

The Letairis Risk Evaluation and Mitigation Strategy (REMS) Program

A Risk Evaluation and Mitigation Strategy is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

The purpose of the Letairis REMS Program is to:

- Inform prescribers, patients, and pharmacists about the risk of serious birth defects and safe-use conditions for Letairis
- Minimize the risk of fetal exposure and adverse fetal outcomes in Females of Reproductive Potential prescribed Letairis
 - Females who are pregnant must not be prescribed Letairis
 - Females taking Letairis must not become pregnant

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FOR PRESCRIBERS (ANNOTATED TEXT...WILL NOT APPEAR ON LIVE SITE)

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In order to ensure that Letairis is prescribed and taken safely, Gilead has worked with the FDA to develop materials for the Letairis REMS Program to inform prescribers and patients about the risk of serious birth defects.

Letairis REMS Program Prescriber Materials

Prescriber Guide to the Letairis REMS Program

Prescriber Enrollment and Agreement Form

Patient Enrollment and Consent Form

Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form

Letairis REMS Program Patient Education Materials

Letairis REMS Program Guide for Females Who Can Get Pregnant

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Overview of the Letairis REMS Program

- Prescribers must enroll in the Letairis REMS Program and comply with the Letairis REMS Program requirements to prescribe Letairis
- All female patients must enroll in the Letairis REMS Program to receive Letairis
- Prescribers must educate and counsel Females of Reproductive Potential and Pre-Pubertal Females as described in the *Prescriber Guide to the Letairis REMS Program*. The parent/guardian of the Pre-Pubertal Female must also be educated and counseled on the risks of Letairis.
- Required pregnancy testing for Females of Reproductive Potential prior to writing a prescription for Letairis and monthly thereafter, including 1 month after stopping treatment with Letairis
- Letairis is only available through a restricted distribution program

Changes to the Letairis REMS Program (October 2014)

- New definition of Female of Non-Reproductive Potential
- Revised form: *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form*

- **The following is a list of participating Certified Pharmacies:**

Accredo

Aetna Specialty Pharmacy

CIGNA Tel-Drug

CuraScript

CVS Caremark

Exactus Pharmacy Solutions

Kaiser Specialty Pharmacy

OptumRx

RightSource Specialty Pharmacy

Walgreens Specialty Pharmacy

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Welcome to the Letairis Risk Evaluation and Mitigation Strategy Program

What is the Letairis 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; however, specific requirements apply to females who can get pregnant.

For Female Patients 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. For women who can get pregnant, these requirements include monthly pregnancy tests and use of appropriate birth control 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

For women who can get pregnant, learn more about the Letairis REMS Program.
Download this helpful guide.

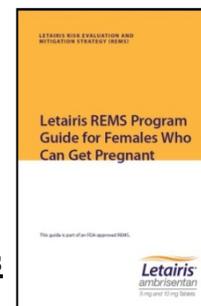
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