



Bosentan REMS Program Software User Guide

[Home](#) » [Bosentan](#) » Bosentan REMS Program Software User Guide 

Contents

- 1 Bosentan REMS Program Software
- 2 What is bosentan?
- 3 What are the serious risks of bosentan?
- 4 What is the Bosentan Risk Evaluation and Mitigation Strategy (REMS)?
 - 4.1 Bosentan REMS Requirements
 - 4.2 Birth Control Options
- 5 Acceptable birth control options Steps to treatment with bosentan
- 6 Documents / Resources
 - 6.1 References
- 7 Related Posts

Bosentan
REMS Program

Bosentan REMS Program Software



What is bosentan?

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

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

What are the serious risks of bosentan?

Bosentan can cause liver problems and, if taken during pregnancy, can cause serious birth defects. All patients – liver function must be monitored:

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

Female patients – pregnancy must be avoided:

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

What is the Bosentan Risk Evaluation and Mitigation Strategy (REMS)?

The Bosentan Risk Evaluation and Mitigation Strategy (REMS) tells patients and healthcare providers about the risks of liver problems and serious birth defects when taking bosentan. This REMS is required by the Food and Drug Administration (FDA). All patients must enroll in the Bosentan REMS to receive bosentan.

Bosentan REMS Requirements

- Be counseled on the requirements of the Bosentan REMS and the risk of liver problems
- Participate in the Bosentan REMS for as long as you are taking the medication, and for females of reproductive

potential, for one month after ending bosentan treatment

- Get liver tests your prescriber orders for you before beginning treatment and monthly thereafter until ending bosentan treatment. Your prescriber will monitor your liver and may adjust or stop your treatment if there are signs of liver problems
- Tell your prescriber if you have had liver problems, including liver problems while on other medicines
- Be contacted by the Bosentan REMS or the pharmacy before receiving bosentan to provide confirmation that a current liver test was completed and you were counseled on the risks of bosentan and your requirements in the Bosentan REMS

Females who can get pregnant have additional requirements in the REMS

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

- Have entered puberty, even if you have not started your menstrual period, and
- Have a uterus, and

Have not gone through menopause (have not had a menstrual period for at least 12 months for natural reasons, or have had your ovaries removed)

- Be counseled on the requirements of the Bosentan REMS and the risk of serious birth defects
- Be counseled before your first prescription and each month thereafter on the need to use reliable birth control during bosentan treatment, and for one month after ending bosentan treatment
- Complete a pregnancy test before beginning treatment with bosentan, monthly during bosentan treatment, and one month after ending bosentan treatment
- Be contacted by the Bosentan REMS or the pharmacy before receiving bosentan to provide confirmation that a pregnancy test was completed before beginning treatment, monthly during treatment, and one month after ending bosentan treatment
- Notify your prescriber immediately if you:
 - Had unprotected sex
 - Think that your birth control failed
 - Missed a menstrual period
 - Think you are pregnant
- Be contacted by a Bosentan REMS representative if you become pregnant while on bosentan or within one month after ending bosentan treatment
- A pre-pubertal female must immediately contact their prescriber when the patient begins to menstruate

Birth Control Options

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

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

Acceptable birth control options

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

Steps to treatment with bosentan

BEFORE YOU START TREATMENT: All Patients

- Understand the risks of liver problems and birth defects (for females) while taking bosentan
- Tell your prescriber if you have had liver problems, including liver problems while taking other medicines
- Get your liver test
- Get your pregnancy test (for females who can get pregnant)
- Enroll in the Bosentan REMS. Complete and sign the Patient Enrollment Form with your prescriber. Your prescriber 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. A parent/legal guardian may sign the form for you

EVERY MONTH: All Patients

- Read the Medication Guide that comes with every prescription. Important information may have been added or changed
- Get the monthly liver tests ordered by your prescriber
- Fill your prescription at a certified pharmacy. A certified pharmacy is a pharmacy that is authorized by the Bosentan REMS to provide bosentan to you. For a list of certified pharmacies, please call the Bosentan REMS at 1-866-359-2612 or visit www.BosentanREMSProgram.com
- The Bosentan REMS or the pharmacy will call you every month to ask if you had your liver tests and were counseled on the risk of liver problems before you can receive your bosentan. If your healthcare provider has already notified the Bosentan REMS that you have completed your testing and counseling, you will not receive

a phone call from the Bosentan REMS that month. The refill may not be ready on time if you have not had your liver tests and counseling

- Tell your prescriber right away if you have any of these symptoms of liver problems while taking bosentan: nausea, vomiting, fever, unusual tiredness, stomach area (abdominal) pain, or yellowing of the skin or the whites of your eyes (jaundice)

EVERY MONTH: Female Patients Who Can Get Pregnant

- Use the reliable birth control method(s) agreed upon with your healthcare provider during treatment
- Get the monthly pregnancy test ordered by your prescriber
- The Bosentan REMS or the pharmacy will call you every month to ask if you had a pregnancy test and were counseled on the risk of birth defects before you can receive your bosentan. If your healthcare provider has already notified the Bosentan REMS that you have completed your testing and counseling, you will not receive a phone call from the Bosentan REMS that month. The refill may not be ready on time if you have not had your pregnancy test and counseling
- Do not get pregnant. Tell your prescriber right away if you: Had unprotected sex, think that your birth control failed, missed a menstrual period, think you are pregnant

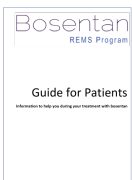
ONE MONTH AFTER ENDING BOSENTAN TREATMENT: Female Patients Who Can Get Pregnant

- Use the reliable birth control method(s) agreed upon with your healthcare provider for one month after ending bosentan treatment
Get the final pregnancy test ordered by your prescriber
- Do not get pregnant. Tell your prescriber right away if you: Had unprotected sex, think that your birth control failed, missed a menstrual period, think you are pregnant

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

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

Documents / Resources

	Bosentan REMS Program Software [pdf] User Guide REMS Program, Software, REMS Program Software
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References

-  [Bosentan REMS](#)