

Is the combination of **Letairis + tadalafil** right for you?

What is Letairis?

Letairis is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of the lungs. When taken with tadalafil, Letairis is used to reduce the risk of your disease progressing, to reduce the risk of hospitalization due to worsening PAH, and to improve your ability to exercise.

Take this discussion guide to your PAH Specialist to:

- 1 Review how you feel today
- 2 Discuss your PAH condition
- 3 Together, set goals for your treatment

1 Review how you feel today. Start by sharing the following information with your PAH Specialist:

Since my last doctor visit, I am feeling:

Better Worse About the same

Provide any specific examples or events:

I am currently experiencing the following symptoms:

Please see additional Important Safety Information throughout this brochure and full [Prescribing Information](#), including Medication Guide with **important warnings**, at www.Letairis.com.

Important Safety Information

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT 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**
- Females who are able to get pregnant must have a negative pregnancy test before starting Letairis, every month while taking Letairis, and 1 month after stopping Letairis. Your doctor will decide when to do the tests, and order the tests for you depending on your menstrual cycle
 - Females who **are able** to get pregnant are females who have entered puberty (even if they have not started their period), **and** have a uterus, **and** have not gone through menopause (menopause means that you have not had a period for at least 12 months for natural reasons, or that you have had your ovaries removed)


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Discuss your condition with your PAH Specialist:

WHO Functional Class

The World Health Organization (WHO) developed a scale based on the amount of physical activity a person with PAH can do. There are four classes, called WHO Functional Classes (FC). A PAH Specialist decides which WHO Functional Class a patient belongs to depending on their PAH symptoms. This scale helps PAH Specialists track a patient's progress.

What is my WHO Functional Class?

FC I FC II FC III FC IV Not known

Has my Functional Class changed since my last visit? Yes No

Notes:

Has my Functional Class changed since diagnosis? Yes No

Notes:

6-Minute Walk Distance

My current 6-Minute Walk Distance (6MWD) is

How do you use my 6MWD to assess my condition?

Has my 6MWD changed since my last visit? Yes No

Since diagnosis? Yes No

What's next?

Is there room for improvement with my PAH condition?

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Important Safety Information (continued)

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT LETAIRIS? (CONTINUED)

Females who are able to get pregnant must use two acceptable forms of birth control while taking Letairis and for 1 month after stopping Letairis because the medicine may still be in the body. See the Letairis Medication Guide for acceptable birth control options.

- If you have had a tubal sterilization or have an IUD (intrauterine device) or progesterone implant, these methods can be used alone and no other form of birth control is needed
- Talk with your doctor to find out about options for acceptable forms of birth control that you may use to prevent pregnancy during treatment with Letairis
- If you decide that you want to change the form of birth control, talk with your doctor to be sure that you choose another acceptable form of birth control
- **Do not have unprotected sex. Talk to your doctor or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your doctor may tell you to use emergency birth control**
- **Tell your doctor right away if you miss a menstrual period or think you may be pregnant**

If you are the parent or caregiver 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 any pubic hair.

Your child may reach puberty before having her first menstrual period.

Females can only receive Letairis through a restricted program called the Letairis Risk Evaluation and Mitigation (REMS) program. If you are a female who can get pregnant, you must talk to your doctor, understand the benefits and risks of Letairis, and agree to all of the instructions in the Letairis REMS program.


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Together, set treatment goals. Let your PAH Specialist know your treatment goals. For example, I would like to:

- ___ Improve my ability to walk farther
- ___ Reduce the risk of my PAH getting worse
- ___ Reduce the likelihood of being hospitalized due to my PAH
- ___ Other goals:

What is your next treatment step? Here are some questions to ask your PAH Specialist:

Would an adjustment to my PAH treatment help me achieve the goals we've discussed?

Yes No

Notes:

Do you feel that combination therapy with Letairis and tadalafil may be right for me? Is there anything else I should know about this therapy?

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Important Safety Information (continued)

WHO SHOULD NOT TAKE LETAIRIS?

Do not take Letairis if:

- **You are pregnant, plan to become pregnant, or become pregnant while taking Letairis. Letairis can cause serious birth defects.** (See "What is the most important information I should know about Letairis?")
- You have Idiopathic Pulmonary Fibrosis (IPF)

WHAT SHOULD I AVOID WHILE TAKING LETAIRIS?

- **Do not get pregnant.** If you miss a menstrual period, or think you might be pregnant, call your doctor right away
- **Do not breastfeed.** It is not known if Letairis passes into your breast milk

WHAT ARE THE OTHER POSSIBLE SIDE EFFECTS OF LETAIRIS?

Serious side effects of Letairis can include:

- **Swelling all over the body** (fluid retention) can happen within weeks after starting Letairis. Tell your doctor right away if you have any unusual weight gain, tiredness, or trouble breathing while taking Letairis. These may be symptoms of a serious health problem. You may need to be treated with medicine or need to go to the hospital
- **Decreased sperm counts** have happened in some men taking a medicine that is like Letairis, which may affect your ability to father a child. Tell your doctor if being able to have children is important to you
- **Low red blood cell levels** (anemia) can happen during the first weeks after starting Letairis. If this happens, you may need a blood transfusion. Your doctor will do blood tests to check your red blood cells before starting Letairis. Your doctor may also do these tests while you are taking Letairis


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Important Safety Information (continued)

WHAT ARE THE OTHER POSSIBLE SIDE EFFECTS OF LETAIRIS? (CONTINUED)

The most common side effects of Letairis when taken with tadalafil are swelling of hands, legs, ankles and feet (peripheral edema), headache, stuffy nose (nasal congestion), cough, low red blood cell levels (anemia), indigestion (dyspepsia) or upper respiratory tract infection (bronchitis).

Some medicines that are like Letairis can cause liver problems. Tell your doctor if you get any of these symptoms while taking Letairis: loss of appetite, nausea or vomiting, fever, achiness, generally do not feel well, pain in the upper right stomach (abdominal) area, yellowing of your skin or the whites of your eyes, dark urine, itching.

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING LETAIRIS?

- **All your medical conditions.** Be sure to tell your doctor if you have a low red blood cell level (anemia) or liver problems
- **All the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.** Letairis and other medicines may affect each other causing side effects. Do not start any new medicines until you check with your doctor
- **Especially tell your doctor if you take cyclosporine (Gengraf, Neoral, Sandimmune).** Your doctor may need to change your dose of Letairis

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Keep Letairis and all medicines out of the reach of children.

For more information, call 1-866-664-5327 or visit www.letairis.com or www.gilead.com.

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