

AMBRISENTAN RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Ambrisentan REMS **GUIDE FOR FEMALE PATIENTS**

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This guide is part of an FDA-approved REMS.

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.

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 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 Ambrisentan REMS is to make sure the benefits of ambrisentan outweigh the risks. All females must enroll in the Ambrisentan REMS to receive ambrisentan. Specific requirements apply to females who can get pregnant.

To receive Ambrisentan:

1) You must talk with your doctor to ensure the benefits outweigh the risks of ambrisentan	2) You must agree to all of the requirements of the Ambrisentan REMS. These requirements include monthly pregnancy tests and use of appropriate birth control for females that can get pregnant while taking ambrisentan and for one month after stopping ambrisentan	3) Your doctor will enroll you in the Ambrisentan REMS	4) Your prescription will be mailed to you from a certified pharmacy that you and your doctor will choose
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How do I enroll in the Ambrisentan REMS?

Follow these steps with your doctor:

- ✓ Read all the patient information about ambrisentan and the Ambrisentan REMS included in this guide or on the Ambrisentan REMS website, www.ambrisentanrems.us.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 Ambrisentan REMS. Make sure you know how to receive and take ambrisentan
- ✓ You and your doctor choose a certified pharmacy to supply ambrisentan. In some cases, your insurance company may need you to use a specific certified pharmacy
- ✓ You and your doctor fill out the **Patient Enrollment Form**. After you read and sign it, your doctor sends it to the Ambrisentan REMS

What are the 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.

To receive ambrisentan, you must:

- Enroll in the Ambrisentan REMS by completing the **Patient Enrollment Form**
- Receive counseling from your prescriber on the risk of serious birth defects (Pre-pubertal females only)
- Tell your prescriber if you become pregnant or your ability to become pregnant changes
- If you are over the age of 8: Be monitored every year to see if your ability to become pregnant changes and tell your prescriber if your ability to become pregnant changes
 - Agree to be contacted by the Ambrisentan REMS if you become pregnant while on ambrisentan or within one month of stopping treatment.
 - 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.

To receive ambrisentan, you must:

- Enroll in the Ambrisentan REMS by completing the **Patient Enrollment Form**.
- Have a negative pregnancy test before you start taking ambrisentan and before you receive your refills. Your doctor orders the pregnancy tests for you. Your certified pharmacy will call you and ask if you have taken this test before shipping your refill.
- **Be sure you take your monthly pregnancy test as ordered by your doctor. Your certified pharmacy may call you and ask if you have taken this test before shipping your refill. If you do not take your pregnancy test every month, you may not receive your ambrisentan on time.**
- Agree to be contacted by the Ambrisentan REMS if you become pregnant while on ambrisentan or within one month of stopping treatment.

Do not have unprotected sex (intercourse). Use appropriate birth control during your ambrisentan treatment and for one month after stopping your ambrisentan treatment because the medicine may still be in your body. Page 4 of this guide shows your birth control options.

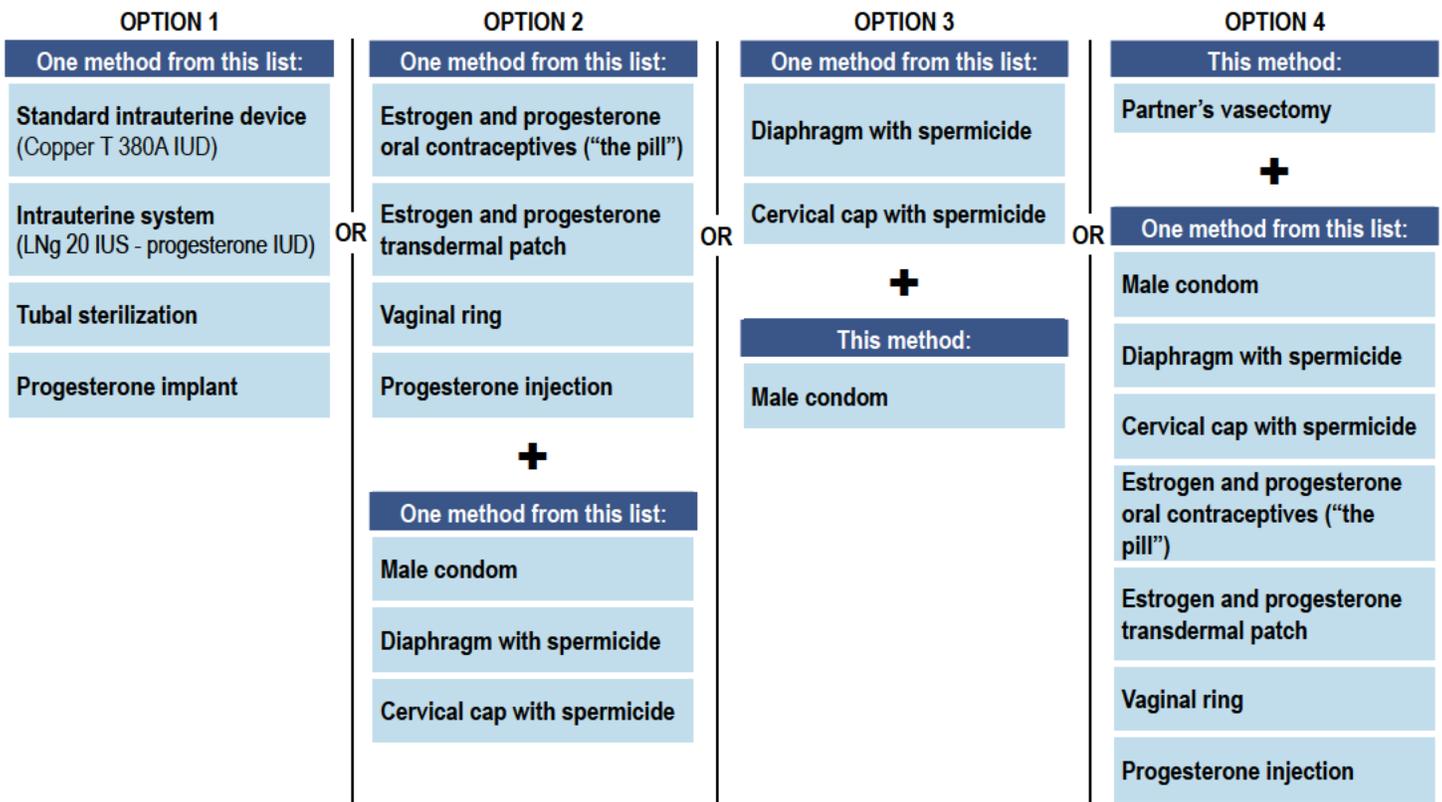
Talk to your doctor or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be pregnant. Your doctor may tell you to use emergency birth control. Do not wait until your next appointment to tell your doctor if you miss your menstrual period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

Your birth control options



How will I receive my Ambrisentan?

Certified pharmacies provide products and services for patients with certain diseases. Only certified pharmacies can provide ambrisentan to you. In some cases, your insurance company may require you to use a specific certified pharmacy.

Your certified pharmacy ships your ambrisentan refill to you. Before each shipment, you will be called to confirm that you have taken a monthly pregnancy test before refilling your prescription. **It is important that your certified pharmacy is able to contact you in order to avoid delays in your refills.**

If you have questions or concerns about ambrisentan, talk to your doctor. Please visit www.ambrisentanrems.us.com or call 1-888-417-3172 for more information about the Ambrisentan REMS.