign in

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

Prescribers
Pharmacies
Patients
Pharmacy Lookup
FAQs

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

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](#)

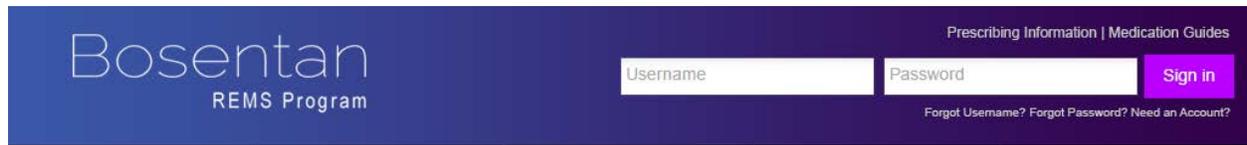
Materials for Pharmacies

-  [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



Pharmacy Staff

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

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username Password [Sign in](#)

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

[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?](#)

Prescribers
Pharmacies
Patients
Pharmacy Lookup
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.

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

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

Prescribing Information | Medication Guides

Username Password [Sign in](#)

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

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

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

Username Password [Sign in](#)

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

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

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](#)

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

[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.](#)

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

1.10 Pharmacy Lookup Results

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username Password [Sign in](#)

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

[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, displaying a list of five questions, each with a blue minus sign icon and the text '<Question>'. The first question is expanded, showing a blue plus sign 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

Username Password [Sign in](#)

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

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

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.](#)

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

2.5 Change Username

Prescribing Information | Medication Guides

Bosentan
REMS Program

Username  My Dashboard

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](#)

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="password"/>
New Password	<input type="password"/>
Confirm New Password	<input type="password"/>

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

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

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.

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

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

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	<input type="text"/>	MI (Optional)	<input type="text"/>
Last Name	<input type="text"/>		
Email	<input type="text"/>		
Confirm Email Address	<input type="text"/>		
Professional Designation	-- Please Select -- 		
Medical Specialty	-- Please Select -- 		
Clinic / Practice Name	<input type="text"/>		
Address	<input type="text"/>		
City	<input type="text"/>		
State	-- Please Select -- 	Zip	<input type="text"/>
Phone	<input type="text"/>	Ext (Optional)	<input type="text"/>
Fax	<input type="text"/>		
Preferred Method of Contact	-- Please Select -- 		

Prescriber Identifiers

DEA Number	<input type="text"/>
NPI Number	<input type="text"/>

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

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

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.

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3.5 Prescriber Confirmation Page

Bosentan
REMS Program

Prescribing Information | Medication Guides

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

Bosentan
REMS Program

Prescribing Information | Medication Guides

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 shows the Bosentan REMS Program website with 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.

Buttons: **Cancel** (white with purple border), **Confirm** (purple)

Background text (partially obscured):

- 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 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.

Buttons: **Continue** (purple)

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

Page-Footer: [Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

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 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 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 selecting a role:

- Authorized Representative of a Specialty Pharmacy** - For the purposes of this REMS specialty pharmacies include but are not limited to retail, pharmacies in hospitals, hospices, long-term care facilities, and prisons. 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.

Buttons:

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

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4.1.4 Authorized Representative Role Selection: Inpatient Pharmacy

The screenshot shows 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' and contains a form with radio buttons for selecting a role. A modal dialog box is overlaid on the form, titled 'Authorized Representative of an Inpatient Pharmacy'. The dialog box contains the following text: 'Based on the response selected, please confirm you are certifying for an Inpatient Pharmacy'. Below this, it explains that inpatient pharmacies include hospitals, hospices, long-term care facilities, and prisons, and that an authorized representative is responsible for ensuring certification, training, and audit readiness. It also provides instructions to press 'Cancel' if the pharmacy does not meet the definition or 'Confirm' to continue. At the bottom of the dialog box are 'Cancel' and 'Confirm' buttons. The background form shows a 'Continue' button and a footer with contact information.

Prescribing Information | Medication Guides

Username Password Sign in

Forgot Username? Forgot Password? Need an Account?

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

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

Please select the role you are certifying for:

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

Authorized Representative of a Pharmacy with Multiple Locations - For the purposes of this REMS pharmacies with multiple locations include but are not limited to retail, pharmacies in hospitals, hospices, long-term care facilities, and prisons. An authorized representative of a pharmacy with multiple locations is responsible for ensuring certification of the pharmacy location, training of the pharmacy staff, and audit readiness.

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.

Cancel Confirm

Continue

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

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.

4.3 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, directing users to click 'Certify Pharmacy' if ready to certify, use the 'My Dashboard' button to return to the dashboard, or close their browser if the session is complete. A purple link provides 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 -- Please Select -- Zip

Phone Fax

Pharmacy Identifiers

DEA

NPI

NCPDP

Can your pharmacy management system adjudicate claims online?
 -- Please Select --

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.

Contact Us
Privacy Policy
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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

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

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

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

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 REMS Program logo on the left and links for 'Prescribing Information | Medication Guides', 'Username', and 'My Dashboard' on the right. Below the navigation bar is a menu with five tabs: 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. A progress indicator below the menu shows three steps: '1 INTAKE', '2 ATTESTATION', and '3 CONFIRMATION', with the third step being active. The main content area is titled 'Pharmacy Certification Confirmation'. It features a green checkmark icon and a message: 'Your pharmacy is now certified in the Bosentan REMS Program.' Below this, there is a callout box with 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.' Below the callout box, the 'IVR Access ID' is displayed as '12341234'. A printer icon is located below the IVR Access ID. At the bottom of the main content area, there is a note: 'To add additional pharmacies or manage your pharmacies, please use the My Dashboard button at the top of the page.' Below the main content area, there is a purple link: 'For additional information about the Bosentan REMS Program, please call 1-866-359-2612.' At the very bottom, there is a footer 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

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Pharmacy Certification Confirmation

Your pharmacy is now certified 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.

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.

Contact Us | Privacy Policy | Terms and Conditions | 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.

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

4.12 Chain 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 'My Dashboard' 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 features a central message box with a green checkmark icon. The message states: '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.' Below this message, the 'IVR Access ID' is displayed as '12341234'. A call to action instructs the user to 'Certify Chain Headquarter Pharmacy' if ready, and to close the browser if the session is complete. A purple link provides 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'.

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

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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

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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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

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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 shows the Bosentan REMS Program interface. At the top, there is a dark blue header with the Bosentan logo and 'REMS Program' on the left, and 'Prescribing Information | Medication Guides' on the right. Below the header is a navigation bar with tabs for 'Prescribers', 'Pharmacies', 'Patients', 'Pharmacy Lookup', and 'FAQs'. The 'Pharmacies' tab is selected. The main content area is titled 'Chain Pharmacy Dispensing Location Confirmation'. It features a green success message in a box: 'The pharmacy dispensing location has been successfully added.' Below this message, there is a text prompt: 'To add another pharmacy dispensing location, please use the **Add Pharmacy Dispensing Location** button below.' A purple button labeled 'Add Pharmacy Dispensing Location' is centered below the text. 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 contains 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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Pharmacies
Patients
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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.

4.19 Pharmacy Staff Search with No Results

Bosentan
REMS Program

Prescribers Pharmacies Patients Support 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		
<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

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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

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.

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Bosentan_Website_Screen_Captures

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4.20 Pharmacy Staff Intake Page

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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

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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

[Back](#)

[Submit](#)

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

4.22 Pharmacy Staff Confirmation Page

Bosentan
REMS Program

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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 for your records.

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



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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Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

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

Prescribing Information | Medication Guides

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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

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

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

Prescribing Information | Medication Guides

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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

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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

Prescribing Information | Medication Guides

Username My 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.

First Name	MI	Last Name	DOB	Enrollment Status	Actions						
Giacomo	P	Gullizzoni	04/21/2007	Enrolled	Please Select <ul style="list-style-type: none"> Add Patient Tests & Counseling View Patient Profile Change Patient Reproductive Status Update Annual Verification Refill Dispense Exception 						
<p>Enrollment ID: PAT 989999 Gender: Female Patient Reproductive Classification: Female Non- Reproductive Potential, Pre-pubertal Female Relationship Status: Active</p> <table border="1"> <thead> <tr> <th>Liver Test</th> <th>Pregnancy Test</th> <th>Monthly Counseling</th> </tr> </thead> <tbody> <tr> <td>11/21/2016</td> <td>N/A</td> <td><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	Please Select						

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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6.2 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

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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' text. To the right, there are links for 'Prescribing Information | Medication Guides', 'Username', and a 'My Dashboard' button. Below the navigation bar is a 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 Complete...', and 'Travel Outside of the United States...'. A purple popup window titled 'Refill Dispense Exception Confirmation' is overlaid on the page, displaying the message: 'The exception has been approved for one (1) dispense to occur within the next 45 days.' with an 'OK' button. Below the popup, 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 the patient information section, there is a disclaimer and two buttons: 'Cancel' and 'Submit'. At the very bottom of the page, there is a footer with the text: 'For additional information about the Bosentan REMS Program, please call 1-866-359-2612.' and a navigation 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.

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6.7 Prescriber Dashboard: Patient Test and Counseling

Bosentan
REMS Program

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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

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 completion of required tests and patient counseling must be confirmed with the Bosentan REMS Program.

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 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 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

Patient Testing and Counseling Confirmation

You are confirming the following:

- Liver Test
- Pregnancy Test
- Counseling

The patient must be counseled on the risks of hepatotoxicity and embryo-fetal toxicity as appropriate for the reproductive potential status.

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

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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	<ul style="list-style-type: none"> -- 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.

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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	FAC100000000	Certified	Please Select Go
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Outpatient	FAC100000001	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.

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

6.12 Pharmacy Dashboard: Chain Pharmacy Headquarters

Bosentan
Prescribing Information | Medication Guides

Username

My Dashboard

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; gap: 5px;"> <div style="border: 1px solid #ccc; padding: 2px;">Please Select ▼</div> <div style="background-color: #7f8c8d; color: white; padding: 2px 5px;">Go</div> </div> <div style="background-color: #2c3e50; color: white; padding: 2px 5px; margin-top: 2px;">View Pharmacy Profile</div>
XYZ Rx	123 West Pharmacy Lane Phoenix AZ 85008	FAC100000123	Incomplete	<div style="display: flex; gap: 5px;"> <div style="border: 1px solid #ccc; padding: 2px;">Please Select ▼</div> <div style="background-color: #7f8c8d; color: white; padding: 2px 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.

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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

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 Go </div> <div style="border: none; padding: 2px;"> Request Pre-dispense Authorization Reverse Pre-dispense Authorization Disassociate from Pharmacy </div>
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

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[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, along with links for 'Prescribing Information | Medication Guides', 'Username', and 'My Dashboard'. Below this is a horizontal menu 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, displaying 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 pharmacy entries: 'ABC Pharmacy' and 'XYZ Pharmacy'. The 'XYZ Pharmacy' entry includes details: '15 East Prescription Street Phoenix AZ 85008', 'Outpatient', and 'Certified'. There are also search and filter controls on the right side of the table.

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.

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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?

Yes

My Certification

Certification ID: **FAC123112312**

Cancel Save

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

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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.

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

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

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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](#)

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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

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[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.](#)

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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

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

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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

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

Pre-dispense Authorization

To determine if the patient is eligible for the program, please complete the pre-dispense authorization information below and select the appropriate response. 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

All fields listed below are required.

Patient Info

Date of Birth Zip Code

Pre-dispense Authorization Request

Date of Fill

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

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

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

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

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

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

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

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

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

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



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

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

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

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 ▼

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

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  [My Dashboard](#)

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

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 menu with '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

Bosentan
REMS Program

Prescribing Information | Medication Guides

Username  My Dashboard

Prescribers Pharmacies Patients Pharmacy Lookup FAQs

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.

Instructions

For immediate enrollment, please go to www.BosentanREMSProgram.com.

To submit this form via fax or mail, please complete all required fields below and fax to 1-800-730-8231 or mail to the Bosentan REMS Program, P.O. Box 29080, Phoenix, AZ 85038. You will receive a confirmation via the contact preference you list below.

If you have questions, require additional information, or need additional copies of Bosentan REMS Program documents, please visit the program website at www.BosentanREMSProgram.com, or call the Bosentan REMS Program at 1-866-359-2612.

Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to oversee implementation of and compliance with the Bosentan REMS Program. I attest to understanding the Bosentan REMS Program requirements, and accept responsibility to:

1. Complete and sign this **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 PDA 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

Continued on the following page.

Pharmacy Management System Information (Select one)

Can your outpatient pharmacy management system adjudicate claims online?

Yes By selecting "Yes," you are confirming that your pharmacy management system CAN support electronic (online) telecommunication verification with the Bosentan REMS Program using established telecommunications standards. Bosentan will be dispensed only after obtaining a PDA for all bosentan prescriptions, including cash claims, through your pharmacy management system. After submitting this form, you will receive instructions through the contact preference indicated in the authorized representative information section on how to submit test transactions to the Bosentan REMS Program. This is to ensure that your pharmacy management system has been successfully configured to allow for communication with the Bosentan REMS Program.

No By selecting "No," you are confirming that your pharmacy management system cannot support electronic (online) telecommunication verification with the Bosentan REMS Program and you will access the **Bosentan REMS Program Website** at www.BosentanREMSProgram.com or call the Bosentan REMS Program Contact Center at 1-866-359-2612 to obtain a PDA before dispensing each bosentan prescription. A complete PDA request requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.

Pharmacy Information (All fields required)

Pharmacy Name:

Pharmacy Identifiers: NCPDP: NPI: DEA:

Address: City:

State: Zip:

Phone: Fax:

Authorized Representative Information (All fields required)

First Name: Last Name:

Credentials: R.Ph PharmD BCPS Other

Phone: Fax: Email:

Preferred method of contact: Fax Email

Authorized Representative Signature

By signing below, you signify your understanding of the risks of bosentan treatment, your obligations as a pharmacy certified in the Bosentan REMS Program as outlined above, and you agree to oversee the implementation of and compliance with the Bosentan REMS Program requirements for this pharmacy.

Signature:

Date:

Please fax all pages of this form to the Bosentan REMS Program Contact Center at 1-800-730-8231 or mail them to P.O. Box 29080, Phoenix, AZ 85038.

Instructions

For [immediate enrollment](http://www.BosentanREMSProgram.com), please go to www.BosentanREMSProgram.com.

To submit this form via fax or mail, please complete all required fields below and fax to 1-800-730-8231 or mail to the Bosentan REMS Program, P.O. Box 29080, Phoenix, AZ 85038. You will receive a confirmation via the contact preference you list below.

If you have questions, require additional information, or need additional copies of Bosentan REMS Program documents, please visit the program website at www.BosentanREMSProgram.com, or call the Bosentan REMS Program at 1-866-359-2612.

Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to oversee implementation of and compliance with the Bosentan REMS Program. I attest to understanding the Bosentan REMS Program requirements, and accept responsibility to:

1. Complete and sign this ***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

Chain Pharmacy Headquarters Information (All fields required)

Pharmacy Name:

Chain ID:

Address:

City:

State:

Zip:

Phone:

Fax

Authorized Representative Information (All fields required)

First Name:

Last Name:

Credentials:

R.Ph

PharmD

BCPS

Other

Phone:

Fax:

Email:

Preferred method of contact: Fax Email

Continued on the following page.

Authorized Representative Signature

By signing below, you signify your understanding of the risks of bosentan treatment, your obligations as a pharmacy certified in the Bosentan REMS Program as outlined above, and you agree to oversee the implementation of and compliance with the Bosentan REMS Program requirements for this pharmacy.

Signature:

Date:

Next Steps

1. After completing and signing this form, please fax to 1-800-730-8231 or mail to the Bosentan REMS Program, P.O. Box 29080, Phoenix, AZ 85038
2. Once this form is processed, you will receive instructions on submitting test transactions to the Bosentan REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Bosentan REMS Program
3. After successful completion of the test transactions, you will receive a pharmacy certification confirmation. Upon receipt, your chain pharmacy headquarters is certified and your dispensing locations are now eligible to complete their training
4. Once each dispensing location is trained, it is your responsibility to report confirmation of training to the Bosentan REMS Program online through www.BosentanREMSProgram.com, or by calling 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

Please fax all pages of this form to the Bosentan REMS Program Contact Center at 1-800-730-8231 or mail them to
P.O. Box 29080, Phoenix, AZ 85038

Bosentan

REMS Program

Pharmacy Guide

The Bosentan **R**isk **E**valuation and **M**itigation **S**trategy (REMS) Program is a single shared program for brand and generic bosentan medication 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.

This guide contains important information for pharmacies about the risks of bosentan, including boxed warnings for hepatotoxicity and embryo-fetal toxicity, and includes:

- Authorized Representatives and Pharmacy Certification Information
- Pre-Dispense Authorization (PDA) for Dispensing Bosentan
- Outpatient and Chain Pharmacies' Role in the Bosentan REMS Program: Step by Step
- Inpatient Pharmacies' Role in the Bosentan REMS Program: Step by Step
- Counseling and Contraception for Females of Reproduction Potential

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About Bosentan

Tracleer® is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1):

- in adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%).
- in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Bosentan is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1):

- in adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%).

Risk of Hepatotoxicity

Bosentan may cause liver damage. Liver function monitoring is essential prior to initiation of treatment and monthly thereafter. It is important to adhere strictly to the monthly monitoring schedule for the duration of treatment.

Changes in aminotransferases may occur early or late in treatment. There have been rare postmarketing reports of liver failure and unexplained hepatic cirrhosis in a setting of close monitoring; the contribution of bosentan could not be excluded.

Elevations in aminotransferases require close attention. If elevated aminotransferase levels are seen, changes in monitoring and treatment must be initiated. Use of bosentan should generally be avoided in patients with elevated aminotransferases ($>3 \times$ ULN) **at baseline** because monitoring for hepatotoxicity may be more difficult.

Risk of Embryo-fetal Toxicity

Bosentan is contraindicated in females who are or may become pregnant and may cause fetal harm when administered to a pregnant woman. Animal studies have shown that bosentan is likely to cause major birth defects when administered during pregnancy. If bosentan is used during pregnancy, apprise the patient of the potential hazard to a fetus. To prevent pregnancy, females of reproductive potential must use reliable contraception prior to beginning treatment with bosentan, during treatment and for one month after ending bosentan treatment. Patients must not become pregnant while taking bosentan.

What is the Bosentan REMS Program?

Due to the risks of hepatotoxicity and embryo-fetal toxicity, bosentan is only available through a single shared system required and approved by the Food and Drug Administration (FDA), called the Bosentan REMS Program. The Bosentan REMS Program is a shared program including all brand and generic bosentan products.

The goal of the Bosentan REMS Program is to mitigate the risk of hepatotoxicity and embryo-fetal toxicity associated with bosentan by:

- Ensuring prescribers are educated on the following:
 - the risks of hepatotoxicity and embryo-fetal toxicity
- Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Bosentan REMS Program
 - monitoring patients at baseline and monthly
- Ensuring that pharmacies are educated on the following:
 - the risks of hepatotoxicity and embryo-fetal toxicity
- Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing bosentan
- Ensuring that patients are informed about:
 - the risks of hepatotoxicity and embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

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

<u>Pharmacy Type</u>	<u>Definition</u>
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.

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
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (pre-menarchal)

▪ 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**

Authorized Representatives and Pharmacy Certification

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 Service

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

Specific duties of an outpatient pharmacy authorized representative are referenced on [page 9](#)

Specific duties of a chain pharmacy authorized representative are referenced on [page 11](#)

Specific duties of an inpatient pharmacy authorized representative are referenced on [page 13](#)

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

Pre-Dispense Authorization (PDA) for Dispensing Bosentan for Outpatient Pharmacies

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 dispense of bosentan 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
 - If counseling is not confirmed, call the Bosentan REMS Program Contact Center to complete the counseling requirement before dispensing bosentan
- Current embryo-fetal toxicity counseling for each female of reproductive potential is confirmed
 - If counseling is not confirmed, call the Bosentan REMS Program Contact Center to receive complete the counseling requirement before dispensing bosentan

To verify the safe use conditions in the Bosentan REMS Program, chain and outpatient pharmacies must submit the following prescription information, at a minimum:

- Patient First Name
- Patient Last Name
- Patient Date of Birth
- Patient Zip Code
- Prescriber Identifier (e.g. DEA or NPI)
- Date of Fill
- Days' Supply
- Quantity
- Product / NDC

Once a PDA is obtained, the chain or outpatient pharmacy can dispense bosentan to the patient.

A PDA must be reversed if bosentan is not dispensed to the patient.

- If your outpatient pharmacy supports electronic telecommunication verification with the Bosentan REMS Program system, your pharmacy must process reverse the 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 reverse the PDA by calling the Bosentan REMS Program Contact Center or accessing the ***Bosentan REMS Program Website***

A prescriber may authorize a refill dispense exception.

A refill dispense exception allows 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:** The prescriber attests 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:** The prescriber attests 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

If upon patient consult with the prescriber, the prescriber chooses to continue the patient on bosentan, a refill dispense exception must be provided to the Bosentan REMS Program from the prescriber.

After the prescriber provides the refill dispense exception, the Bosentan REMS Program will issue a PDA which allows your outpatient pharmacy to dispense bosentan to the patient.

Outpatient Pharmacies' Role in the Bosentan REMS Program: Step by Step

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

1. **READ the Prescribing Information for bosentan and Medication Guide and this 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 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 form online or download paper copies from the *Bosentan REMS Program Website* at www.BosentanREMSProgram.com and fax the form to the Bosentan REMS Program at 1-800-730-8231
 - If your outpatient pharmacy supports electronic telecommunication verification with the Bosentan REMS Program system, during the enrollment process your authorized representative will be instructed to verify the PDA is operational using established telecommunication standards, and by running the standardized validation test transactions to validate the system enhancements
3. **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 pharmacy staff 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
4. **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 for each patient prior to dispensing bosentan**
 - Outpatient pharmacies must obtain a 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 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 to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program**
8. **NOTIFY the Bosentan REMS Program of all adverse events including those suggestive of hepatotoxicity**
9. **REPORT any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program**

All Bosentan REMS Program forms can be completed online or downloaded from the website at **www.BosentanREMSProgram.com**. Hard copies can be faxed to the program at 1-800-730-8231. Other information about the Bosentan REMS Program can be found on the ***Bosentan REMS Program Website***. The Bosentan REMS Program Contact Center can be reached at 1-866-359-2612.

Chain Pharmacies' Role in the Bosentan REMS Program: Step by Step

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

1. **READ** the Prescribing information for bosentan and Medication Guide and this 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** 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 form online or download paper copies from the *Bosentan REMS Program Website* at www.BosentanREMSProgram.com 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** 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** 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** 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 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 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 to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program**
8. **NOTIFY the Bosentan REMS Program of all adverse events including those suggestive of hepatotoxicity**
9. **REPORT any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program**

All Bosentan REMS Program forms can be completed online or downloaded from the website at **www.BosentanREMSProgram.com**. Hard copies can be faxed to the program at 1-800-730-8231. Other information about the Bosentan REMS Program can be found on the ***Bosentan REMS Program Website***. The Bosentan REMS Program Contact Center can be reached at 1-866-359-2612.

Inpatient Pharmacies' Role in the Bosentan REMS Program: Step by Step

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

1. **READ** the Prescribing information for bosentan and Medication Guide and this 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 enrolling their pharmacy
2. **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 form online or download paper copies from the *Bosentan REMS Program Website* at www.BosentanREMSProgram.com and fax the form to the Bosentan REMS Program at 1-800-730-8231
3. **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
4. **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** for each patient prior to dispensing bosentan
 - Dispense bosentan to patients only after calling the Bosentan REMS 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
6. **DISPENSE** no more than a 15-day supply of bosentan upon discharge
7. **NOT TRANSFER BOSENTAN** to any pharmacy, practitioner, or any healthcare setting not certified in the Bosentan REMS Program
8. **NOTIFY** the Bosentan REMS Program of all adverse events including those suggestive of hepatotoxicity
9. **REPORT** any pregnancy and all available information during treatment with bosentan to the Bosentan REMS Program

All Bosentan REMS Program forms can be completed online or downloaded from the website at www.BosentanREMSProgram.com. Hard copies can be faxed to the program at 1-800-730-8231. Other information about the Bosentan REMS Program can be found on the ***Bosentan REMS Program Website***. The Bosentan REMS Program Contact Center can be reached at 1-866-359-2612.

Counseling and Contraception for Females of Reproductive Potential

All females of reproductive potential must use reliable contraception during treatment with bosentan and for one month after ending bosentan treatment. Patients should also have monthly contraceptive counseling with either the prescriber or another designated healthcare provider trained in contraceptive counseling. Please refer to the table below for a complete list of acceptable contraceptive methods. A similar table can be found in the ***Bosentan REMS Program Guide for Patients*** and should be used to discuss acceptable birth control options with patients. The patient should be instructed to select one of the options listed below.

Option 1	Option 2	Option 3	Option 4
<p>One method from this list:</p> <p>Standard intrauterine device (Copper T 380A IUD)</p> <p>Intrauterine system (LNg 20 IUS; progesterone IUS)</p> <p>Tubal sterilization</p>	<p>One method from this list:</p> <p>Estrogen and progesterone oral contraceptives ("the pill")</p> <p>Estrogen and progesterone transdermal patch</p> <p>Vaginal ring</p> <p>Progesterone injection</p> <p>Progesterone implant</p> <p>PLUS</p> <p>One Method from this list:</p> <p>Male condom</p> <p>Diaphragm with spermicide</p> <p>Cervical cap with spermicide</p>	<p>One method from this list:</p> <p>Diaphragm with spermicide</p> <p>Cervical cap with spermicide</p> <p>PLUS</p> <p>One Method from this list:</p> <p>Male condom</p>	<p>One method from this list:</p> <p>Partner's vasectomy</p> <p>PLUS</p> <p>One Method from this list:</p> <p>Male condom</p> <p>Diaphragm with spermicide</p> <p>Cervical cap with spermicide</p> <p>Estrogen and progesterone oral contraceptives ("the pill")</p> <p>Estrogen and progesterone transdermal patch</p> <p>Vaginal ring</p> <p>Progesterone injection</p> <p>Progesterone implant</p>

Bosentan

REMS Program

You can reach the Bosentan REMS Program Contact Center by calling toll free 1-866-359-2612. For more information about the Bosentan REMS Program, please visit **www.BosentanREMSProgram.com**.

Please see the Prescribing Information for bosentan, including complete Boxed Warning for hepatotoxicity and embryo-fetal toxicity, and Medication Guides for each approved bosentan product, which can be found at **www.BosentanREMSProgram.com**.

Notify the Bosentan REMS Program of all adverse events, including those suggestive of hepatotoxicity, during treatment with bosentan. Notify the Bosentan REMS Program of any pregnancy and all available information during treatment with bosentan.