The Ambrisantan REMS (Risk Evaluation and Mitigation Strategy) is a safety program that manages the risk of serious birth defects when taking ambrisantan. The Ambrisantan REMS is required by the Food and Drug Administration (FDA).

- Only prescribers and pharmacies certified by the Ambrisantan REMS can prescribe and dispense ambrisantan to patients.
- Patients must be enrolled in the Ambrisantan REMS and follow all the safety rules in the REMS in order to receive ambrisantan.

**Prescribers**

To prescribe ambrisantan:

1. Review the Prescribing Information and Prescriber and Pharmacy Guide
2. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the Ambrisantan REMS
3. Assess the patient’s reproductive status as defined in the Prescriber and Pharmacy Guide
4. Enroll all females in the Ambrisantan REMS by completing and submitting the Patient Enrollment Form to the Ambrisantan REMS
5. Report any changes in the reproductive status of a female patient via the Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form

**Female Patients**

To receive ambrisantan:

1. Review the Guide for Female Patients
2. Receive counseling from your prescriber to understand the risks associated with ambrisantan
3. Enroll in the Ambrisantan REMS by completing the Patient Enrollment Form with your healthcare provider
4. For females who can get pregnant:
   - Complete a monthly pregnancy test and use appropriate birth control while taking ambrisantan and for one month after treatment discontinuation
5. For females who cannot get pregnant:
   - Tell your healthcare provider if you become pregnant or your ability to become pregnant changes.
   - If you are over the age of 18, be monitored every year to see if your ability to become pregnant changes and tell your healthcare provider if your ability to become pregnant changes
6. Report changes in reproductive status to your healthcare provider

**Outpatient Pharmacies**

To dispense ambrisantan:

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Ambrisantan REMS on behalf of the pharmacy
2. Have the authorized representative enroll in the Ambrisantan REMS by completing the Outpatient Pharmacy Enrollment Form, and submitting it to the Ambrisantan REMS
3. Train staff involved in dispensing ambrisantan and comply with Ambrisantan REMS requirements
4. Obtain authorization to dispense each prescription by contacting the Ambrisantan REMS online or by phone to verify the patient’s prescriber is enrolled for all patients and if the patient is female, verify the patient is enrolled
   - For females of Reproductive Potential (RPR)
     - Disperse no more than a 30-day’s supply
5. Support electronic data exchanges and communication with the Ambrisantan REMS system

**Inpatient Pharmacies**

To dispense ambrisantan:

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Ambrisantan REMS on behalf of the pharmacy
2. Have the authorized representative enroll in the Ambrisantan REMS by completing the Inpatient Pharmacy Enrollment Form, and submitting it to the Ambrisantan REMS
3. Train staff involved in dispensing ambrisantan and comply with Ambrisantan REMS requirements
4. Obtain authorization to dispense each prescription by contacting the Ambrisantan REMS online or by phone to verify the patient’s prescriber is enrolled for all patients and if the patient is female, verify the patient is enrolled
   - Dispense no more than a 15-day’s supply at discharge

**PDFs for Download**

- Ambrisantan REMS Prescriber and Pharmacy Guide
- Ambrisantan REMS Prescriber Enrollment and Agreement Form
- Ambrisantan REMS Prescriber Enrollment Form
- Ambrisantan REMS Patient Enrollment and Consent Form
- Ambrisantan REMS Guide for Female Patients
- Ambrisantan REMS Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form
- Ambrisantan REMS Outpatient Pharmacy Enrollment Form
- Ambrisantan REMS Outpatient Pharmacy Guide
- Ambrisantan REMS Inpatient Pharmacy Enrollment Form
- Ambrisantan REMS Inpatient Pharmacy Guide
- Ambrisantan REMS Inpatient Pharmacy Guide

To learn more about the serious risks associated with ambrisantan, please refer to the US Prescribing Information including Boxed Warning, Ambrisantan REMS Prescriber and Pharmacy Guide and Ambrisantan REMS Guide for Female Patients.
### List of products covered under the Ambrisentan REMS

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Dosage</th>
<th>Company</th>
<th>Contact</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prescribing Information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Generic:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Name</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Prescribers

The goal of the Ambrisantan Risk Evaluation and Mitigation Strategy (REMS) is to mitigate the risk of embryo-fetal toxicity associated with ambrisantan by:

- Ensuring prescribers are educated on the following:
  - the risks of embryo-fetal toxicity

- Ensuring prescribers are educated on and adhere to the following:
  - counselling patients about these risks and the need for monthly monitoring
  - enrolling patients in the Ambrisantan REMS
  - monitoring patients at baseline and monthly

- Ensuring that pharmacies are educated on the following:
  - the risks of embryo-fetal toxicity

- Ensuring that pharmacies are educated on and adhere to the following:
  - confirming that the appropriate patient monitoring and counseling has occurred before dispensing ambrisantan

- Ensuring that patients are informed about:
  - the risks of embryo-fetal toxicity
  - appropriate baseline and monthly patient monitoring
  - appropriate contraception

Prescriber Requirements

How do I become certified in the Ambrisantan REMS?

1. Review the following educational materials to understand the Ambrisantan REMS and the risks of ambrisantan:
   - Prescribing Information
   - Prescriber and Pharmacy Guide

2. Complete and submit the Prescriber Enrollment Form:
   - Online
   - By fax

How do I enroll my patient in the Ambrisantan REMS and what steps should I take prior to treatment initiation?

1. For all females: Assess the female’s reproductive status as described in the Prescriber and Pharmacy Guide.
2. For all females: Counsel the patient that the drug is only available through a restricted distribution program.
3. For females of reproductive potential: Counsel the patient on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, and the need to use emergency contraception using the Guide for Female Patients.
4. For females of reproductive potential: Assess the patient’s pregnancy status by ordering and reviewing her pregnancy test result.
5. For females of reproductive potential: Prescribe no more than a 30 days’ supply.
6. For a Pre-Pubertal Female: Counsel the patient and parent/guardian on the risk of embryo-fetal toxicity using the Guide for Female Patients.
7. Enroll all female patients by completing the Patient Enrollment Form prior to prescribing ambrisantan:
   - Online
   - By fax

Once a patient is on ambrisantan, how often should I monitor my patients?

- For a female of reproductive potential: Counsel the patient if she is not complying with the required testing or if she is not using appropriate contraception.
- For a female of reproductive potential: Assess the patient’s pregnancy status by ordering and reviewing her pregnancy test result.
- For a Pre-Pubertal Female: Assess the patient’s reproductive status regularly.
- For a Pre-Pubertal Female at least age 8 or older: Document reproductive status and submit to the Ambrisantan REMS at least annually using the Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form.
- At all times for all patients, report a change or misclassification in reproductive status to the Ambrisantan REMS using the Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form within 10 days of being aware of a change:
  - Online
  - By fax

Notify the Ambrisantan REMS if any patient becomes pregnant during ambrisantan treatment or within one month following treatment discontinuation.
Patients

What is Ambriusant?
Ambriusant is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs. Ambriusant can improve your ability to exercise and it can help slow down the worsening of your physical condition and symptoms.

What are the serious risks of Ambriusant?
Ambriusant can cause serious birth defects if taken during pregnancy. Females must not be pregnant when they start taking Ambriusant or become pregnant while taking Ambriusant, or for one month after stopping Ambriusant.

How do I become enrolled in the Ambriusant REMS?
1. Read the Guideline for Female Patients
2. Review this information with your doctor.
3. Enroll in the Ambriusant REMS by completing the Patient Enrollment Form with your doctor.

Please refer to the details provided below and in the Guideline for Female Patients for further clarification on the Ambriusant REMS requirements.

What are the Ambriusant REMS requirements for me?

Females Who Cannot Get Pregnant
You are considered a female who cannot get pregnant if you have not yet entered puberty, or you do not have a uterus, or you have gone through menopause, or you are infertile for any other medical reason and this infertility is permanent and cannot be reversed.

To receive Ambriusant, you must:
- Talk to your doctor to ensure the benefits outweigh the risks of Ambriusant.
- Review this information with the Guideline for Female Patients.
- Enroll in the Ambriusant REMS by completing the Patient Enrollment Form.
- Receive counseling from your prescriber on the risk of serious birth defects (see paragraph below for females only).
- Tell your prescriber if you become pregnant or if your ability to become pregnant changes, and tell your prescriber if your ability to become pregnant changes.
- If you are pregnant or a patient of a female who cannot get pregnant, you should check your medical history to see if the drug is developing signs of puberty. Tell your doctor right away if you notice that she is developing breast buds or a pubic hair. Your doctor should check if you have not reached puberty. Your child may reach puberty before having her first menstrual period.

Females Who Can Get Pregnant
You are considered to be a female who can get pregnant if you have entered puberty, have a uterus, and have not gone through Menopause.

To receive Ambriusant, you must:
- Talk to your doctor to ensure the benefits outweigh the risks of Ambriusant.
- Review this information with the Guideline for Female Patients.
- Have a negative pregnancy test before you start taking Ambriusant and before you receive your refills. Your doctor orders the pregnancy test for you.
- Enroll in the Ambriusant REMS by completing the Patient Enrollment Form.
- Receive counseling from your prescriber on the risk of serious birth defects.
- Be sure to take your monthly pregnancy test as ordered by your doctor. Your certified pharmacy will call you and let you know if you have taken this test before stopping your refills. If you don't take your pregnancy test every month, you may not receive your Ambriusant on time.
- Agree to be contacted by the Ambriusant REMS if you become pregnant while on Ambriusant or within one month of stopping treatment.

Do not have unprotected sex (intercourse). Use appropriate birth control during your Ambriusant treatment, and for one month after stopping your Ambriusant treatment because the medicine may still be in your body.

Talk to your doctor or pharmacist right away if you have unprotected sex, if you think your birth control method has failed, or if you think you may be pregnant. Your doctor may tell you to use emergency birth control. Do not wait until your next appointment to tell your doctor if you miss your menstrual period or if you think you may be pregnant.

What are my birth control options?
If you are a female who can get pregnant, your doctor will talk to you about your birth control options. Use the diagram below to help decide which birth control options are best for you. Talk to your doctor if you have questions about your birth control options. Tell your doctor if you want to change your birth control method. You may choose from the four options listed below. More than one birth control method might be needed every time you have sex.

How will I receive my Ambriusant medicine?
Certified pharmacies provide products and services for patients with certain diseases. Only certified pharmacies can provide Ambriusant to you. In some cases, your insurance company may require you to use a specific certified pharmacy. Your certified pharmacy ships your Ambriusant refill to you. Before each shipment, you will be called to confirm that you have taken a pregnancy test before refilling your prescription. It is important that your certified pharmacy is able to contact you in order to avoid delays in your refills.

If you have questions or concerns about Ambriusant, talk to your doctor. Please call 1-888-457-3572 for more information about the Ambriusant REMS.
Outpatient Pharmacies

Only a limited number of certified pharmacies will dispense ambrisentan for outpatients. In order for patients to receive ambrisentan, all outpatient pharmacies that wish to stock this product, must enroll in the Ambrisentan REMS and agree to comply with the requirements of the program.

Contact the Ambrisentan REMS to obtain contact information for certified outpatient pharmacies and distributors who are authorized to ship to certified outpatient pharmacies.

To become certified, outpatient pharmacies must:

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Ambrisentan REMS on behalf of the pharmacy.

2. Review the Prescriber and Pharmacy Guide.

3. Enroll in the Ambrisentan REMS by completing the Outpatient Pharmacy Enrollment Form and submitting it to the Ambrisentan REMS:
   - By fax

4. Train all relevant staff involved in dispensing ambrisentan on Ambrisentan REMS procedures and materials using the Prescriber and Pharmacy Guide.

5. Ensure the pharmacy is able to support electronic data exchanges and communications with the Ambrisentan REMS.

6. Establish processes and procedures to verify the patient’s prescriber is enrolled for all patients and if the patient is female, verify the patient is enrolled and the reproductive status of the patient has not changed.

7. For females of reproductive potential: establish processes and procedures to verify that pregnancy testing is completed or the prescriber authorizes the refill.

To Ensure Compliance with Ambrisentan REMS requirements, outpatient pharmacies must:

1. Before dispensing ambrisentan,
   - Obtain authorization to dispense each prescription by contacting the Ambrisentan REMS online or by phone at 1-888-417-3172 to verify that the patient’s prescriber is enrolled for all patients and if the patient is female, verify the patient is enrolled and the reproductive status has not changed.
   - For Females of Reproductive Potential:
     - Counsel patient on the risk of embryo-fetal toxicity and the need to use highly reliable contraception and emergency contraception, to get monthly pregnancy tests and to inform the prescriber of a pregnancy immediately.
     - Contact each FRP or their prescriber, every month to verify that the pregnancy testing is complete or the prescriber authorizes the refill.
     - Dispense no more than a 30 days’ supply

2. At all Times:
   - Report pregnancies to the Ambrisentan REMS.
   - Report a change or misclassification in reproductive status to the Ambrisentan REMS
   - Do not distribute, transfer, loan, or sell ambrisentan, except to certified dispensers
   - Maintain and submit records of daily product dispensing data for female patients to the Ambrisentan REMS
   - Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and being followed.

Login is available for certified pharmacies.
Inpatient Pharmacies

Due to the risk of embryo-fetal toxicity, ambrisentan is available only through a restricted program called the Ambrisentan Risk Evaluation and Mitigation Strategy (REMS). In order for patients to receive ambrisentan, all inpatient pharmacies that wish to stock this product, must enroll in the Ambrisentan REMS and agree to comply with the requirements of the Ambrisentan REMS.

Contact the Ambrisentan REMS to obtain contact information for certified outpatient pharmacies and distributors who are authorized to ship to certified inpatient pharmacies.

To become certified, inpatient pharmacies must:

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Ambrisentan REMS on behalf of the pharmacy.
2. Have the authorized representative review the Prescriber and Pharmacy Guide.
3. Enroll in the Ambrisentan REMS by completing the Inpatient Pharmacy Enrollment Form and submitting it to the Ambrisentan REMS:
   - Online
   - By fax
4. Train all relevant staff involved in dispensing on Ambrisentan REMS procedures and materials using the Prescriber and Pharmacy Guide.
5. Establish processes and procedures to verify the patient’s prescriber is enrolled for all patients and if the patient is female verify the patient is enrolled.
6. For females of reproductive potential: establish processes and procedures to verify that the patient has been counseled on the risk of embryo-fetal toxicity, the need to use highly reliable contraception, and emergency contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately.

To Ensure Compliance with Ambrisentan REMS requirements, inpatient pharmacies must:

1. Before dispensing ambrisentan:
   - Verify with the Ambrisentan REMS that the patient’s prescriber is enrolled for all patients and if the patient is female, verify the patient is enrolled by contacting the Ambrisentan REMS online or by phone at 1-888-417-3172.
   - For females of reproductive potential: verify that the patient has been counseled on the risk of embryo-fetal toxicity and pregnancy testing is complete.
2. Prior to discharge of a Patient:
   - Dispense no more than a 15 days’ supply upon discharge.
3. At all Times:
   - Report pregnancies to the Ambrisentan REMS.
   - Report a change or misclassification in reproductive status to the Ambrisentan REMS.
   - Do not distribute, transfer, loan, or sell ambrisentan, except to certified dispensers.
   - Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and being followed.

Login is available for certified pharmacies.
Contact us

Phone: 1-888-417-3172
Fax: 1-866-750-9802
Hours of Operation:
Monday - Friday
8:00 AM - 8:00 PM ET

Report pregnancies to the Ambrisentan REMS at www.ambrisentanrems.us or by calling 1-888-417-3172.
Report adverse events to FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.

For Ambrisentan REMS information contact:
Phone: 1-888-417-3172
Fax: 1-866-750-9802