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## Ambrisentan

pronounced as (am" bri sen' tan)

### IMPORTANT WARNING:

Do not take ambrisentan if you are pregnant or plan to become pregnant. Ambrisentan may harm the fetus. If you are a woman and able to become pregnant, you should not begin taking ambrisentan until a pregnancy test has shown that you are not pregnant. You must use two reliable methods of birth control during treatment with this medication and for 1 month after stopping treatment. Do not have unprotected sex. Talk to your doctor about birth control methods that will work for you. Call your doctor immediately if you miss a menstrual period or think you may be pregnant while you are taking ambrisentan.

Because of the risk of birth defects, ambrisentan is available to females only through a special restricted distribution program. A program called Ambrisentan REMS ( Risk Evaluation and Mitigation Strategy) has been set up to make sure that female patient have appropriate lab tests before and while they are receiving ambrisentan. Women can get ambrisentan only if they are registered with this program. Your doctor must enroll you in this program. You can only receive the medication from a pharmacy that participates in the program. Ask your doctor if you have any questions about participating in the program or how to get your medication.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests during your treatment with ambrisentan.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with ambrisentan and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking ambrisentan.

### Why is this medication prescribed?

Ambrisentan is used alone or in combination with tadalafil (Adcirca, Cialis) to treat pulmonary arterial hypertension (PAH, high blood pressure in the vessels that carry blood to the lungs). Ambrisentan may improve the ability to exercise and slow the worsening of symptoms in people with PAH. Ambrisentan is in a class of medications called endothelin receptor antagonists. It works by stopping the action of endothelin, a natural substance that causes blood vessels to narrow and prevents normal blood flow in people who have PAH.

## How should this medicine be used?

Ambrisentan comes as a tablet to take by mouth. It is usually taken with or without food once a day. Take ambrisentan at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ambrisentan exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole; do not split, chew, or crush them.

Your doctor may start you on a low dose of ambrisentan and gradually increase your dose.

Ambrisentan controls the symptoms of PAH but does not cure it. Continue to take ambrisentan even if you feel well. Do not stop taking ambrisentan without talking to your doctor. If you suddenly stop taking ambrisentan, your condition may worsen.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking ambrisentan,

- tell your doctor and pharmacist if you are allergic to ambrisentan, any other medications, or any of the ingredients in ambrisentan tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention if you are taking cyclosporine (Gengraf, Neoral, Sandimmune). Your doctor may need to change the dose of your medications or monitor you carefully for side effects.
- tell your doctor if you have idiopathic pulmonary fibrosis (scarring of the lungs with an unknown cause). Your doctor will probably tell you not to take ambrisentan.
- tell your doctor if you have or have ever had anemia (a lower than normal amount of red blood cells) or liver disease.
- tell your doctor if you are breastfeeding. Do not breastfeed if you are taking ambrisentan.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Ambrisentan may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- flushing
- pale skin
- fast heartbeat
- headache

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:**

- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- difficulty swallowing or breathing
- rash
- unusual weight gain
- extreme tiredness
- loss of appetite
- lack of energy
- nausea
- vomiting
- pain in the upper right stomach area
- yellowing of the skin or eyes
- flu-like symptoms
- itching
- dark colored urine

Some men taking a medication similar to ambrisentan developed a lower than normal sperm count (number of male reproductive cells); an effect that might affect their ability to father a child. Talk to your doctor about the risks of taking ambrisentan if you would like to have children in the future.

Ambrisentan may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- headache
- flushing
- dizziness
- nausea
- nasal congestion

## What other information should I know?

Do not let anyone else take your medication.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Letairis<sup>®</sup>

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