

## The Ambrisentan REMS (Risk Evaluation and Mitigation Strategy)

The Ambrisentan REMS is a safety program that manages the **risk of serious birth defects** when taking ambrisentan. The Ambrisentan REMS is required by the Food and Drug Administration (FDA).

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

### Prescribers

[Click here to learn how to prescribe ambrisentan](#)

To prescribe ambrisentan:

- 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 Ambrisentan REMS
- 3 Assess the patient's reproductive status as defined in the *Prescriber and Pharmacy Guide*
- 4 Enroll all females in the Ambrisentan REMS by completing and submitting the *Patient Enrollment Form* to the Ambrisentan 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

[Click here to learn how to receive ambrisentan](#)

To receive ambrisentan:

- 1 Review the *Guide for Female Patients*
- 2 Receive counseling from your prescriber to understand the risks associated with ambrisentan
- 3 Enroll in the Ambrisentan 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 ambrisentan 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 8: 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

[Click here to learn how to dispense ambrisentan](#)

To dispense ambrisentan:

- 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 enroll in the Ambrisentan REMS by completing the *Outpatient Pharmacy Enrollment Form*, and submitting it to the Ambrisentan REMS
- 3 Train staff involved in dispensing ambrisentan and comply with Ambrisentan REMS requirements
- 4 Obtain authorization to dispense each prescription by contacting the Ambrisentan 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 (FRP):
    - Dispense no more than a 30-days' supply
- 5 Support electronic data exchanges and communication with the Ambrisentan REMS system

### Inpatient Pharmacies

[Click here to learn how to dispense ambrisentan](#)

To dispense ambrisentan:

- 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 enroll in the Ambrisentan REMS by completing the *Inpatient Pharmacy Enrollment Form*, and submitting it to the Ambrisentan REMS
- 3 Train staff involved in dispensing ambrisentan and comply with Ambrisentan REMS requirements
- 4 Obtain authorization to dispense each prescription by contacting the Ambrisentan 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-days' supply at discharge

### PDFs for Download

### Resources for Prescribers

- [Ambrisentan REMS Prescriber and Pharmacy Guide](#)
- [Ambrisentan REMS Prescriber Enrollment and Agreement Form](#)
- [Ambrisentan REMS Patient Enrollment and Consent Form](#)
- [Ambrisentan REMS Guide for Female Patients](#)
- [Ambrisentan REMS Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form](#)

### Resources for Female Patients

- [Ambrisentan REMS Guide for Female Patients](#)

### Resources for Outpatient Pharmacies

- [Ambrisentan REMS Outpatient Pharmacy Enrollment Form](#)
- [Ambrisentan REMS Prescriber and Pharmacy Guide](#)

### Resources for Inpatient Pharmacies

- [Ambrisentan REMS Inpatient Pharmacy Enrollment Form](#)
- [Ambrisentan REMS Prescriber and Pharmacy Guide](#)

[Click here for a list of approved products covered under the Ambrisentan REMS](#)

To learn more about the serious risks associated with ambrisentan, please refer to the [US Prescribing Information](#) including Boxed Warning, [Ambrisentan REMS Prescriber and Pharmacy Guide](#) and [Ambrisentan REMS Guide for Female Patients](#).

## List of products covered under the Ambrisentan REMS

### Brand:

Brand Name	Generic Name	Dosage	Company	Contact	Links
					<a href="#">Prescribing Information</a>
					<a href="#">Prescribing Information</a>

### Generic:

Drug Name	Dosage	Company	Contact	Links
				<a href="#">Prescribing Information</a>
				<a href="#">Prescribing Information</a>

 Prescribers

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

- Ensuring prescribers are educated on the following:
  - the risks of embryo-fetal toxicity
- Ensuring prescribers are educated on and adhere to the following:
  - counseling patients about these risks and the need for monthly monitoring
  - enrolling patients in the Ambrisentan 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 ambrisentan
- 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 Ambrisentan REMS?

- 1 Review the following educational materials to understand the Ambrisentan REMS and the risks of ambrisentan:
  - [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 Ambrisentan 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 ambrisentan:
  - [Online](#)
  - [By fax](#)

### Once a patient is on ambrisentan, 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 Ambrisentan 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 Ambrisentan 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 Ambrisentan REMS if any patient becomes pregnant during ambrisentan treatment or within one month following treatment discontinuation.

 PDFs for Download

#### Resources for Prescribers

[Ambrisentan REMS Prescriber and Pharmacy Guide](#)

[Ambrisentan REMS Prescriber Enrollment and Agreement Form](#)

[Ambrisentan REMS Patient Enrollment and Consent Form](#)

[Ambrisentan REMS Guide for Female Patients](#)

[Ambrisentan REMS Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form](#)

 Patients

## What is Ambrisentan?

Ambrisentan is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs. Ambrisentan 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 Ambrisentan?

Ambrisentan can cause serious birth defects if taken during pregnancy. Females must not be pregnant when they start taking ambrisentan or become pregnant while taking ambrisentan, or for one month after stopping ambrisentan.

## How do I become enrolled in the Ambrisentan REMS?

- 1 Read the *Guide for Female Patients*.
- 2 Review and discuss all information with your doctor.
- 3 Enroll in the Ambrisentan REMS by completing the *Patient Enrollment Form* with your doctor.

Please refer to the details provided below and in the *Guide for Female Patients* for further clarification on the Ambrisentan REMS requirements.

## What are the Ambrisentan 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 ambrisentan, you must:

- Talk to your doctor to ensure the benefits outweigh the risks of ambrisentan.
- Review this webpage or the *Guide for Female Patients*.
- Enroll in the Ambrisentan REMS by completing the *Patient Enrollment Form*.
- Receive counseling from your prescriber on the risk of serious birth defects (pre-pubertal females only).
- Tell your prescriber if you become pregnant or your ability to become pregnant changes.
- If you are over the age of 8: Be monitored every year to see if your ability to become pregnant changes and tell your prescriber if your ability to become pregnant changes.
- If you are the parent or caregiver of a female child who started taking ambrisentan 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 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 ambrisentan, you must:

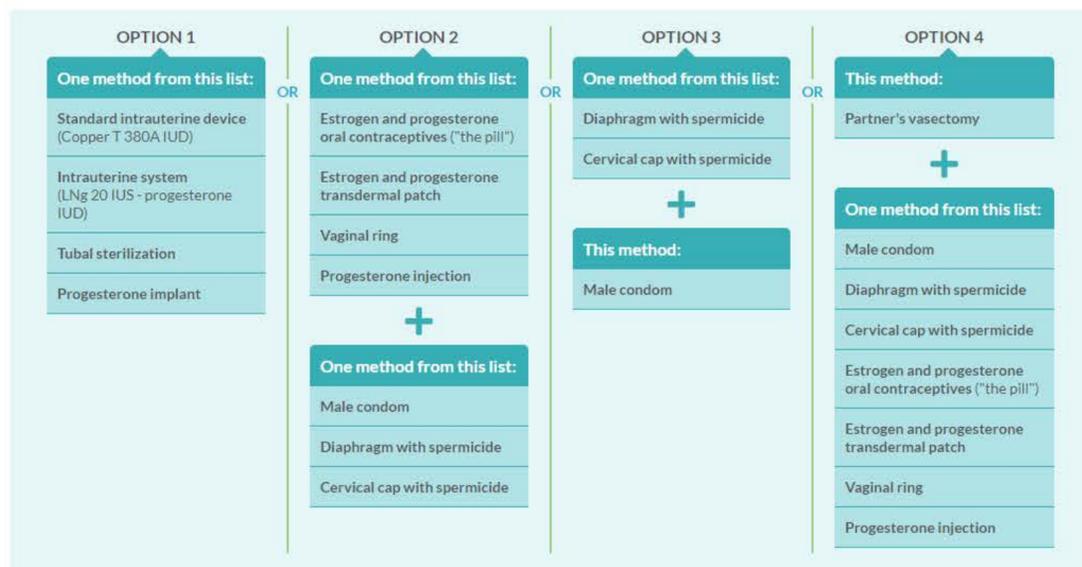
- Talk to your doctor to ensure the benefits outweigh the risks of ambrisentan.
- Review this webpage or the *Guide for Female Patients*.
- Have a negative pregnancy test before you start taking ambrisentan and before you receive your refills. Your doctor orders the pregnancy test for you.
- Enroll in the Ambrisentan 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 ask if you have taken this test before shipping your refill. If you do not take your pregnancy test every month, you may not receive your ambrisentan on time.
- Agree to be contacted by the Ambrisentan REMS if you become pregnant while on ambrisentan or within one month of stopping treatment.

Do not have unprotected sex (intercourse). Use appropriate birth control during your ambrisentan treatment and for one month after stopping your ambrisentan 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 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 what 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 ambrisentan medicine?

Certified pharmacies provide products and services for patients with certain diseases. Only certified pharmacies can provide ambrisentan to you. In some cases, your insurance company may require you to use a specific certified pharmacy.

Your certified pharmacy ships your ambrisentan refill to you. Before each shipment, you will be called to confirm that you have taken a monthly 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 ambrisentan, talk to your doctor. Please call **1-888-417-3172** for more information about the Ambrisentan REMS.

 PDFs for Download

### Resources for Patients

[Ambrisentan REMS Guide for Female Patients](#)

## Rx 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.

### PDFs for Download

#### Resources for Outpatient Pharmacies

[Ambrisentan REMS Outpatient Pharmacy Enrollment Form](#)

[Ambrisentan REMS Prescriber and Pharmacy Guide](#)

## 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.

## PDFs for Download

### Resources for Inpatient Pharmacies

[Ambrisentan REMS Inpatient Pharmacy Enrollment Form](#)

[Ambrisentan REMS Prescriber and Pharmacy Guide](#)

## 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.com](http://www.ambrisentanrems.us.com) or by calling 1-888-417-3172.  
Report adverse events to FDA by visiting [www.fda.gov/medwatch](http://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

[Privacy Policy](#) [Terms of Use](#) [Contact us](#)

ARC008\_ApprovalYYYYMMMM\_V#.#

## Resources

### Resources for Prescribers

- [!\[\]\(79516a995cff76a1aff85c3662aea2c5\_img.jpg\) Ambrisentan REMS Prescriber and Pharmacy Guide](#)
- [!\[\]\(eccb9a483ab0e7e56efdd579e29a52b0\_img.jpg\) Ambrisentan REMS Prescriber Enrollment and Agreement Form](#)
- [!\[\]\(2ccbb51543148aca2718e727021d6f32\_img.jpg\) Ambrisentan REMS Patient Enrollment and Consent Form](#)
- [!\[\]\(614b86a555077c71ed3d6e9d16a182e8\_img.jpg\) Ambrisentan REMS Guide for Female Patients](#)
- [!\[\]\(c895f6c5222814e36cf85dd9fbc44a1e\_img.jpg\) Ambrisentan REMS Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form](#)

### Resources for Female Patients

- [!\[\]\(f0543fe51acd79be3858008749d93a88\_img.jpg\) Ambrisentan REMS Guide for Female Patients](#)

### Resources for Outpatient Pharmacies

- [!\[\]\(73ae4d61a44e0d3e280171a702047018\_img.jpg\) Ambrisentan REMS Outpatient Pharmacy Enrollment Form](#)
- [!\[\]\(240de69c4eae84075121456f04252941\_img.jpg\) Ambrisentan REMS Prescriber and Pharmacy Guide](#)

### Resources for Inpatient Pharmacies

- [!\[\]\(3f0880663a5184fb79b391f4bd12984c\_img.jpg\) Ambrisentan REMS Inpatient Pharmacy Enrollment Form](#)
- [!\[\]\(96dd2eedc263d947480cdb15db2fca12\_img.jpg\) Ambrisentan REMS Prescriber and Pharmacy Guide](#)

Report pregnancies to the Ambrisentan REMS at [www.ambrisentanrems.us.com](http://www.ambrisentanrems.us.com) or by calling 1-888-417-3172. Report adverse events to FDA by visiting [www.fda.gov/medwatch](http://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

[Privacy Policy](#) [Terms of Use](#) [Contact us](#)

ARC008\_ApprovalYYYYMMMM\_V#.#

## Login

Access to the application is limited to certified prescribers and pharmacies. If you have not received a user name, please contact the Ambrisentan REMS at 1-888-417-3172.

### Login

Please enter your User Name

LOGIN

[Forgot User Name](#)