

PS-AMBRISENTAN RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Please visit www.PSAmbrisentanREMS.com or call 1-888-301-0333 9am to 5pm ET, Monday - Friday

PS-Ambrisentan REMS Guide for Female Patients

PS-Ambrisentan
— REMS —

This document is part of an FDA-approved REMS
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Information for Female Patients

What is ambrisentan?

Ambrisentan is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs. Ambrisentan can improve your ability to exercise and it can help slow down the worsening of your physical condition and symptoms.

It is not known if ambrisentan is safe and effective in children.

What are the serious risks of ambrisentan?

Ambrisentan can cause serious birth defects if taken during pregnancy. Females must not be pregnant when they start taking ambrisentan or become pregnant while taking ambrisentan, or for one month after stopping ambrisentan.

What is the PS-Ambrisentan Risk Evaluation and Mitigation Strategy (REMS)?

Because of the risk of serious birth defects, the FDA has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for

ambrisentan. The purpose of the PS-Ambrisentan REMS is to make sure the benefits of ambrisentan outweigh the risks. All females must enroll in the PS-Ambrisentan REMS to receive ambrisentan, even if you have been previously enrolled in the Letairis REMS. Specific requirements apply to females who can get pregnant.

To receive ambrisentan:

- You must talk with your doctor to ensure the benefits outweigh the risks of ambrisentan
- You must agree to all of the requirements of the PS-Ambrisentan REMS. For females who can get pregnant, these requirements include monthly pregnancy tests and use of appropriate birth control while taking ambrisentan and for one month after stopping ambrisentan.
- Your doctor will enroll you in the PS-Ambrisentan REMS

- Your prescription must be filled by a pharmacy enrolled in the PS-Ambrisentan REMS. You and your doctor can find a list of pharmacies enrolled in the PS-Ambrisentan REMS on the PS-Ambrisentan REMS website: www.PSAmbrisentanREMS.com. You may also contact your insurance carrier for help in knowing what pharmacies and ambrisentan products are supported by your current insurance plan.
- How you receive your prescription will depend on which pharmacy you choose. Some pharmacies may mail your prescription to you while others may provide your prescription at your pharmacy.

How do I enroll in the PS-Ambrisentan REMS?

You must be enrolled in the PS-Ambrisentan REMS to receive ambrisentan, even if you have been previously enrolled in the Letairis REMS. Enrollment may be completed online at www.PSAmbrisentanREMS.com, on the prescriber and patient mobile apps, or by faxing a completed

Patient Enrollment and Consent Form to the REMS Coordinating Center at (888) 870-1819. Follow these steps with your doctor:

- Read all the patient information about ambrisentan and the PS-Ambrisentan REMS included in this guide, on the patient mobile app, or on the PS-Ambrisentan REMS website: www.PSAmbrisentanREMS.com.
- Talk with your doctor to ensure the benefits outweigh the risks of ambrisentan
- Ask questions. Make sure you understand what you need to do to enroll and take part in the PS-Ambrisentan REMS. Make sure you know how to receive and take ambrisentan
- You and your doctor will fill out the ***Patient Enrollment and Consent Form***. After you read and sign it, your doctor will send it to the PS-Ambrisentan REMS Coordinating Center.

Can I be pre-enrolled in the PS-Ambrisentan REMS?

Your doctor must complete the enrollment, but you can start the enrollment with the **Patient Pre-Enrollment** process on either the PS-Ambrisentan REMS website (www.PSAmbrisentanREMS.com) or the patient mobile app.

You will enter information such as your name, address, phone number, date of birth, and email address. When you are done, you will receive a "Patient Pre-Enrollment Confirmation Number." Give this number to your doctor to complete your enrollment.

What are the PS-Ambrisentan REMS requirements for me?

Females Who Cannot Get Pregnant:

You are considered a female who cannot get pregnant if you have not yet entered puberty, or you do not have a uterus, or you have gone through menopause, or you are infertile for any other medical reason and this infertility is permanent and cannot be reversed.

Before starting ambrisentan, you must:

- Review this guide.
- Enroll in the REMS by completing the ***Patient Enrollment and Consent Form*** with your prescriber.
- Receive counselling from your prescriber on the risk of serious birth defects (Pre-pubertal females only)

At all times, you must:

- Inform your doctor if there is a change in your ability to become pregnant
- If you have not yet entered puberty and are over the age of 8: Be monitored regularly to see if your ability to become pregnant changes and tell your prescriber if your ability to become pregnant changes

If you are the parent or caregiver of a female child who started taking ambrisentan before reaching puberty, you should check your child regularly to see if she is developing signs of puberty. Tell your

doctor right away if you notice that she is developing breast buds or pubic hair. Your doctor should decide if your child has reached puberty. **Your child may reach puberty before having her first menstrual period.**

Females Who Can Get Pregnant:

You are considered to be a female who can get pregnant if you have entered puberty, have a uterus, and have not gone through menopause.

Before starting ambrisentan, you must:

- Review this guide.
- Get a pregnancy test. Your doctor orders the pregnancy tests for you.
- Enroll in the REMS by completing the ***Patient Enrollment and Consent Form*** with your prescriber.
- Receive counseling from your prescriber on the risk of serious birth defects, the need to use highly reliable birth control during treatment

and for one month after stopping treatment, and emergency birth control.

Before each prescription while taking ambrisentan, you must:

- Receive counseling from the REMS Coordinating Center or the healthcare provider who dispenses ambrisentan on the risk of serious birth defects, the need to use highly reliable birth control during treatment and for one month after stopping treatment, emergency birth control, to get monthly pregnancy tests, and to report a pregnancy immediately.
- Get a pregnancy test. Your doctor orders the pregnancy tests for you. The REMS Coordinating Center will contact you to ask if you have taken this test before ambrisentan is refilled. **Be sure you get your monthly pregnancy test as ordered by your doctor. If you do not get your pregnancy test every**

month, you may not receive your ambrisentan on time.

Do not have unprotected sex. Use appropriate birth control during your ambrisentan treatment and for 1 month after stopping your ambrisentan treatment because the medicine may still be in your body. Page 8 of this guide shows your birth control options.

Talk to your doctor or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be pregnant. Your doctor may tell you to use emergency birth control. Do not wait until your next appointment to tell your doctor if you miss your menstrual period or if you think you may be pregnant.

What are my birth control options?

If you are a female who can get pregnant, your doctor will talk to you about your birth control options. Use the diagram on the next page to help decide what birth control options are best for you.

Talk to your doctor if you have questions about your birth control options. Tell your doctor if you want to change your birth control method.

You may choose from the four options listed on the next page. More than one birth control method might be needed every time you have sex (intercourse).

Your birth control options (select one option)

OPTION 1

One method from this list:
Standard intrauterine device (Copper T380A IUD)
Intrauterine system (LNg 20 IUS – progesterone IUD)
Tubal sterilization
Progesterone implant

OPTION 2

One method from this list:
Estrogen and progesterone oral contraceptives (“the pill”)
Estrogen and progesterone transdermal patch
Vaginal ring
Progesterone injection

+

One method from this list:
Male condom
Diaphragm with spermicide
Cervical cap with spermicide

OPTION 3

One method from this list:
Diaphragm with spermicide
Cervical cap with spermicide
+
This method:
Male condom

OPTION 4

This method:
Partner’s vasectomy
+
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

How will I receive my ambrisentan?

Your prescription must be filled by a pharmacy enrolled in the PS-Ambrisentan REMS. Both community and specialty pharmacies participate in the PS-Ambrisentan REMS. You should decide what type of pharmacy is best for you.

You and your doctor can find a list of pharmacies enrolled in the PS-Ambrisentan REMS on the PS-Ambrisentan REMS website: www.PSAmbrisentanREMS. You may also contact your insurance carrier for help in knowing which pharmacies and ambrisentan products are supported by your current insurance plan.

How you receive your prescription will depend on which pharmacy you choose. Some pharmacies may mail your prescription to you while others may give you your prescription at your local pharmacy.

If you are a female who can get pregnant, each month you will be contacted by your preferred method of contact to confirm that you have taken a monthly pregnancy test before refilling

your prescription. It is important that you are able to be contacted in order to avoid delays in your refills. Once the monthly pregnancy test has been confirmed, you will receive a **REMS Dispense Authorization (RDA)** through your preferred method.

You will need an RDA to get your prescription filled. Show this RDA to the pharmacist. If you do not have an RDA, the pharmacist may call the REMS Coordinating Center or check the PS-Ambrisentan REMS website to confirm if an RDA has been given. If an RDA has not been given, the pharmacist will ask you to contact the REMS Coordinating Center to confirm that you have had your monthly pregnancy test.

If you have questions or concerns about ambrisentan, talk to your doctor.

Please visit

www.PSAmbrisentanREMS.com or call **1-888-301-0333** for more information about the PS-Ambrisentan REMS.

