

Instructions

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

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

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

Prescriber Responsibilities

Specifically, you attest to the following:

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

Prescriber Information (All fields required unless otherwise indicated)

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

Prescriber Signature

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

Signature:

Date: