

Bosentan

REMS Program

Guide for Patients

Information to help you during your treatment with bosentan

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What is bosentan?

Bosentan is a prescription medicine used to treat people with 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 damage** 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 healthcare provider 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 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:

1. Read this ***Bosentan REMS Program Guide for Patients*** and the Medication Guide which comes with your medicine
2. Ask your healthcare provider any questions you have about taking bosentan and the Bosentan REMS Program
3. 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 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

What are the Bosentan REMS Program requirements for me?

- Participate in the Bosentan REMS Program for as long as you are taking the medication, and for one month after ending bosentan treatment
- Be counseled on the requirements of the Bosentan REMS Program and the risk of liver damage
- Go for any other liver tests your healthcare provider orders for you. Your healthcare provider will monitor your liver function monthly and may adjust or stop your treatment if there are signs of liver damage
- Tell your healthcare provider if you have had liver problems, including liver problems while on other medicines
- Call your healthcare provider right away if you have any of these symptoms of liver problems while you are on bosentan:
 - Nausea, vomiting, fever, unusual tiredness, stomach area (abdominal) pain, or yellowing of the skin or the whites of your eyes (jaundice)
- Read the Medication Guide and the ***Bosentan REMS Program Guide for Patients***
- Complete a liver function test before beginning treatment, and monthly thereafter until ending bosentan treatment
- Be contacted by the Bosentan REMS Program before receiving bosentan to provide confirmation that a current liver function test was completed and you were counseled on the risks of bosentan and your requirements in the Bosentan REMS Program
- Complete and sign the ***Bosentan REMS Program Patient Enrollment Form*** with your healthcare provider

Females who can get pregnant have additional requirements in the program

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

- Have entered puberty, even if you have not started your period, and
 - Have a uterus, and
 - Have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had your ovaries removed)
- 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 for one month after ending bosentan treatment
 - Be contacted by the Bosentan REMS Program before receiving bosentan to provide confirmation that a pregnancy test was completed before beginning treatment, monthly during treatment, and for one month after ending bosentan treatment
 - Be counseled on the requirements of the Bosentan REMS Program and the risk of serious birth defects
 - Notify your healthcare provider immediately if you miss a menstrual period or suspect that you are pregnant
 - Be contacted by a Bosentan REMS Program representative if you become pregnant while on bosentan or within one month after ending bosentan treatment
 - A pre-pubertal female and/or her parent/legal guardian must immediately contact their healthcare provider if she has a menstrual period

What are my 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 One method from this list:	or	Option 2 One method from this list:	or	Option 3 One method from this list:	or	Option 4 One method from this list:
Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNg 20 IUS: progesterone IUS) Tubal sterilization		Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant		Diaphragm with spermicide Cervical cap with spermicide PLUS One Method from this list: Male condom		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

How will I receive bosentan?

Bosentan is available only through certified pharmacies in the Bosentan REMS Program. A certified pharmacy is a pharmacy that is authorized by the Bosentan REMS Program to provide bosentan to you.

- Each month, before you receive bosentan, you will be contacted by the Bosentan REMS Program to confirm that you have completed your testing and to talk to you about the benefits and risks of bosentan. If your healthcare provider has already notified the Bosentan REMS Program that you have completed your testing, you will not receive a phone call from the Bosentan REMS Program that month
- Read the Medication Guide each time you receive it. Important information may have been added or changed

For a list of certified pharmacies, please call the Bosentan REMS Program at 1-866-359-2612 or visit www.BosentanREMSProgram.com.

Your steps to treatment with bosentan

Use this helpful checklist to get started with bosentan and to stay on track during your treatment.

BEFORE YOU START TREATMENT: All Patients

- Review the ***Bosentan REMS Program Guide for Patients***
- Make sure you understand the risks and benefits of taking bosentan
- Tell your healthcare provider if you have had liver problems, including liver problems while taking other medicines
- Go for your liver function test
- Go for your pregnancy test (for females who can get pregnant)
- Enroll in the Bosentan REMS Program

EVERY MONTH: All Patients

- Read the Medication Guide that comes with every prescription
- Complete the monthly liver function tests ordered by your healthcare provider
- Fill your prescription at a certified pharmacy
- A healthcare provider from the Bosentan REMS Program will call you every month to ask if you had your liver function tests and were counseled on the risk of liver damage before you can receive your bosentan. **If your healthcare provider has already notified the Bosentan REMS Program that you have completed your testing and counseling, you will not receive a phone call from the Bosentan REMS Program that month.** The refill may not be ready on time if you have not had your liver tests and counseling
- Tell your healthcare provider 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 and for one month after you stop taking bosentan

- Complete the monthly pregnancy test ordered by your healthcare provider
- A healthcare provider from the Bosentan REMS Program 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 Program that you have completed your testing and counseling, you will not receive a phone call from the Bosentan REMS Program 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 healthcare provider right away if you:
 - Had unprotected sex
 - Think that your birth control failed
 - Miss a menstrual period
 - Think you are pregnant

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REMS Program

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

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