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Medication Guide

Ambrisentan (am" bri sen' tan) Tablets

Read this Medication Guide before you start taking ambrisentan tablets 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 ambrisentan tablets?

- **Serious birth defects. Ambrisentan tablets can cause serious birth defects if taken during pregnancy.**
 - o Females must not be pregnant when they start taking ambrisentan tablets or become pregnant during treatment with ambrisentan tablets.
 - o Females who are able to get pregnant must have a negative pregnancy test before beginning treatment with ambrisentan tablets, each month during treatment with ambrisentan tablets, and one month after stopping ambrisentan tablets. Talk to your doctor about your menstrual cycle. Your doctor will decide when to do a pregnancy test, and will order a pregnancy test 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 menstrual period, **and**
 - have a uterus, **and**
 - have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.
 - Females who **are not able** to get pregnant are females who:
 - have not yet entered puberty, **or**
 - do not have a uterus, **or**
 - have gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed, **or**
 - who are infertile for any other medical reason and this infertility is permanent and cannot be reversed

Females who are able to get pregnant must use two acceptable forms of birth control during treatment with ambrisentan tablets, and for one month after stopping ambrisentan tablets because the medicine may still be in the body.

- o 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.

- o Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out about options for acceptable forms of birth control that you may use to prevent pregnancy during treatment with ambrisentan tablets.
- o If you decide that you want to change the form of birth control that you use, talk with your doctor or gynecologist to be sure that you choose another acceptable form of birth control.

See the chart below for Acceptable Birth Control Options during treatment with ambrisentan tablets.

Acceptable Birth Control Options

Option 1	Option 2	Option 3	Option 4
One method from this list:	OR	One method from this list:	OR
Standard intrauterine device (Copper T 380A IUD)		Estrogen and progesterone oral contraceptives ("the pill")	
Intrauterine system (LNg 20 IUS – progesterone IUD)		Estrogen and progesterone transdermal patch	
Tubal sterilization		Vaginal ring	
Progesterone implant		Progesterone injection	
		PLUS	
		One method from this list:	
		Male condom	
		Diaphragm with spermicide	
		Cervical cap with spermicide	
		Male condom	
		Cervical cap with spermicide	
		Estrogen and progesterone oral contraceptive ("the pill")	
		Estrogen and progesterone transdermal patch	
		Vaginal ring	
		Progesterone injection	

- o **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.**
- o **Tell your doctor right away if you miss a menstrual period or think you may be pregnant for any reason.**

If you are the parent or caregiver of a female child who started taking ambrisentan tablets 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 pubic hair. Your doctor should decide if your child has reached puberty. **Your child may reach puberty before having her first menstrual period.**

Females can only receive ambrisentan tablets through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Ambrisentan REMS. If you are a female who can get pregnant, you must talk to your doctor, understand the benefits and risks of ambrisentan tablets, and agree to all of the instructions in the Ambrisentan REMS. Males can receive ambrisentan tablets without taking part in the Ambrisentan REMS.

What are ambrisentan tablets?

- Ambrisentan tablets are a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.
- Ambrisentan tablets can improve your ability to exercise and it can help slow down the worsening of your physical condition and symptoms.
- It is not known if ambrisentan tablets are safe and effective in children.

Who should not take ambrisentan tablets?

Do not take ambrisentan tablets if:

- **you are pregnant, plan to become pregnant, or become pregnant during treatment with ambrisentan tablets. Ambrisentan tablets can cause serious birth defects.** (See "What is the most important information I should know about ambrisentan tablets?") Serious birth defects from ambrisentan tablets happen early in pregnancy.
- you have a condition called Idiopathic Pulmonary Fibrosis (IPF)

What should I tell my doctor before taking ambrisentan tablets?

Before you take ambrisentan tablets, tell your doctor if you:

- have been told that you have a low red blood cell level (anemia)
- have liver problems
- have any other medical conditions

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Ambrisentan tablets 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 ambrisentan tablets.

How should I take ambrisentan tablets?

- Ambrisentan tablets will be mailed to you by a certified pharmacy. Your doctor will give you complete details.
- Take ambrisentan tablets exactly as your doctor tells you to take it. Do not stop taking ambrisentan tablets unless your doctor tells you to stop.
- You can take ambrisentan tablets with or without food.
- Do not split, crush or chew ambrisentan tablets.
- It will be easier to remember to take ambrisentan tablets if you take it at the same time each day.
- If you take more than your regular dose of ambrisentan tablets, 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 ambrisentan tablets?

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

What are the possible side effects of ambrisentan tablets?

Ambrisentan tablets can cause serious side effects including:

- See “**What is the most important information I should know about ambrisentan tablets?**”
- **Swelling all over the body** (fluid retention) can happen within weeks after starting ambrisentan tablets. Tell your doctor right away if you have any unusual weight gain, tiredness, or trouble breathing while taking ambrisentan tablets. 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 count.** Decreased sperm counts have happened in some men taking a medicine that is like ambrisentan tablets. A decreased sperm count may affect the 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 ambrisentan tablets. If this happens, you may need a blood transfusion. Your doctor will do blood tests to check your red blood cells before starting ambrisentan tablets. Your doctor may also do these tests during treatment with ambrisentan tablets.

The most common side effects of ambrisentan tablets include:

- 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 ambrisentan tablets can cause liver problems. Tell your doctor if you get any of these symptoms of a liver problem while taking ambrisentan tablets:

- 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 ambrisentan tablets. 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. For more information call 1-800-818-4555.

How should I store ambrisentan tablets?

Store ambrisentan tablets at room temperature between 68°F to 77°F (20°C to 25°C), in the package they come in.

Keep ambrisentan tablets and all medicines out of the reach of children.

General information about the safe and effective use of ambrisentan tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ambrisentan tablets for a condition for which it was not prescribed. Do not give ambrisentan tablets 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 ambrisentan tablets. If you would like more information, ask your doctor. You can ask your doctor or pharmacist for information about ambrisentan tablets that is written for health professionals.

What are the ingredients in ambrisentan tablets?

Active ingredient: ambrisentan

Inactive Ingredients: anhydrous lactose, colloidal silicon dioxide, croscarmellose sodium, 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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