



# 5 questions to ask your doctor about PAH and Letairis

Print this short list of questions and discuss them with your doctor.

1. What are the side effects associated with taking Letairis I should be aware of?

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2. What are some ways to help manage any side effects I may be experiencing?

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3. How do I know the difference between normal and severe shortness of breath?

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4. Should I make any dietary changes while taking Letairis?

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5. Is starting an exercise plan right for me?

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Letairis (ambrisentan) is a prescription medicine to treat pulmonary arterial hypertension (PAH) (WHO Group 1) in patients with WHO Class II or III symptoms. PAH is high blood pressure in the arteries of the lungs. Letairis can improve your ability to exercise, and it can help slow down the worsening of your physical condition and symptoms.

Please see [full Prescribing Information](#), including [Medication Guide](#), with **important warnings** on the **risk of serious birth defects**, or visit [www.Letairis.com](http://www.Letairis.com).

Please see Important Safety Information on next pages.

## 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 beginning Letairis, each month during treatment, and one 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 women who:
    - Have entered puberty (even if they have not started their period), **and** have a uterus, **and** have not gone through menopause (have not had a period for at least 12 months for natural reasons, or who have had their ovaries removed)

**Females who are able to get pregnant must use two acceptable forms of birth control, while taking Letairis and for one month after stopping Letairis because the medication may still be in the body.**

- If you have had a tubal sterilization or have an IUD or progesterone implant, these methods can be used alone and no other form of birth control is needed.
- Talk with your doctor or gynecologist 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.**

### Who should not take Letairis?

**Do not take Letairis if:**

- **You are pregnant, plan to become pregnant, or become pregnant during treatment with Letairis. Letairis can cause serious birth defects.** (See “What is the most important information I should know about Letairis?”)
- You have a condition called Idiopathic Pulmonary Fibrosis (IPF)

Please see additional Important Safety Information on next page.

## IMPORTANT SAFETY INFORMATION (continued)

**Tell your doctor about all your medical conditions and all the medicines you take including prescription and nonprescription medicines.** 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 the medicine cyclosporine (Gengraf, Neoral, Sandimmune).** Your doctor may need to change your dose of Letairis. Do not take more than 5 mg of Letairis per day while taking cyclosporine.

### How should I take Letairis?

- Take Letairis exactly as your doctor tells you. Do not stop taking Letairis unless your doctor tells you.
- You can take Letairis with or without food.
- Do not split, crush or chew Letairis tablets.
- If you take more than your regular dose of Letairis, call your doctor right away.
- If you miss a dose, take it as soon as you remember that day. Take your next dose at the regular time. Do not take two doses at the same time to make up for a missed dose.

### What should I avoid while taking Letairis?

- **Do not get pregnant** while taking Letairis. (See the serious birth defects section of “What is the most important information I should know about Letairis?”) If you miss a menstrual period, or think you might be pregnant, call your doctor right away.
- **It is not known if Letairis passes into your breast milk. You should not breastfeed if you take Letairis.**

### What are the possible side effects of Letairis?

#### Serious side effects of Letairis include:

- **Serious birth defects.** (See “What is the most important information I should know about Letairis?”)
- **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.
- **Sperm count reduction.** Reduced sperm counts have been observed in some men taking a drug similar to Letairis, an effect which might impair their ability to father a child. Tell your doctor if remaining fertile is important to you.

Please see additional Important Safety Information on next page.

## IMPORTANT SAFETY INFORMATION (continued)

- **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 during treatment with Letairis.

### **The most common side effects of Letairis are:**

- Swelling of hands, legs, ankles and feet (peripheral edema)
- Stuffy nose (nasal congestion)
- Inflamed nasal passages (sinusitis)
- Hot flashes or getting red in the face (flushing)

Some medicines that are like Letairis can cause liver problems. Tell your doctor if you get any of these symptoms of a liver problem 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

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of Letairis. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 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](http://www.letairis.com) or [www.gilead.com](http://www.gilead.com).**

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