

Instructions

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

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

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

Authorized Representative Responsibilities

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

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

Continued on the following page.

Pharmacy Management System Information (Select one)

Can your outpatient pharmacy management system adjudicate claims online?

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

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

Pharmacy Information (All fields required)

Pharmacy Name:

Pharmacy Identifiers: NCPDP: NPI: DEA:

Address: City:

State: Zip:

Phone: Fax:

Authorized Representative Information (All fields required)

First Name: Last Name:

Credentials: R.Ph PharmD BCPS Other

Phone: Fax: Email:

Preferred method of contact: Fax Email

Authorized Representative Signature

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

Signature:

Date:

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