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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

Bosentan REMS Program Overview

- All healthcare providers must verify 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 contacted about completing required monitoring testing and counseling.
  - For all patients:
    - Prescriptions must contain all patients' personal information, including name, address, and age, as well as the date of birth and sex, and the name of the prescribing healthcare provider.
    - Prescriptions must contain all patients' personal information, including name, address, and age, as well as the date of birth and sex, and the name of the prescribing healthcare provider.
    - Prescriptions must contain all patients' personal information, including name, address, and age, as well as the date of birth and sex, and the name of the prescribing healthcare provider.
    - Prescriptions must contain all patients' personal information, including name, address, and age, as well as the date of birth and sex, and the name of the prescribing healthcare provider.
  - For all female patients:
    - Prescriptions must contain the reproductive potential status (menopausal or premenopausal) of the patient at the time of the prescription.
    - Prescriptions must contain the reproductive potential status (menopausal or premenopausal) of the patient at the time of the prescription.
    - Prescriptions must contain the reproductive potential status (menopausal or premenopausal) of the patient at the time of the prescription.
    - Prescriptions must contain the reproductive potential status (menopausal or premenopausal) of the patient at the time of the prescription.
  - For all patients:
    - Prescriptions must contain the reproductive potential status (menopausal or premenopausal) of the patient at the time of the prescription.
    - Prescriptions must contain the reproductive potential status (menopausal or premenopausal) of the patient at the time of the prescription.
    - Prescriptions must contain the reproductive potential status (menopausal or premenopausal) of the patient at the time of the prescription.
    - Prescriptions must contain the reproductive potential status (menopausal or premenopausal) of the patient at the time of the prescription.

Bosentan REMS Program Enrollment Requirements

- For patients who are at risk for liver injury:
  - Prescriptions must contain all patients' personal information, including name, address, and age, as well as the date of birth and sex, and the name of the prescribing healthcare provider.
  - Prescriptions must contain all patients' personal information, including name, address, and age, as well as the date of birth and sex, and the name of the prescribing healthcare provider.
  - Prescriptions must contain all patients' personal information, including name, address, and age, as well as the date of birth and sex, and the name of the prescribing healthcare provider.
  - Prescriptions must contain all patients' personal information, including name, address, and age, as well as the date of birth and sex, and the name of the prescribing healthcare provider.

Bosentan REMS Program Enrollment Process

- Patients must enroll in the Bosentan REMS Program prior to receiving bosentan.
  - Patients must enroll in the Bosentan REMS Program prior to receiving bosentan.
  - Patients must enroll in the Bosentan REMS Program prior to receiving bosentan.
  - Patients must enroll in the Bosentan REMS Program prior to receiving bosentan.

For additional information about the Bosentan REMS Program, please call 1-866-350-2612.
1.3 Prescriber Landing Page

Bosentan REMS Program

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 menstruation
  - Counsel the patient and/or a parent/legal guardian to immediately use reliable contraception if she becomes aware of the change
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 1-800-730-8311, 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 1-800-730-8311
    - 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 ≥2 x 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 1-800-730-8311
    - 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 hepatoxicity

9. REPORT

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

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:

<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient Pharmacy</td>
<td>For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.</td>
</tr>
<tr>
<td>Chain Pharmacy</td>
<td>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.</td>
</tr>
<tr>
<td>Inpatient Pharmacy</td>
<td>For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.</td>
</tr>
</tbody>
</table>

To become certified, pharmacies must designate an authorized representative to compete 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
- Completes 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 re-certify 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

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.
1.4.1 Pharmacy Landing Page: Outpatient Pharmacy

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.

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

<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient Pharmacy</td>
<td>For the purposes of this REMS, outpatient pharmacies include but are not limited to retail, specialty, mail-order, and closed system pharmacies.</td>
</tr>
<tr>
<td>Chain Pharmacy</td>
<td>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.</td>
</tr>
<tr>
<td>Inpatient Pharmacy</td>
<td>For the purposes of this REMS, inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.</td>
</tr>
</tbody>
</table>

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 all activities required for the pharmacy and/or pharmacy staff in the Bosentan REMS Program.
- Establishes and maintains 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.
- Other activities as required by the Bosentan REMS Program.

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

Becoming your pharmacy type below for more information.

---

OUTPATIENT PHARMACY

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

1. READ

READ the prescribing information for bosentan and the REMS Program 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 of the hospital or pharmacy acknowledges they understand 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 forms and fax them to the Bosentan REMS Program at 1-800-720-5231.
- If your outpatient pharmacy supports electronic verification with the Bosentan REMS Program system, the enrollment process will be instructed to verify the pre-dispense authorization (PDA).

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 employees 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.

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

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:

<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient Pharmacy</td>
<td>For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and closed system pharmacies.</td>
</tr>
<tr>
<td>Chain Pharmacy</td>
<td>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.</td>
</tr>
<tr>
<td>Inpatient Pharmacy</td>
<td>For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.</td>
</tr>
</tbody>
</table>

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 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.
- Completes 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 recently 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:

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 1-600-730-5321
- Ensures the pharmacy enables its pharmacy management system to support communication with the Bosentan REMS Program system, using established telecommunication standards, and runs the standardized validation test transactions to validate the system enhancements

3. TRAIN

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

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

DOCUMENT all staff training

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

5. VERIFY SAFE USE CONDITIONS

VERIFY SAFE USE CONDITIONS for each patient prior to dispensing bosentan

- Chain pharmacies must dispense bosentan to patients only after obtaining a pre-dispense authorization (PDA) by processing the prescription including cash claims through their pharmacy management system.
  - If a PDA is not issued, prior to dispensing bosentan the pharmacy may perform the corresponding activity to address the reasons that a PDA was not issued.
  - Confirm 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

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

Pharmacy staff must enroll in the Bosentan REMS Program to obtain a Prescriber Authorization (FDA) 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:

<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient Pharmacy</td>
<td>For the purposes of this REMS outpatient pharmacies include but are not limited to retail, specialty, mail order, and chain system pharmacies.</td>
</tr>
<tr>
<td>Chain Pharmacy</td>
<td>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.</td>
</tr>
<tr>
<td>Inpatient Pharmacy</td>
<td>For the purposes of this REMS inpatient pharmacies include but are not limited to pharmacies in hospitals, hospices, long-term care facilities, and prisons.</td>
</tr>
</tbody>
</table>

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 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 of all processes and procedures in place and being followed for the Bosentan REMS Program and provides upon request to the Bosentan Sponsors, or a third party acting on their behalf.
- Completes audits of the Bosentan Sponsors or a third party acting on behalf of the Bosentan Sponsors to ensure all processes and procedures are in place and being followed for the Bosentan REMS Program.

Note: Pharmacies must recently 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:

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 affirms understanding the risks of bosentan and agrees to comply with the Bosentan REMS Program.
- The authorized representative can complete the enrollment forms online or download the form here and fax the form to the Bosentan REMS Program at 1-800-730-0231.

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 for:
  - 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

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 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

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

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](#).

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
1.6 Prescribing Information for bosentan and Medication Guides

<table>
<thead>
<tr>
<th>Prescribing Information for bosentan and Medication Guides</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name Products</td>
</tr>
<tr>
<td>Trade Name</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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</tbody>
</table>

<table>
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<tr>
<th>Generic Products</th>
</tr>
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<td>-------------</td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

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@FDA website.

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

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

#### Prescribers
- Prescriber Home Page
- Prescriber FAQs
- Patient Enrollment
- Patient Management FAQs

#### General
- Contact Us
- General FAQs
- Prescribing Information for bosentan
- Privacy Policy
- Transition FAQs
- Terms and Conditions
- Pharmacy Lookup

#### Pharmacies
- Pharmacy Home Page
- Pharmacy Staff Home Page
- Pharmacy FAQs

#### Patients
- Patient Home Page

---

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

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

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 [5] miles of your location.

or

City

State

and

or

DEA

NPI

NCPDP

or

or

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

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:

- Zip Code:
  Please enter your zip code to find a certified pharmacy within a 5-mile radius of your location.

- City

- State

- DEA

- NPI

- NCPDP

Search

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Pharmacy Address</th>
<th>Pharmacy Phone</th>
<th>Pharmacy Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uptown Drugs</td>
<td>5220 N Roxie Drive DURH</td>
<td>915-335-7325</td>
<td>Outpatient</td>
</tr>
</tbody>
</table>

Showing 1 to 1 of 1 entries

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

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

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

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

Password
Confirm Password

☐ I'm not a robot

Submit
Cancel

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

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.
2.3 Forgot Username

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.
2.4 Forgot Password

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.
2.5 Change Username

Change Username

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

Username

Use Email Address as Username

Suggest Username

Cancel
Save

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

Change Password

To change your password, please complete the fields below.

Current Password
New Password
Confirm New Password

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
## 2.7 Edit Prescriber Profile

![Prescriber Profile Form](image)

### My Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>John</td>
</tr>
<tr>
<td>Last Name</td>
<td>Doe</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:john.doe@email.com">john.doe@email.com</a></td>
</tr>
<tr>
<td>Professional Designation</td>
<td>MD</td>
</tr>
<tr>
<td>Medical Specialty</td>
<td>Cardiology</td>
</tr>
<tr>
<td>Clinic / Practice Name (Optional)</td>
<td>Good Health Clinic</td>
</tr>
<tr>
<td>Address</td>
<td>1 Main Street</td>
</tr>
<tr>
<td>City</td>
<td>New York</td>
</tr>
<tr>
<td>State</td>
<td>New York</td>
</tr>
<tr>
<td>Zip</td>
<td>10001</td>
</tr>
<tr>
<td>Phone</td>
<td>650-555-0555</td>
</tr>
<tr>
<td>Fax</td>
<td>655-555-0000</td>
</tr>
<tr>
<td>Preferred Method of Contact</td>
<td>Email</td>
</tr>
</tbody>
</table>

### Prescriber Identifiers

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA</td>
<td>A823423412</td>
</tr>
<tr>
<td>NPI</td>
<td>23423423423</td>
</tr>
</tbody>
</table>

### My Certification

**Certification ID:** HCP123112312

---

For additional information about the Bosentan REMS Program, please call 1-866-359-2512.
2.8 Edit Authorized Representative Profile

My Profile

My Information

<table>
<thead>
<tr>
<th>First Name</th>
<th>John</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Name</td>
<td>Doe</td>
</tr>
<tr>
<td>Email Address</td>
<td><a href="mailto:email@email.com">email@email.com</a></td>
</tr>
<tr>
<td>Credentials</td>
<td>PharmaD</td>
</tr>
<tr>
<td>Phone</td>
<td>555-055-5555</td>
</tr>
<tr>
<td>Fax</td>
<td>555-555-0000</td>
</tr>
<tr>
<td>Preferred Method of Contact</td>
<td>Email</td>
</tr>
</tbody>
</table>

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
2.9 Edit Pharmacy Staff Profile

My Profile

My Information

- **First Name:** John
- **Last Name:** Doe
- **Email Address:** jDoe@gmail.com
- **Phone:** 555-555-5555
- **Fax:** 555-555-3434
- **Preferred Method of Contact:** Email

My Enrollment

**Enrollment ID:** HCP22200088

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

3.1 Prescriber Search with Results

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):

<table>
<thead>
<tr>
<th>Identifiers</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI Number</td>
<td>DEA Number</td>
</tr>
<tr>
<td>or</td>
<td></td>
</tr>
<tr>
<td>First Name</td>
<td>Last Name</td>
</tr>
<tr>
<td>Phone</td>
<td>Fax</td>
</tr>
<tr>
<td>Certification ID (Optional)</td>
<td>Email</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>John</td>
<td>Doe</td>
<td>555-555-5555</td>
</tr>
</tbody>
</table>

Showing 1 to 1 of 1 entries

For additional information about the Bosentan REMS Program, please call 1-866-350-2612.
3.2 Prescriber Search with no Results

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.

New User

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
### 3.3 Prescriber Intake Page

**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
- Last Name
- Email
- Confirm Email Address
- Professional Designation
- Medical Specialty
- Clinic / Practice Name
- Address
- City
- State
- Zip
- Phone
- Fax
- Preferred Method of Contact

**Prescriber Identifiers**

- DEA Number
- NPI Number

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

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 acknowledgment 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 1-800-735-8231 or mail it to the Bosentan REMS Program, P.O. Box 29560, Phoenix, AZ 85019.

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 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 embryonic/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 embryonic/fetal toxicity, (ii) the need to use reliable contraception as defined in the Bosentan REMS Program Guide for Patients, (iii) the need to immediately contact their prescriber if they miss 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 9 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: 

Back Submit

For additional information about the Bosentan REMS Program, please call 1-866-359-2012.
3.5 Prescriber Confirmation Page

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.
4. Pharmacy Online Certification

4.1 Authorized Representative Role Selection Pages

4.1.1 Authorized Representative Role Selection

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

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.

Confirm
Cancel

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.1.3 Authorized Representative Role Selection: 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.

Cancel  Confirm

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.1.4 Authorized Representative Role Selection: Inpatient Pharmacy

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

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

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.2 Authorized Representative Search with Results

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):

<table>
<thead>
<tr>
<th>Identifiers</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA Number</td>
</tr>
<tr>
<td>NPI Number</td>
</tr>
<tr>
<td>NCPDP Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Zip Code</th>
<th>DEA Number</th>
<th>NPI Number</th>
<th>NCPDP Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Certification ID (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone (Optional)</th>
<th>Fax (Optional)</th>
<th>Email (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Pharmacy Address</th>
<th>Pharmacy Phone</th>
<th>Pharmacy Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Pharmacy</td>
<td>4343 N. Scottsdale Road, AZ 85251</td>
<td>788-959-0000</td>
<td>Inpatient Pharmacy</td>
</tr>
</tbody>
</table>

Showing 1 to 1 of 1 entries

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.3 Authorized Representative Search with no Results

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):

<table>
<thead>
<tr>
<th>Zip Code</th>
<th>DEA Number</th>
<th>NPI Number</th>
<th>NCPDP Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

and

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Certification ID (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone (Optional)</th>
<th>Fax (Optional)</th>
<th>Email (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Pharmacy Name</th>
<th>Pharmacy Address</th>
<th>Pharmacy Phone</th>
<th>Pharmacy Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mary</td>
<td>More</td>
<td>ABC Pharmacy</td>
<td>4343 N. Scottsdale Road, AZ 85251</td>
<td>788-950-0000</td>
<td>Inpatient Pharmacy</td>
</tr>
</tbody>
</table>

Showing 1 to 1 of 1 entries

New User Submit

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.4 Outpatient and Inpatient Pharmacy Authorized Representative Intake Page

**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
- 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.
4.5 Outpatient and Inpatient Pharmacy Authorized Representative Confirmation Page

Confirmation

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.

If you are now an authorized representative of the Bosentan REMS program, you may certify pharmacy. 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.
4.6 Outpatient Pharmacy Intake Page

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 pharmacies enrolled in the Bosentan REMS are required to maintain current DEA information.

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.

<table>
<thead>
<tr>
<th>Pharmacy Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Name</td>
</tr>
<tr>
<td>Pharmacy Type</td>
</tr>
<tr>
<td>Address</td>
</tr>
<tr>
<td>City</td>
</tr>
<tr>
<td>State — Please Select —</td>
</tr>
<tr>
<td>Zip</td>
</tr>
<tr>
<td>Phone</td>
</tr>
<tr>
<td>Fax</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacy Identifiers</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA</td>
</tr>
<tr>
<td>NPI</td>
</tr>
<tr>
<td>NCPDP</td>
</tr>
</tbody>
</table>

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

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 pharmacies certified via REMS are considered a specialty pharmacy.

**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:**

**Pharmacy Identifiers** (at least one identifier required)

- **DEA:**
- **NPI:**
- **NCPDP:**

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.8 Outpatient Pharmacy Attestation Page

Note: The following message will be displayed when user hover overs 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

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 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. Report any adverse events including those suggestive of hepatotoxicity to the Bosentan REMS Program
5. Report any communication with the Bosentan Sponsors or a third party acting on behalf of the Bosentan Sponsors
6. 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
7. Maintain documentation that all processes and procedures are in place and are being followed for the Bosentan REMS Program
8. For additional information about the Bosentan REMS Program, please call 1-866-359-2612.

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

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

Pharmacy Certification Confirmation

Your pharmacy is now certified in 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

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.
4.11 Chain Pharmacy Authorized Representative Intake Page

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
-- Please Select --

Phone
Fax

Preferred Method of Contact
-- Please Select --

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.12 Chain Pharmacy Authorized Representative Confirmation Page

Confirmation

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.

You are now an Authorized Representative of Bosentan REMS Program.

IVR Access ID: 12341234

If you are ready to certify your chain headquarter pharmacy now please use Certify Chain Headquarter Pharmacy.

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

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.13 Chain Pharmacy Headquarters Intake Page

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: Please Select
- Zip Code
- Phone
- Fax

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.14 Chain Pharmacy Headquarters Attestation Page

Note: The following message will be displayed when user hover overs 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

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.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.16 Chain Pharmacy Dispensing Location Intake Page

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

<table>
<thead>
<tr>
<th>Field</th>
<th>Input</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Name</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td>-- Please Select --</td>
</tr>
<tr>
<td>Zip</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Training Status</td>
<td>-- Please Select --</td>
</tr>
</tbody>
</table>

Pharmacy Identifiers

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Input</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCPDP Number</td>
<td></td>
</tr>
<tr>
<td>(Provide at least one)</td>
<td></td>
</tr>
<tr>
<td>DEA Number</td>
<td></td>
</tr>
<tr>
<td>NPI Number</td>
<td></td>
</tr>
</tbody>
</table>

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.17 Chain Pharmacy Dispensing Location Confirmation Page

Chain Pharmacy Dispensing Location Confirmation

The pharmacy dispensing location has been successfully added.

To add another pharmacy dispensing location, please use the Add Pharmacy Dispensing Location button below.

Add Pharmacy Dispensing Location

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.18 Pharmacy Staff Search with Results

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):

<table>
<thead>
<tr>
<th>Pharmacy Zip Code</th>
<th>DEA Number</th>
<th>NPI Number</th>
<th>NCPDP Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>and</td>
<td>or</td>
<td>or</td>
<td></td>
</tr>
</tbody>
</table>

Pharmacy Staff Information

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Phone</th>
<th>Pharmacy Name</th>
<th>Pharmacy Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>John</td>
<td>Doe</td>
<td>555-555-5555</td>
<td>ABC Pharmacy</td>
<td>1234 W Polo Verde Lane Tempe AZ 85283</td>
</tr>
</tbody>
</table>

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 New User button to begin your enrollment process in the Bosentan REMS Program.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.19 Pharmacy Staff Search with No Results

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: 
DEA Number: 
NPI Number: 
NCOPD Number: 

Phone (Optional): 
Fax (Optional): 
Email (Optional):

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: 

Showing 1 to 1 of 1 entries

New User

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
## 4.19.1 Pharmacy Staff Pharmacy Search

### 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):

<table>
<thead>
<tr>
<th>Pharmacy Zip Code</th>
<th>DEA Number</th>
<th>NPI Number</th>
<th>NCPDP Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pharmacy Staff Information**

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Phone</th>
<th>Pharmacy Name</th>
<th>Pharmacy Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>John</td>
<td>Doe</td>
<td>555-555-5555</td>
<td>ABC Pharmacy</td>
<td>1234 W Fab Verde Lane Tempe AZ 85283</td>
</tr>
</tbody>
</table>

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 **New User** button to begin your enrollment process in the Bosentan REMS Program.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.20 Pharmacy Staff Intake Page

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 — Please Select —

Cancel  Next

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.21 Pharmacy Staff Attestation Page

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 enrolment, 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

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
4.22 Pharmacy Staff Confirmation Page

You are now an enrolled pharmacy staff member in 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

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 1-866-369-2612.
5. Patient Enrollment

5.1 Patient Intake Page: Initial Enrollment

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
Last Name
Email (Optional)
Gender — Please Select —
Date of Birth MM/DD/YYYY
Address
City
State — Please Select —
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

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

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  Please Select  Patient Sub-Category  Please Select

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.
5.4 Patient Confirmation Page: Initial Enrollment

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.
6. Dashboard and Dashboard Actions

6.1 Prescriber Dashboard

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
### 6.2 Prescriber Dashboard: Edit Patient Profile

#### Patient Profile

<table>
<thead>
<tr>
<th>Patient Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Name</strong></td>
<td>John</td>
</tr>
<tr>
<td><strong>Last Name</strong></td>
<td>Doe</td>
</tr>
<tr>
<td><strong>Email (Optional)</strong></td>
<td><a href="mailto:john.doe@email.com">john.doe@email.com</a></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Male</td>
</tr>
<tr>
<td><strong>Date of Birth</strong></td>
<td>01/01/1962</td>
</tr>
<tr>
<td><strong>Address</strong></td>
<td>1 Main Street</td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>New York</td>
</tr>
<tr>
<td><strong>State</strong></td>
<td>New York</td>
</tr>
<tr>
<td><strong>Zip</strong></td>
<td>10001</td>
</tr>
<tr>
<td><strong>Primary Phone</strong></td>
<td>555-555-0000</td>
</tr>
<tr>
<td><strong>Alternate Phone</strong></td>
<td>555-555-5555</td>
</tr>
<tr>
<td><strong>Parent/Legal Guardian</strong></td>
<td>Jane Doe</td>
</tr>
<tr>
<td><strong>Relationship (Optional)</strong></td>
<td>Mother</td>
</tr>
</tbody>
</table>

#### Patient Enrollment

- Enrollment ID: PAT123112312

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

**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.

<table>
<thead>
<tr>
<th>Patient Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong> Jane Doe</td>
</tr>
<tr>
<td><strong>Date of Birth:</strong> 09/02/1957</td>
</tr>
<tr>
<td><strong>Authorization Number:</strong> AUTH-1234-5678-910</td>
</tr>
<tr>
<td><strong>Refill Dispense Exception:</strong> Required Testing Not Confirmed - Benefit Outweighs the Risk</td>
</tr>
</tbody>
</table>

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

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: 09/02/1987
Authorization Number: AUTH-1234-5678-B910
Refill Dispense Exception: Travel Outside of the United States for more than 30 days

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

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

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 Reproductive Status Change and Pre-pubertal Annual Verification

**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 the REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menarche (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: Female of non-reproductive potential – Patient is pre-pubertal

**Reason for change in classification:**

- Status Change Reason: -- Please Select --

**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:**

[Submit]

---

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.7 Prescriber Dashboard: Patient Test and Counseling

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: MMDODYYYY

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: MMDODYYYY

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

Note: Popup messaging will be consistent with the results of the activity within this function.
6.9 Pharmacy Dashboard: Inpatient Pharmacies

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

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

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

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

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.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.14  Pharmacy Staff Dashboard: Outpatient Pharmacies that Do Not Support Electronic Telecommunication Verification

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.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.15 Pharmacy Staff Dashboard: Associate to a Pharmacy – Search Results

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):

<table>
<thead>
<tr>
<th>Identifiers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Zip Code</td>
</tr>
<tr>
<td>and</td>
</tr>
</tbody>
</table>

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.

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.16 Pharmacy Staff Dashboard: Disassociate from a Pharmacy

![Pharmacy Staff Dashboard]

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.17 Pharmacy Dashboard: Edit Pharmacy Profile – Inpatient Pharmacy

My Inpatient Pharmacy

My Information

Pharmacy Name: Pharmacy A
Pharmacy Type: Inpatient Pharmacy
Address: 4343 N Scottsdale Road
City: Scottsdale
State: Arizona
Zip: 85251
Phone: 602-123-3456
Fax: 602-123-3456
Email: john.doe@website.com

Pharmacy Identifiers (at least one identifier required)

DEA Number: AB23423423
NPI Number: 1232342342
NCPDP Number: 2342342342

My Certification

Certification ID: FAC123112312

Cancel  Save

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.18 Pharmacy Dashboard: Edit Pharmacy Profile – Outpatient Pharmacy

My Outpatient Pharmacy

My Information

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Pharmacy A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Type</td>
<td>Outpatient Pharmacy</td>
</tr>
<tr>
<td>Address</td>
<td>123 Main Street</td>
</tr>
<tr>
<td>City</td>
<td>New York</td>
</tr>
<tr>
<td>State</td>
<td>New York</td>
</tr>
<tr>
<td>Zip Code</td>
<td>10001</td>
</tr>
<tr>
<td>Phone</td>
<td>555-555-5555</td>
</tr>
<tr>
<td>Fax</td>
<td>555-555-0000</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:john.doe@website.com">john.doe@website.com</a></td>
</tr>
</tbody>
</table>

Pharmacy Identifiers

<table>
<thead>
<tr>
<th>DEA Number</th>
<th>A523423423</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI Number</td>
<td>123234234234</td>
</tr>
<tr>
<td>NCPDP Number</td>
<td>234234234</td>
</tr>
</tbody>
</table>

Can your pharmacy management system adjudicate claims online? 
Yes

My Certification

Certification ID: FAC123112312

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.19 Pharmacy Dashboard: Edit Pharmacy Profile – Chain Pharmacy Headquarters

My Chain Pharmacy Headquarters

<table>
<thead>
<tr>
<th>My Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chain ID:</strong></td>
</tr>
<tr>
<td><strong>Pharmacy Name:</strong></td>
</tr>
<tr>
<td><strong>Pharmacy Type:</strong></td>
</tr>
<tr>
<td><strong>Address:</strong></td>
</tr>
<tr>
<td><strong>City:</strong></td>
</tr>
<tr>
<td><strong>State:</strong></td>
</tr>
<tr>
<td><strong>Zip</strong>:</td>
</tr>
<tr>
<td><strong>Phone</strong>:</td>
</tr>
<tr>
<td><strong>Fax</strong>:</td>
</tr>
</tbody>
</table>

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.20 Pharmacy Dashboard: Edit Pharmacy Profile – Chain Pharmacy Dispensing Location

My Dispensing Location

My Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chain ID</td>
<td>123456</td>
</tr>
<tr>
<td>Dispensing Location Name</td>
<td>Pharmacy A</td>
</tr>
<tr>
<td>Pharmacy Type</td>
<td>Chain Store</td>
</tr>
<tr>
<td>Address</td>
<td>4343 N Scottsdale Road</td>
</tr>
<tr>
<td>Address Line 2</td>
<td>Suite 2003</td>
</tr>
<tr>
<td>City</td>
<td>Scottsdale</td>
</tr>
<tr>
<td>State</td>
<td>Arizona</td>
</tr>
<tr>
<td>Zip</td>
<td>85251</td>
</tr>
<tr>
<td>Phone</td>
<td>602-123-3456</td>
</tr>
<tr>
<td>Fax</td>
<td>601-123-3456</td>
</tr>
</tbody>
</table>

Pharmacy Identifiers (at least one identifier required)

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCPDP Number</td>
<td>123456</td>
</tr>
<tr>
<td>DEA Number</td>
<td>BN5623740</td>
</tr>
<tr>
<td>NPI Number</td>
<td>1234567891</td>
</tr>
</tbody>
</table>

My Training

<table>
<thead>
<tr>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete</td>
</tr>
</tbody>
</table>

Cancel  Save

For additional information about the Bosentan REMS Program, please call 1-866-359-2812.
6.21  **Authorized Representative Pharmacy Dashboard: View Pharmacy Staff**

For additional information about the Bosentan REIMS Program, please call 1-866-359-2612.
6.22  **Authorized Representative Pharmacy Dashboard: Remove Pharmacy Staff**

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:** MCP123456789

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.

[Submit]  [Cancel]

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

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)

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 1-888-359-2612.

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

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

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

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

Pre-dispense Authorization Request

- Date of Fill: MM/DD/YYYY
- Manufacturer
- NDC Number
- Days Supply
- Quantity

Prescriber Information (at least one identifier is required)

- Prescriber DEA Number (Optional)
- Prescriber NPI Number

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.27 Pharmacy Dashboard: Pre-dispense Authorization
Result – Authorized with Counseling Confirmed

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-1234-5678-9910

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.28 Pharmacy Dashboard: Pre-dispense Authorization Result
Authorized with Counseling Not Confirmed

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: 08/02/1962
Patient ID #: PAT123456789
Authorization Number: AUTH-1234-5678-8910

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.29 Pharmacy Dashboard: Pre-dispense Authorization Result – Rejected

Pre-dispense Authorization Result

⚠️ Do not dispense bosentan to this patient.

Name: Jane Doe
DOB: 08/02/1982
Patient ID #: PAT123456789
<Reject Reason>

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

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: AUTH-1234-5678-9010

Forgot the authorization number? Look it up here

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

Authorization Number: AUTH-1234-5678-9010
Patient First Name: Randy
Patient Last Name: Botton
Patient DOB: 09/02/1997
Date Processed: 10/01/2016 10:45 AM

Showing 1 to 1 of 1 entries

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

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.

<table>
<thead>
<tr>
<th>Authorization Number</th>
<th>Patient First Name</th>
<th>Patient Last Name</th>
<th>Patient DOB</th>
<th>Date Processed</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUTH-1234-5678-9010</td>
<td>Randy</td>
<td>Bottom</td>
<td>09/02/1997</td>
<td>10/01/2016 10:45 AM</td>
</tr>
<tr>
<td>AUTH-4444-5678-9010</td>
<td>John</td>
<td>Doe</td>
<td>09/02/1997</td>
<td>10/01/2016 10:45 AM</td>
</tr>
</tbody>
</table>

Showing 1 to 2 of 2 entries

[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

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.

Pre-dispense Authorization Reversal

Select Confirm to reverse the pre-dispense authorization or Cancel to return to the pre-dispense authorization results.

Authorization Number

AUTH-1234-5678-9010

Patient First Name

Randy

Patient Last Name

Botton

Patient DOB

09/02/1967

Date Processed

10/01/2016 10:45 AM

Showing 1 to 1 of 1 entries

For additional information about the Bosentan REMS Program, please call 1-866-359-2612.
6.34 Pharmacy Dashboard: Reverse Pre-dispense Authorization – Confirmation

Pharmacy Pre-dispense Authorization Reversal Confirmation

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

- Patient Name: Jane Doe
- Patient DOB: 09/02/1962
- Authorization Number: AUTH-1234-5678-9010

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