

LETAIRIS RISK EVALUATION AND MITIGATION STRATEGY (REMS)

# Letairis REMS Program Guide for Female Patients

This guide is part of an FDA-approved REMS.



**Letairis<sup>®</sup>**  
*ambrisentan*

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*5 mg and 10 mg Tablets*

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## Information for Female Patients

### What is Letairis?

Letairis is a prescription medicine to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs. Letairis 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 Letairis?

**Letairis can cause serious birth defects if taken during pregnancy.** Females must not be pregnant when they start taking Letairis or become pregnant while taking Letairis, or for 1 month after stopping Letairis.

### What is the Letairis Risk Evaluation and Mitigation Strategy (REMS) Program?

Because of the risk of serious birth defects, the FDA has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for Letairis. The purpose of the Letairis REMS Program is to make sure the benefits of Letairis outweigh the risks. All females must enroll in the Letairis REMS Program to receive Letairis. Specific requirements apply to females who can get pregnant.

To receive Letairis:

- 1) You must talk with your doctor to ensure the benefits outweigh the risks of Letairis
- 2) You must agree to all of the requirements of the Letairis REMS Program. These requirements include monthly pregnancy tests and use of appropriate birth control for females who can get pregnant while taking Letairis and for 1 month after stopping Letairis
- 3) Your doctor will enroll you in the Letairis REMS Program
- 4) Your prescription will be mailed to you from a Certified Pharmacy that you and your doctor will choose

## How do I enroll in the Letairis REMS Program?

Follow these steps with your doctor:

- Read all the patient information about Letairis and the Letairis REMS Program included in this guide or on the Letairis REMS Program website, [www.letairisrems.com](http://www.letairisrems.com)
- Talk with your doctor to ensure the benefits outweigh the risks of Letairis
- Ask questions. Make sure you understand what you need to do to enroll and take part in the Letairis REMS Program. Make sure you know how to receive and take Letairis
- You and your doctor choose a Certified Pharmacy to supply Letairis. In some cases your insurance company may need you to use a specific Certified Pharmacy
- You and your doctor fill out the Letairis REMS Patient Enrollment and Consent Form. After you read and sign it, your doctor sends it to the Letairis REMS Coordinating Center

## What are the Letairis REMS Program 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 Letairis, you must:

- 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 the parent or guardian of a female child who started taking Letairis 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 passed through Menopause.

To receive Letairis, you must:

- **Have a negative pregnancy test before you start taking Letairis 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 tests as ordered by your doctor. You may not receive your Letairis refill on time if you do not take your monthly pregnancy tests**

Do not have unprotected sex. Use appropriate birth control during your Letairis treatment and for 1 month after stopping your Letairis treatment because the medicine may still be in your body. Page 5 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

### OPTION 1

One method from this list:

Standard intrauterine device  
(Copper T 380A IUD)

Intrauterine system  
(LNg 20 IUS - progesterone IUD)

Tubal sterilization

Progesterone implant

OR

### 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

OR

### OPTION 3

One method from this list:

Diaphragm with spermicide

Cervical cap with spermicide

+

This method:

Male condom

OR

### 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 Letairis?

Certified Pharmacies provide products and services for patients with certain diseases. Only Certified Pharmacies can provide Letairis to you. In some cases, your insurance company may require you to use a specific Certified Pharmacy.

Your Certified Pharmacy ships your Letairis refill to you. If you are a female who can get pregnant, 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 Letairis, talk to your doctor. Please visit [www.letairisrems.com](http://www.letairisrems.com) or call **1-866-664-5327** for more information about the Letairis REMS Program.



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*ambrisentan*

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The Letairis logo features a stylized orange and yellow wave graphic above the brand name. The word "Letairis" is in a bold, dark blue font with a registered trademark symbol, and "ambrisentan" is in a smaller, italicized, dark blue font. A thin horizontal line separates the brand name from the dosage information, which is also in an italicized font.