

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

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

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

Instructions

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

The patient's prescriber must use this form to:

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

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

Patient Information (All fields required unless otherwise indicated)

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

Prescriber Information (All fields required unless otherwise indicated)

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

Definitions of Reproductive Potential Status

Females of Reproductive Potential

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

Females of Non-Reproductive Potential

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

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

Patient has had a change in reproductive status

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

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

Reason for change in classification (choose one):

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

Annual verification of pre-pubertal status

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

Prescriber Signature

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

Prescriber
Signature

Date