

Medication Guide
LETAIRIS® (le-TAIR-is)
(ambrisentan)
Tablets

Read this Medication Guide before you start taking LETAIRIS and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about LETAIRIS?

- **Serious birth defects.**

LETAIRIS can cause serious birth defects if taken during pregnancy.

- **Women must not be pregnant when they start taking LETAIRIS or become pregnant during treatment.**
- Women who are able to get pregnant must have a negative pregnancy test before beginning treatment with LETAIRIS and each month during treatment. Your doctor will decide when to do the test, depending on your menstrual cycle.

Women who are able to get pregnant must use two acceptable forms of birth control, during LETAIRIS treatment and for one month after stopping LETAIRIS.

- If you have had a tubal sterilization or have an IUD, these methods can be used alone and no other form of birth control is needed.
- Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out about how to prevent pregnancy.
- **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.**

LETAIRIS is available only through a restricted program called the LETAIRIS Education and Access Program (LEAP). To receive LETAIRIS, you must talk to your doctor, understand the benefits and risks of LETAIRIS, and agree to all of the instructions in the LEAP program.

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.

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?”) Serious birth defects from LETAIRIS happen early in pregnancy.

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. You should not take more than 5 mg of LETAIRIS each day if you also take cyclosporine.

LETAIRIS has not been studied in children.

How should I take LETAIRIS?

LETAIRIS will be mailed to you by a specialty pharmacy. Your doctor will give you complete details.

- 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.
- It will be easier to remember to take LETAIRIS if you take it at the same time each day.
- 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.
- **Breastfeeding is not recommended** while taking LETAIRIS. It is not known if LETAIRIS can pass through your milk and harm your baby.

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.
- **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:

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| • loss of appetite | • pain in the upper right stomach (abdominal) area |
| • nausea or vomiting | • yellowing of your skin or the whites of your eyes |
| • fever | • dark urine |
| • achiness | • itching |
| • generally do not feel well | |

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.

How should I store LETAIRIS?

Store LETAIRIS at 59 °F to 86 °F (15 °C to 30 °C), in the package it comes in.

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

General information about LETAIRIS

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LETAIRIS for a condition for which it was not prescribed. Do not give LETAIRIS to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about LETAIRIS. If you would like more information, ask your doctor. You can ask your doctor or pharmacist for information about LETAIRIS that is written for healthcare professionals.

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

What are the ingredients in LETAIRIS?

Active ingredient: ambrisentan

Inactive Ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The tablets are film-coated with a coating material containing FD&C Red #40 aluminum lake, lecithin, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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