What is the most important information I should know about ambrisentan tablets?

**What are the possible side effects of ambrisentan tablets?**

Side effects that may be serious include:

- Birth defects

Other side effects include:

- Changes in menstrual cycle
- Decrease in hemoglobin
- Decrease in sperm counts
- Edema
- Increase in liver enzymes
- Injection site reaction
- Increase in blood pressure

**Who should not take ambrisentan tablets?**

People with the following conditions should not take ambrisentan tablets:

- Pregnancy
- Breastfeeding
- Allergy to ambrisentan

**What other drugs will affect ambrisentan tablets?**

Talk to your doctor if you are taking other prescription or nonprescription medicines.

**How should I store ambrisentan tablets?**

Store ambrisentan tablets at room temperature and away from moisture.

**Keep ambrisentan tablets out of reach of children.**

**Ambrisentan Tablets**

Ambrisentan tablets are available as 5 mg and 10 mg film-coated tablets for once daily oral administration. The tablets contain the following inactive ingredients: lactose monohydrate, starch, pregelatinized starch, talc, titanium dioxide, and yellow iron oxide.
You can take ambrisentan tablets with or without food.

How should I take ambrisentan tablets?

• 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.
• Ambrisentan tablets will be mailed to you by a certified pharmacy. Your doctor will give you complete details.

What should I avoid while taking ambrisentan tablets?

• Avoid alcohol and all other substances (including illegal drugs) that may cause drowsiness or dizziness while taking ambrisentan tablets. Stop any of these activities if you feel these symptoms.

What are the possible side effects of ambrisentan tablets?

• These are not all the possible side effects of ambrisentan tablets. For more information, call Par Pharmaceutical at 1-800-828-9393.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ambrisentan tablets

Before starting ambrisentan tablets, talk with your doctor about the best way to feed your baby if you take ambrisentan tablets. Talk with your doctor about the use of other medicines that can affect your baby.

Instruct your prescribing doctors and midwives of the possibility of fetal harm and ensure that all women of reproductive potential are properly counseled. Ask female patients (and their guardians, if applicable) to sign an enrollment form as part of the Ambrisentan REMS. Instruct females of reproductive potential to immediately contact their doctor if they become pregnant while taking ambrisentan tablets.

What is the most important information I should know about ambrisentan tablets?

• Liver problems (hepatic failure) can happen within weeks after starting ambrisentan tablets. Tell your doctor right away if you have any of the following signs of liver problems: sudden weight gain, nausea, tiredness, loss of appetite, vomiting, or yellowing of the skin or eyes (jaundice).
• Severe fluid retention (edema) can happen within weeks after starting ambrisentan tablets. Tell your doctor right away if you have any of the following signs of fluid retention: swelling of your feet, legs, or abdomen; difficult or labored breathing; or shortness of breath.
• Some side effects of ambrisentan tablets may occur even after you stop taking it. Tell your doctor if you have any of these side effects, which may also occur after you stop taking ambrisentan tablets: sudden or uncontrolled loss of consciousness; uncontrolled or unresponsive eye movements; unusual movements of the limbs; changes in vision; and blurred vision.

For more information, call Par Pharmaceutical at 1-800-828-9393.