

RISK EVALUATION AND MITIGATION STRATEGY (REMS) Document

Ambrisentan Shared System REMS Program

I. Administrative Information

Initial Shared System REMS Approval:[03/2019]

Most Recent REMS Update: [12/2020]

II. REMS Goal

The goal of the Ambrisentan REMS Program is to mitigate the risk of embryo-fetal toxicity associated with ambrisentan by:

1. Ensuring prescribers are educated on the following:
 - the risk of embryo-fetal toxicity
2. Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about the risk and the need for monthly monitoring
 - enrolling patients in the Ambrisentan REMS Program
 - monitoring patients at baseline and monthly
3. Ensuring that pharmacies are educated on the following:
 - the risk of embryo-fetal toxicity
4. Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing ambrisentan
5. Ensuring that patients are informed about:
 - the risk of embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

III. REMS Requirements

Ambrisentan Applicants must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe ambrisentan must:

To become certified to prescribe

1. Review the drug's Prescribing Information.
 2. Review the following: [Prescriber and Pharmacy Guide](#).
 3. Enroll in the REMS by completing the [Prescriber Enrollment Form](#) and submitting it to the REMS Program.
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Before treatment initiation (first dose)

4. For all females: Assess the patient's reproductive status using the definitions in the [Prescriber and Pharmacy Guide](#). Document and submit the results to the REMS Program using the [Patient Enrollment Form](#).
 5. For all females: Counsel the patient that the drug is only available through a restricted distribution program.
 6. 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 emergency contraception using the [Guide for Female Patients](#).
 7. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result.
 8. For pre-pubertal females: Counsel the patient on the risk of embryo-fetal toxicity using the [Guide for Female Patients](#).
 9. Enroll all female patients by completing the [Patient Enrollment Form](#) and submitting it to the REMS Program.
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During treatment; before each prescription

10. For females of reproductive potential: Counsel the patient if she is not complying with the required testing or if she is not using appropriate contraception.
 11. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result.
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During treatment; at least annually

12. For pre-pubertal females at least age 8 or older: Document reproductive status and submit to the REMS Program using [Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form](#).
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1. Healthcare Providers who prescribe ambrisentan must:

After treatment discontinuation; for one month	13. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result.
At all times	14. For pre-pubertal females: Assess the patient's reproductive status. 15. Report pregnancies to the REMS Program.
At all times, within 10 business days	16. Report a change or misclassification in reproductive status to the REMS Program using the Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form .

2. Females of reproductive potential who are prescribed ambrisentan:

Before treatment initiation	<ol style="list-style-type: none">1. Review the Guide for Female Patients.2. Get a pregnancy test.3. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program.4. Receive counseling from the prescriber on the risk of embryo-fetal toxicity and the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the Guide for Female Patients.
During treatment; before dispensing	<ol style="list-style-type: none">5. Receive counseling from the pharmacy or healthcare provider who dispenses ambrisentan on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, emergency contraception, to get monthly pregnancy tests, and to report a pregnancy immediately.6. Get a pregnancy test.7. Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of pregnancy testing.

During treatment and after treatment discontinuation for one month	8. Adhere to the safe use condition: Use highly reliable contraception as described in the Guide for Female Patients .
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After treatment discontinuation; one month	9. Get a pregnancy test.
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3. Pre-pubertal females who are prescribed ambrisentan:

Before treatment initiation	1. Review the Guide for Female Patients .
	2. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program.
	3. Receive counseling from the prescriber on the risk of embryo-fetal toxicity using the Guide for Female Patients .

At all times	4. If over the age of 8: Be monitored for a change in reproductive status.
	5. Inform the prescriber if there is a change in your reproductive status.

4. Post-menopausal females or females with other medical reasons for permanent, irreversible infertility who are prescribed ambrisentan:

Before treatment initiation	1. Review the Guide for Female Patients .
	2. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program.

At all times	3. Inform the prescriber if there is a change in your reproductive status.
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5. Outpatient pharmacies and healthcare providers that dispense ambrisentan must:

To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.
	2. Have the authorized representative review the Prescriber and Pharmacy Guide .

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3. Have the authorized representative enroll in the REMS Program by completing the [Outpatient Pharmacy Enrollment Form](#) and submitting it to the REMS Program.
 4. Train all relevant staff involved in dispensing ambrisentan on the REMS Program requirements using the [Prescriber and Pharmacy Guide](#).
 5. Establish processes and procedures to verify the female patient is enrolled, the reproductive status of the patient has not changed, and the prescriber is certified.
 6. For females of reproductive potential: Establish processes and procedures to verify that pregnancy testing is complete or the prescriber authorizes the refill.
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Before
dispensing

7. 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, emergency contraception, to get monthly pregnancy tests, and inform the prescriber of a pregnancy immediately.
 8. Verify the female patient is enrolled, the reproductive status has not changed, and the prescriber is certified through the processes and procedures established as a requirement of the REMS Program.
 9. For females of reproductive potential: Verify that the pregnancy testing is complete or the prescriber authorizes the refill through the processes and procedures established as a requirement of the REMS Program.
 10. For females of reproductive potential: Dispense no more than a 30 days' supply.
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At all times

11. Report pregnancies to the REMS Program.
 12. Report a change or misclassification in reproductive status to the REMS Program.
 13. Not distribute, transfer, loan, or sell ambrisentan, except to certified dispensers.
 14. For females of reproductive potential: Maintain and submit records of daily product dispensing data.
 15. Maintain records that all processes and procedures are in place and are being followed.
 16. 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 are being followed.
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6. Inpatient pharmacies that dispense ambrisentan must:

To become certified
to dispense

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.
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2. Have the authorized representative review the [Prescriber and Pharmacy Guide](#).
 3. Have the authorized representative enroll in the REMS Program by completing [Inpatient Pharmacy Enrollment Form](#) and submitting it to the REMS Program.
 4. Train all relevant staff involved in dispensing ambrisentan on the REMS Program requirements using the [Prescriber and Pharmacy Guide](#).
 5. Establish processes and procedures to verify the female patient is enrolled or will be enrolled in the REMS Program prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified prescriber.
 6. For females of reproductive potential: Establish processes and procedures to verify pregnancy testing is complete, the patient is counseled on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately.

Before dispensing

7. Verify the female patient is under the supervision and care of a certified prescriber, her reproductive status, she is enrolled or will be enrolled in the REMS Program prior to discharge through the processes and procedures established as a requirement of the REMS Program.
8. For females of reproductive potential: Verify that pregnancy testing is complete, the patient is counseled on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately through the processes and procedures established as a requirement of the REMS Program.

At discharge

9. Dispense no more than a 15 days' supply.

At all times

10. Report pregnancies to the REMS Program.
 11. Report a change or misclassification in reproductive status to the REMS Program.
 12. Not distribute, transfer, loan, or sell ambrisentan, except to certified dispensers.
 13. Maintain records that all processes and procedures are in place and are being followed.
 14. 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 are being followed.
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7. Wholesalers-distributors that distribute ambrisentan must:

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|--------------------------|---|
| To be able to distribute | <ol style="list-style-type: none">1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.2. Train all relevant staff involved in distribution on the REMS Program requirements. |
| At all times | <ol style="list-style-type: none">3. Distribute only to certified pharmacies.4. Maintain records of drug distribution.5. 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 are being followed. |
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Ambrisentan Applicants must provide training to healthcare providers who prescribe ambrisentan.

The training includes the following educational material: [Prescriber and Pharmacy Guide](#). The Training must be available online and hard copy format via mail or fax.

Ambrisentan Applicants must provide training to pharmacies that dispense ambrisentan.

The training includes the following educational material: [Prescriber and Pharmacy Guide](#). The Training must be available online and hard copy format via mail or fax.

To support REMS Program operations, Ambrisentan Applicants must:

1. Establish and maintain a REMS Program website, www.ambrisentanrems.us.com. The REMS Program website must include the capability to complete prescriber and inpatient pharmacy certification or enrollment online, the capability to enroll and manage patients online, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).
2. Make the REMS Program website fully operational and all REMS materials available through website and REMS coordinating center prior to the marketing of any ambrisentan product covered by this REMS that was approved under an ANDA.
3. Establish and maintain a REMS coordinating center for REMS participants at 1-888-417-3172.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and certified in the REMS Program.
5. Ensure prescribers and inpatient pharmacies are able to complete the certification process by fax and online.
6. Ensure outpatient pharmacies are able to complete the certification process by fax.
7. Ensure prescribers are able to report change in reproductive status by fax and online.
8. Ensure prescribers are able to complete the patient enrollment process by fax and online.
9. Ensure pharmacies are able to confirm patient enrollment and prescriber certification before dispensing by phone and online.

10. Ensure that the REMS coordinating center contacts the prescriber of a pre-pubertal female annually to have the prescriber verify the pre-pubertal female's reproductive status by completing the [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#).
11. Ensure the REMS coordinating center updates the database and notifies certified pharmacies of a patient's change in reproductive status within one business day of receipt of a completed [Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#).
12. Ensure pharmacies are able to enroll as inpatient (including, but not limited to, pharmacies in hospitals, long-term care facilities, prisons, and state psychiatric units) or outpatient pharmacies.
13. Notify prescribers and pharmacies within one business day after they become certified in the REMS Program.
14. Provide certified prescribers access to the database of certified pharmacies and enrolled patients.
15. Provide certified pharmacies access to the database of certified prescribers and enrolled patients.

To ensure REMS participants' compliance with the REMS Program, Ambrisentan Applicants must:

16. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: ambrisentan distribution and dispensing; certification of prescribers, pharmacies; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.
17. Establish a plan for addressing noncompliance with REMS Program requirements.
18. Monitor prescribers, pharmacies, and wholesaler-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.
19. Audit all certified outpatient pharmacies, registered wholesalers-distributors and the REMS coordinating center within 180 calendar days of being certified/registered in the REMS and annually to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements, and include risk-based auditing of inpatient pharmacies annually.
20. Take reasonable steps to improve implementation of and compliance with the requirements in the REMS Program based on monitoring and evaluation of the REMS Program.

IV. REMS Assessment Timetable

Ambrisentan NDA Applicants must submit REMS Assessments annually from the date of the initial REMS approval (03/28/2019). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Ambrisentan NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Ambrisentan REMS:

Enrollment Forms

Prescriber:

1. [Prescriber Enrollment and Agreement Form](#)

Patient:

2. [Patient Enrollment and Consent Form](#)

Pharmacy:

3. [Outpatient Pharmacy Enrollment Form](#)
4. [Inpatient Pharmacy Enrollment Form](#)

Training and Educational Materials

Prescriber:

5. [Prescriber and Pharmacy Guide](#)

Patient:

6. [Guide for Female Patients](#)

Pharmacy:

7. [Prescriber and Pharmacy Guide](#)

Patient Care Form

8. [Change in Reproductive Status and Pre-Pubertal Annual Verification Form](#)

Other Materials

9. [REMS Program website \(www.ambrisentanrems.us.com \)](http://www.ambrisentanrems.us.com)
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Ambrisentan REMS Prescriber Enrollment and Agreement Form

To enroll in the Ambrisentan REMS, complete and fax this form to 1-866-750-9802 or complete and submit online at www.ambrisentanrems.us.com

1 Prescriber Information (PLEASE PRINT)			
First Name:	Middle Initial:	Last Name:	
Suffix:			
Specialty:	Name of Facility:		
Office Contact (First and Last Name):			
Address:	City:	State:	Zip:
Email:	Phone:	Fax:	
State License #:	NPI #:		
2 Prescriber Agreement			
By signing below, you attest to the following:			
<ul style="list-style-type: none">I have reviewed the Prescribing Information and the Prescriber and Pharmacy Guide and agree to comply with the REMS requirements.I will enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS.			
For all females:			
<ul style="list-style-type: none">I will determine the reproductive potential status of all female patients using the definitions provided in the Prescriber and Pharmacy Guide and document and submit the results to the REMS using the Patient Enrollment Form.I will counsel all female patients that ambrisentan is only available through a restricted distribution program called the Ambrisentan REMS.I will enroll all female patients by completing and submitting the Patient Enrollment Form.			
For females of reproductive potential:			
<ul style="list-style-type: none">I will counsel Females of Reproductive Potential about the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the Guide for Female Patients.I will assess the pregnancy status of Females of Reproductive Potential by ordering and reviewing a pregnancy test before treatment initiation, before writing each prescription, and for one month after treatment discontinuation.I will counsel Females of Reproductive Potential if they are not complying with the required testing or if they are not using appropriate contraception.			
Pre-pubertal females:			
<ul style="list-style-type: none">I will counsel each Pre-Pubertal Female patient and her parent/guardian on the risk of embryo-fetal toxicity using the Guide for Female Patients.I will regularly assess the reproductive status of each Pre-Pubertal Female during their treatment with ambrisentan.I will assess the reproductive status for Pre-Pubertal Females who are 8 years of age and older and will document and submit findings to the REMS at least annually using the Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form.			
At all times:			
<ul style="list-style-type: none">I will report any change or misclassification in reproductive status to the Ambrisentan REMS using Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form within 10 business days of becoming aware of the change in reproductive status.I will report pregnancies to the REMS.			
REQUIRED	Prescriber Signature:		Date:

Please visit www.ambrisentanrems.us.com or call 1-888-417-3172 for more information about the Ambrisentan REMS.

This form is part of an FDA-approved REMS.

Ambrisentan REMS Patient Enrollment and Consent Form

To enroll in the Ambrisentan REMS, complete and fax this form to 1-866-750-9802 or complete and submit online at www.ambrisentanrems.us.com

1 Patient Information (PLEASE PRINT)			
First Name:	Middle Initial:	Last Name:	
Address:	City:	State:	Zip:
Birthdate: / /	Gender: <input type="checkbox"/> Female	Preferred time to contact: <input type="checkbox"/> Day <input type="checkbox"/> Evening	
Home Phone:	Mobile Phone:	E-mail:	
Alternate Contact Name:		Alternate Phone:	
Relationship:			
2 Female Patient Agreement			
For Females Who Can Get Pregnant:			
Before I begin ambrisentan treatment I will:			
<ul style="list-style-type: none">Review the Guide for Female Patients.Get a pregnancy test.Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS.Receive counseling from the prescriber on the risk of serious birth defects, the need to use highly reliable contraception during treatment and for one month after stopping treatment, and emergency contraception using the Guide for Female Patients.			
Before I receive each prescription of ambrisentan I will:			
<ul style="list-style-type: none">Receive counseling from the pharmacy or prescriber on risk of serious birth defects and the need to use highly reliable contraception during treatment and for one month after stopping treatment, emergency contraception, to get monthly pregnancy tests, and to report a pregnancy immediately.Get a pregnancy test.Communicate with the pharmacy to confirm pregnancy testing.			
During my treatment with ambrisentan and for one month after stopping treatment, I will:			
<ul style="list-style-type: none">Use highly reliable contraception as described in the Guide for Female Patients.Get a pregnancy test monthly during treatment and for one month after I stop taking ambrisentan.Agree to be contacted by the REMS to obtain information about my pregnancy if I become pregnant while on ambrisentan or within 30 days after stopping treatment.			
For Pre-Pubertal Females (and their parent/guardian):			
Before I begin ambrisentan treatment, I will:			
<ul style="list-style-type: none">Review the Guide for Female Patients.Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS.Receive counseling from the prescriber on the risk of serious birth defects using the Guide for Female Patients.			
If I am over the age of 8 and while I am being treated with ambrisentan, I will be monitored regularly for a change in reproductive status.			
I will tell my prescriber if my reproductive status (ability to become pregnant) changes.			
For Post-menopausal Females or Females with other medical reasons for permanent, irreversible infertility:			
Before I begin ambrisentan treatment, I will:			
<ul style="list-style-type: none">Review the Guide for Female Patients.Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS.			
I will tell my prescriber if my reproductive status (ability to become pregnant) changes.			
REQUIRED FOR ALL FEMALE PATIENTS	Patient or Parent/Guardian Signature:		Date:
3 Prescriber Information (PLEASE PRINT)			
First Name:	Last Name:		State License #:
Address:	City:	State:	Zip:
Phone:	Fax:	NPI#:	
Office Contact (First and Last Name):			E-mail:

4 Statement of Medical Necessity

Diagnosis: Pulmonary Arterial Hypertension (The following list is not to suggest approved uses or indications. Please select one category below.)

ICD-10 I27.0 Primary Pulmonary Hypertension

- Idiopathic PAH
- Heritable PAH

ICD-10 I27.21 Secondary Pulmonary Arterial Hypertension

- Connective tissue disease
- Congenital heart disease with repaired shunts
- Other (please specify): _____

5 Prescriber Authorization (REQUIRED FOR ALL FEMALE PATIENTS)

Only 1 box should be checked. For female patients, please indicate the patient's current reproductive status below. (Please see definitions of these terms below)

Female of Reproductive Potential

Has a negative pregnancy test been confirmed prior to prescribing ambrisentan?

- Yes
- No

OR

Female of Non-Reproductive Potential (choose one below)

- Pre-Pubertal Female
- Post-Menopausal Female
- Other medical reasons for permanent, irreversible infertility

I certify that for female patients, I have provided the appropriate counseling and REMS materials, and I will continue to fulfill my obligations under the REMS.

**REQUIRED
FOR ALL
PRESCRIBERS**

Prescriber Signature: _____

Date: _____

Definitions

Females of Reproductive Potential

- Females of Reproductive Potential include girls who have entered puberty and all women who have a uterus and have not passed through Menopause (as defined below).
- For the purposes of REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).

Females of Non-Reproductive Potential

- Pre-Pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.
- Post-Menopausal Females: Females who have passed through Menopause (as defined below).
- Other medical reasons for permanent, irreversible infertility.

Menopause

Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy.

Prescriber obligations under the REMS

For All Females

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that ambrisentan is available only through a restricted distribution program under an FDA-required REMS.
- I will evaluate the patient and agree to document any change in reproductive potential status by submitting a **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form** within 10 business days of becoming aware of the change.

For Females of Reproductive Potential

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of ambrisentan, including the risk of serious birth defects, and that I have reviewed the **Guide for Female Patients** with the patient (and parent/guardian when appropriate).
- I will order and review pregnancy tests prior to initiation of ambrisentan treatment, monthly during treatment, and for 1 month following treatment discontinuation in accordance with the REMS.

For Pre-Pubertal Females

- I acknowledge that I have counseled the patient and parent/guardian on the risks of ambrisentan, including the risk of serious birth defects, and that I have reviewed the **Guide for Female Patients** with the patient (and parent/guardian when appropriate).
- I will evaluate the patient's reproductive potential status, verify reproductive potential status annually for Pre-Pubertal Females who are at least 8 years of age and older, and agree to report any change in reproductive potential status on a **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form** within 10 business days of becoming aware of the change.

6 Complete and fax this enrollment form to 1-866-750-9802 or complete and submit the form online at www.ambrisentanrems.us.com.

Please visit www.ambrisentanrems.us.com or call 1-888-417-3172 for more information about the Ambrisentan REMS.

This form is part of an FDA-approved REMS.

Ambrisentan REMS Outpatient Pharmacy Enrollment Form

To enroll in the Ambrisentan REMS, complete and fax this form to 1-866-750-9802

Due to the risk of embryo-fetal toxicity, ambrisentan is available only through a restricted program called the Ambrisentan REMS (Risk Evaluation and Mitigation Strategy). 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.

An Authorized Representative must be designated to carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy. As the authorized representative, complete and submit this form on behalf of your outpatient pharmacy.

If you have any questions, require additional information, or need further copies of REMS materials, please visit the REMS website at www.ambrisentanrems.us.com, or call the Ambrisentan REMS at 1-888-417-3172.

Outpatient Pharmacy Information (PLEASE PRINT)

Pharmacy Name:

Identification (please complete one of the following):

Facility Health Industry Number (HIN #):

Facility National Provider Identifier (NPI #):

Other identifier:

Address:

City:

State:

Zip:

Phone #:

Fax #:

Ship To Address (if different from above)

Address:

City:

State:

Zip:

Phone #:

Fax #:

Outpatient Pharmacy Authorized Representative Information (PLEASE PRINT)

Name:

Position/Title:

Credentials: RPh PharmD BCPS Other

Authorized Representative phone #:

Fax #:

Authorized Representative email:

Contact Preference (please select one) Email Fax

Outpatient Pharmacy Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the REMS.

Therefore, I must:

- Carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy.
- Review the **Prescriber and Pharmacy Guide**.
- Enroll in the REMS by completing and submitting the **Outpatient Pharmacy Enrollment Form**.
- Train all relevant staff involved in dispensing ambrisentan on REMS procedures and materials using the **Prescriber and Pharmacy Guide**.
- Ensure the pharmacy is able to support electronic data exchanges and communications with the Ambrisentan REMS.
- Establish processes and procedures to verify if the female patient is enrolled, the reproductive status of the patient has not changed, and the prescriber is certified.
- Establish processes and procedures to verify that pregnancy testing is complete or the prescriber authorizes the refill for females of reproductive potential.

On behalf of the pharmacy, I agree to comply with the following program requirements:

Prior to dispensing, the outpatient pharmacy must:

- Counsel females of reproductive potential on the risk of embryo-fetal toxicity, the need to use highly reliable contraception, emergency contraception, to get monthly pregnancy tests, and inform the prescriber of a pregnancy immediately.
- Verify the female patient is enrolled, the reproductive status has not changed, and the prescriber is certified through the processes and procedures established as a requirement of the REMS.
- For females of reproductive potential, verify that the pregnancy testing is complete or the prescriber authorizes the refill through the processes and procedures established as a requirement of the REMS.
- Dispense no more than a 30 days' supply for females of reproductive potential.

At all times, the outpatient pharmacy must:

- Report pregnancies to the REMS.
- Report a change or misclassification in reproductive status to the REMS.
- Not distribute, transfer, loan, or sell ambrisentan, except to certified dispensers.
- Maintain and submit records of daily product dispensing data for female patients of reproductive potential.
- Maintain records that all processes and procedures are in place and are being followed.
- 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 are being followed.

Outpatient Pharmacy Authorized Representative Consent

By signing below, you signify your understanding of the risks of ambrisentan treatment, your obligations as a pharmacy certified in the REMS as outlined above, and you agree to oversee the implementation of and compliance with the REMS requirements for this pharmacy.

Note: If your outpatient pharmacy needs ambrisentan and is not enrolled in the REMS, contact the Ambrisentan REMS at 1-888-417-3172 for assistance in initiating enrollment of the pharmacy.

Signature:

Date:

Please visit www.ambrisentanrems.us.com or call 1-888-417-3172 for more information about the Ambrisentan REMS Program.

This form is part of an FDA-approved REMS.

Ambrisentan REMS Inpatient Pharmacy Enrollment Form

To enroll in the Ambrisentan REMS, complete and fax this form to 1-866-750-9802 or complete and submit online at www.ambrisentanrems.us.com

Due to the risk of embryo-fetal toxicity, ambrisentan is available only through a restricted program called the Ambrisentan REMS (Risk Evaluation and Mitigation Strategy). In order for inpatients 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 program.

An Authorized Representative must be designated to carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy. As the authorized representative, complete and submit this form on behalf of your inpatient pharmacy.

If you have any questions, require additional information, or need further copies of REMS materials, please visit the REMS website at www.ambrisentanrems.us.com, or call the Ambrisentan REMS at 1-888-417-3172.

Inpatient Pharmacy Information (PLEASE PRINT)

Pharmacy Name:

Hospital Nursing home Hospice Asylum/Mental facility Assisted Living Prison Rehabilitation

Other (Please specify):

Identification (please complete one of the following):

Facility Health Industry Number (HIN #): Facility National Provider Identifier (NPI #): Other identifier:

Address:

City: State: Zip:

Phone #: Fax #:

Ship To Address (if different from above)

Address:

City: State: Zip:

Phone #: Fax #:

Inpatient Pharmacy Authorized Representative Information (PLEASE PRINT)

Name: Position/Title: Hospital pharmacist Head of Pharmacy and Therapeutics (P&T) committee
 Other title:

Credentials: RPh PharmD BCPS Other

Authorized Representative phone #: Fax #:

Authorized Representative email:

Contact Preference (please select one) Email Fax

Inpatient Pharmacy Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the REMS. Therefore, I must:

- Carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy.
 - Review the **Prescriber and Pharmacy Guide**.
 - Enroll in the REMS by completing and submitting the **Inpatient Pharmacy Enrollment Form**.
 - Train all relevant staff involved in dispensing ambrisentan on REMS procedures and materials using the **Prescriber and Pharmacy Guide**.
 - Establish processes and procedures to verify the female patient is enrolled or will be enrolled in the REMS prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified provider.
 - For females of reproductive potential: establish processes and procedures to verify pregnancy testing is complete, and the patient is counseled on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month after stopping treatment, emergency contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately.
- reproductive status, and she is enrolled or will be enrolled in the REMS prior to discharge through the processes and procedures established as a requirement of the REMS.
- For females of reproductive potential: Verify that the pregnancy testing is complete, the patient is counseled on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately through the processes and procedures established as a requirement of the REMS.

At discharge of a patient, the inpatient pharmacy must:

- Dispense no more than a 15 days' supply.

At all times, the inpatient pharmacy must:

- Report pregnancies to the REMS.
- Report a change or misclassification in reproductive status to the REMS.
- Not distribute, transfer, loan, or sell ambrisentan, except to certified dispensers.
- Maintain records that all processes and procedures are in place and are being followed.
- 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 are being followed.

On behalf of the pharmacy, I agree to comply with the following program requirements:

Prior to dispensing, the inpatient pharmacy must:

- Verify the female patient is under the supervision and care of a certified prescriber, her

Inpatient Pharmacy Authorized Representative Consent

By signing below, you signify your understanding of the risks of ambrisentan treatment, your obligations as a pharmacy certified in the REMS as outlined above, and you agree to oversee the implementation of and compliance with the REMS requirements for this pharmacy.

Note: If your inpatient pharmacy needs ambrisentan and is not enrolled in the REMS, contact the REMS at 1-888-417-3172 for assistance in initiating enrollment of the pharmacy.

Signature:

Date:

Please visit www.ambrisentanrems.us.com or call 1-888-417-3172 for more information about the Ambrisentan REMS Program.

This form is part of an FDA-approved REMS.

AMBRISENTAN RISK EVALUATION
AND MITIGATION STRATEGY (REMS)

Ambrisentan REMS
**PRESCRIBER AND
PHARMACY GUIDE**

This guide is part of an FDA-approved REMS.

Table of Contents

Ambrisentan REMS	2
Overview of the Ambrisentan REMS	3
Summary of the Ambrisentan REMS Requirements by Patient Category	3
Your Role in the Ambrisentan REMS	4
Contraceptive Options for Females of Reproductive Potential	6
Role of Certified Pharmacies	7
The Ambrisentan REMS	7

Ambrisentan REMS

Indication

Ambrisentan is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability and delay clinical worsening.

Studies establishing effectiveness included trials predominantly in patients with WHO Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).

Risk of embryo-fetal toxicity

Ambrisentan may cause fetal harm when administered to a pregnant female and is contraindicated during pregnancy. There is limited data on ambrisentan use in pregnant females; the possibility of serious birth defects in humans cannot be excluded.

Pregnancy must be excluded prior to the initiation of ambrisentan treatment, monthly thereafter, and for one month following treatment discontinuation.

Ambrisentan REMS

Because of the risk of serious birth defects, ambrisentan is only available to females through a restricted distribution program under an FDA-required REMS. The goal of the Ambrisentan 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

Overview of the Ambrisentan REMS

- Ambrisentan is only available to females through a restricted distribution program
- Prescribers must enroll in the Ambrisentan REMS and comply with the Ambrisentan REMS requirements to prescribe ambrisentan
- All female patients must enroll in the Ambrisentan REMS to receive ambrisentan
- Prescribers must educate and counsel Females of Reproductive Potential and Pre-Pubertal Females on the risks of ambrisentan, including the risk of serious birth defects using the *Guide for Female Patients*. The parent/guardian of the Pre-Pubertal Female must also be educated and counseled on the risks of ambrisentan
- Prescribers must order and review pregnancy tests for Females of Reproductive Potential prior to initiation of treatment, monthly during treatment, and for one month following treatment discontinuation

Requirement	Female of Reproductive Potential	Female of Non-Reproductive Potential		
		Pre-Pubertal	Post-Menopausal	Other medical reasons for permanent, irreversible infertility
Prescriber enrolls female patients into Ambrisentan REMS	X	X	X	X
Review <i>Guide for Female Patients</i>	X	X	X	X
Counseling with <i>Guide for Female Patients</i>	X	X		
Prescriber must order and review pregnancy tests prior to initiation of treatment, monthly during treatment, and for one month following treatment discontinuation	X			
Prescriber must verify reproductive status annually by completing the <i>Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form</i> for females who are at least 8 years of age and older		X		
Prescriber must complete the <i>Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form</i> upon becoming aware of any change in reproductive status within 10 business days of awareness	X	X	X	X

Role of Prescriber in the Ambrisentan REMS

Prescribers must complete the following steps in the Ambrisentan REMS:

1. Read the Ambrisentan Prescribing Information and this guide to understand the Ambrisentan REMS and the risks of ambrisentan

2. Complete the *Prescriber Enrollment Form*

- You will attest to understanding the risks of ambrisentan and agree to comply with the requirements of the Ambrisentan REMS
- Complete the form online at www.ambrisentanrems.us.com or fax the completed form to 1-866-750-9802

3. Determine the reproductive status of female patients

Females of Reproductive Potential:

- Females of Reproductive Potential include girls who have entered puberty and all women who have a uterus and have not passed through Menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)

Females of Non-Reproductive Potential:

- **Pre-Pubertal Females:** Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- **Post-Menopausal Females:** Females who have passed through Menopause (as defined below)
- **Females with other medical reasons for permanent, irreversible infertility**

Definition of Menopause:

- Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy

4. Educate/counsel all female patients about the risks of ambrisentan and about the Ambrisentan REMS

- Advise all females that ambrisentan is only available through a restricted distribution program called the Ambrisentan REMS

For Females of Reproductive Potential:

- Review the **Guide for Female Patients** prior to initiating treatment
- Counsel the patient about the risk of embryo-fetal toxicity, the need to use highly reliable contraception (see page 6) during ambrisentan treatment and for one month following treatment discontinuation, and the need to use emergency contraception using the **Guide for Female Patients**
- Assess the patient's pregnancy status by ordering and reviewing pregnancy tests prior to initiation of ambrisentan treatment, monthly during treatment, and for one month following treatment discontinuation
- Advise the patient of the requirement for monthly pregnancy tests to confirm they are not pregnant so they can receive ambrisentan
- Counsel if she is not complying with the required testing of if she is not using appropriate contraception
- Submit a **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form** within 10 business days of becoming aware of any change in reproductive status
- Prescribe no more than a 30 days' supply at a time
- Notify the Ambrisentan REMS if any patient becomes pregnant during ambrisentan treatment or within one month following treatment discontinuation

For Females of Non-Reproductive Potential:

For Pre-Pubertal Females:

- Review the **Guide for Female Patients** prior to initiating treatment
- Counsel the patient and parent/guardian about the risk of embryo-fetal toxicity using the **Guide for Female Patients**
- Evaluate regularly for any changes in reproductive status while receiving ambrisentan
- Verify the reproductive status annually for Pre-Pubertal Females who are at least 8 years of age and older by completing and submitting the **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form**
- Report a change or misclassification in reproductive status by completing and submitting the **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form** within 10 business days of becoming aware of the change
- Notify the Ambrisentan REMS if any patient becomes pregnant during ambrisentan treatment or within one month following treatment discontinuation

For Post-Menopausal Females:

- Review the **Guide for Female Patients** prior to initiating treatment
- Report a change or misclassification in reproductive status by completing and submitting the **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form** within 10 business days of becoming aware

For females with other medical reasons for permanent, irreversible infertility:

- Review the **Guide for Female Patients** prior to initiating treatment
- Report a change or misclassification in reproductive status by completing and submitting the **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form** within 10 business days of becoming aware

5. Check pregnancy status in Female of Reproductive Potential

- Order and review pregnancy test results for the patient:
 - Prior to initiating treatment
 - Monthly during treatment
 - One month following treatment discontinuation

The patient must agree to be contacted by the certified pharmacy prior to each shipment to confirm that a pregnancy test was completed, and she must also agree to be contacted by the Ambrisentan REMS if she becomes pregnant while on ambrisentan or within one month of stopping treatment.

6. Enroll all female patients into the Ambrisentan REMS

- Complete and submit the **Patient Enrollment Form** via fax to 1-866-750-9802 or login to complete and submit online at www.ambrisentanrems.us.com.
- Keep the original form with the patient's records

7. Evaluate reproductive status of female patients throughout treatment

- Report a change or misclassification in reproductive status to the Ambrisentan REMS within 10 business days of becoming aware of the change by faxing the completed **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form** to 1-866-750-9802 or online at www.ambrisentanrems.us.com. Verify the reproductive status of Pre-Pubertal Females who are at least 8 years of age or older annually by completing and submitting the **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form**
- Counsel females who fail to comply with the Ambrisentan REMS requirements
- Notify the Ambrisentan REMS if any patient becomes pregnant during ambrisentan treatment or within one month following treatment discontinuation

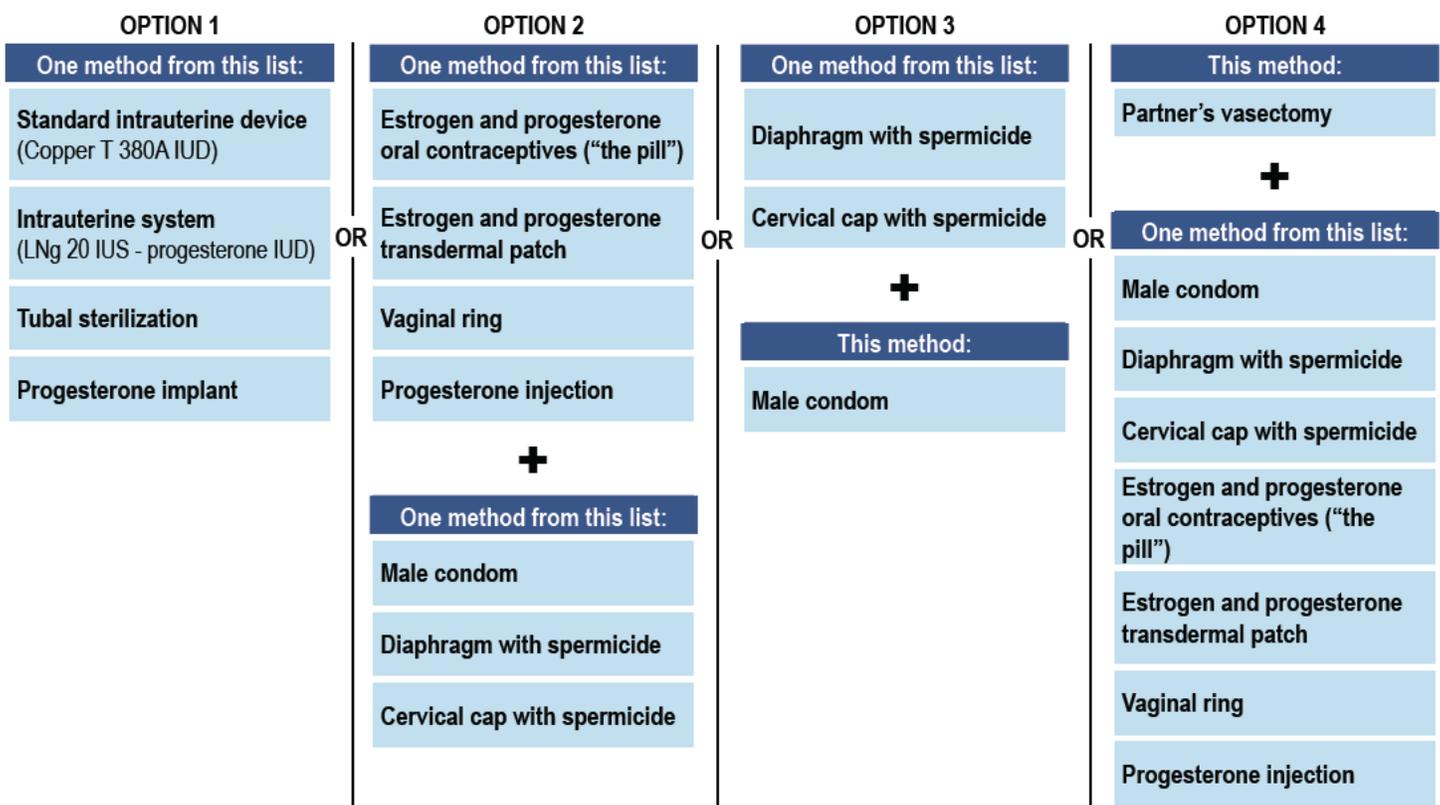
Contraceptive Options for Females of Reproductive Potential

All Females of Reproductive Potential should undergo contraceptive counseling with either the prescriber or another designated healthcare practitioner trained in contraceptive counseling.

Please refer to the diagram below for a complete list of the acceptable contraceptive options. The same diagram also appears in the *Guide for Female Patients* and should be used to discuss acceptable birth control options with patients.

- Educate and counsel Females of Reproductive Potential on the use of emergency contraception in the event of unprotected sex or known or suspected contraceptive failure
- Remind patients to report to you immediately any delay in having a period or any other reason of suspected pregnancy during treatment
- If pregnancy is suspected for any reason, a pregnancy test must be performed
- **The prescriber must notify the Ambrisentan REMS of any pregnancies that occur during treatment or within one month following treatment discontinuation**

Contraceptive Options for Females of Reproductive Potential



Role of Certified Pharmacies

Outpatient Pharmacy Dispensing:

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.

Prior to dispensing, the outpatient pharmacy must:

- For Females of Reproductive Potential: Counsel the patient 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.
- 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 and the reproductive status has not changed.
- For Females of Reproductive Potential: Verify that the pregnancy testing is complete or the prescriber authorizes the refill.
- For Females of Reproductive Potential: Dispense no more than a 30 days' supply
 - A certified prescriber may be eligible to provide the outpatient pharmacy a one time authorization to dispense a greater than 30 day supply for a FRP and the outpatient pharmacy must report the reason to the Ambrisentan REMS for approval. For information on the eligibility to dispense more than a 30 day supply and related authorization process, contact the Ambrisentan REMS at 1-888-417-3172.

At all times, the outpatient pharmacy must:

- Report pregnancies to the Ambrisentan REMS.
- Report a change or misclassification in reproductive status to the Ambrisentan REMS.
- 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 are being followed.

For a list of Certified Pharmacies, call the Ambrisentan REMS at **1-888-417-3172**

Inpatient Pharmacy Dispensing:

Only inpatient pharmacies within institutions such as hospitals, long-term care facilities, and prisons that are certified in the Ambrisentan REMS may stock ambrisentan for patients being treated in the inpatient setting. In order for inpatients 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 program.

Prior to dispensing, the inpatient pharmacy must:

- Verify that the female patient is:
 - Under the supervision and care of a certified prescriber
 - Enrolled or will be enrolled in the REMS prior to discharge
- Verify female patient's reproductive status
- For female of reproductive potential:
 - Verify that the pregnancy testing is complete
 - Counsel the patient on the risk of embryo-fetal toxicity and the need to use highly reliable contraception during treatment and for one month after stopping treatment
 - Counsel patient on the need to get monthly pregnancy tests and the need to inform the prescriber of a pregnancy immediately

Prior to discharge of a patient, the inpatient pharmacy must:

- Dispense no more than a 15 days' supply upon discharge.

At all times, the inpatient pharmacy must:

- Report pregnancies to the Ambrisentan REMS.
- Report a change or misclassification in reproductive status to the Ambrisentan REMS.
- Not distribute, transfer, loan, or sell ambrisentan, except to certified dispensers.
- Maintain records that all processes and procedures are in place and are being followed.
- 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 are being followed.

The Ambrisentan REMS

- Enters every ambrisentan prescriber, female patient, and enrolled pharmacy into the Ambrisentan REMS database
- Collects all **Patient Enrollment Forms, Prescriber Enrollment Forms, Pharmacy Enrollment Forms (Outpatient and Inpatient), and Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Forms**
- Allow access to the certified pharmacies for verification of patient and prescriber information
- Collects information about changes in reproductive status, annual verification of reproductive status for Pre-Pubertal Females, and any occurrences of pregnancies during ambrisentan treatment or within one month following treatment discontinuation

AMBRISENTAN RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Ambrisentan REMS **GUIDE FOR FEMALE PATIENTS**

Table of Contents

Information for Females Patients

What is Ambrisentan?.....	2
What are the serious risks of Ambrisentan?.....	2
What is the Ambrisentan Risk Evaluation and Mitigation Strategy (REMS)?.....	2
How do I enroll in the Ambrisentan REMS?.....	2
What are the Ambrisentan REMS requirements for me?.....	3
What are my birth control options?.....	3 & 4
How will I receive my Ambrisentan?.....	4

This guide is part of an FDA-approved REMS.

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.

What is the Ambrisentan Risk Evaluation and Mitigation Strategy (REMS)?

Because of the risk of serious birth defects, the FDA has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for ambrisentan. The purpose of the Ambrisentan REMS is to make sure the benefits of ambrisentan outweigh the risks. All females must enroll in the Ambrisentan REMS to receive ambrisentan. Specific requirements apply to females who can get pregnant.

To receive Ambrisentan:

1) You must talk with your doctor to ensure the benefits outweigh the risks of ambrisentan	2) You must agree to all of the requirements of the Ambrisentan REMS. These requirements include monthly pregnancy tests and use of appropriate birth control for females that can get pregnant while taking ambrisentan and for one month after stopping ambrisentan	3) Your doctor will enroll you in the Ambrisentan REMS	4) Your prescription will be mailed to you from a certified pharmacy that you and your doctor will choose
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How do I enroll in the Ambrisentan REMS?

Follow these steps with your doctor:

- ✓ Read all the patient information about ambrisentan and the Ambrisentan REMS included in this guide or on the Ambrisentan REMS website, www.ambrisentanrems.us.com
- ✓ Talk with your doctor to ensure the benefits outweigh the risks of ambrisentan
- ✓ Ask questions. Make sure you understand what you need to do to enroll and take part in the Ambrisentan REMS. Make sure you know how to receive and take ambrisentan
- ✓ You and your doctor choose a certified pharmacy to supply ambrisentan. In some cases, your insurance company may need you to use a specific certified pharmacy
- ✓ You and your doctor fill out the **Patient Enrollment Form**. After you read and sign it, your doctor sends it to the Ambrisentan REMS

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:

- 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
 - Agree to be contacted by the Ambrisentan REMS if you become pregnant while on ambrisentan or within one month of stopping treatment.
 - 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:

- Enroll in the Ambrisentan REMS by completing the **Patient Enrollment Form**.
- Have a negative pregnancy test before you start taking ambrisentan and before you receive your refills. Your doctor orders the pregnancy tests for you. Your certified pharmacy will call you and ask if you have taken this test before shipping your refill.
- **Be sure you take your monthly pregnancy test as ordered by your doctor. Your certified pharmacy may 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. Page 4 of this guide shows your birth control options.

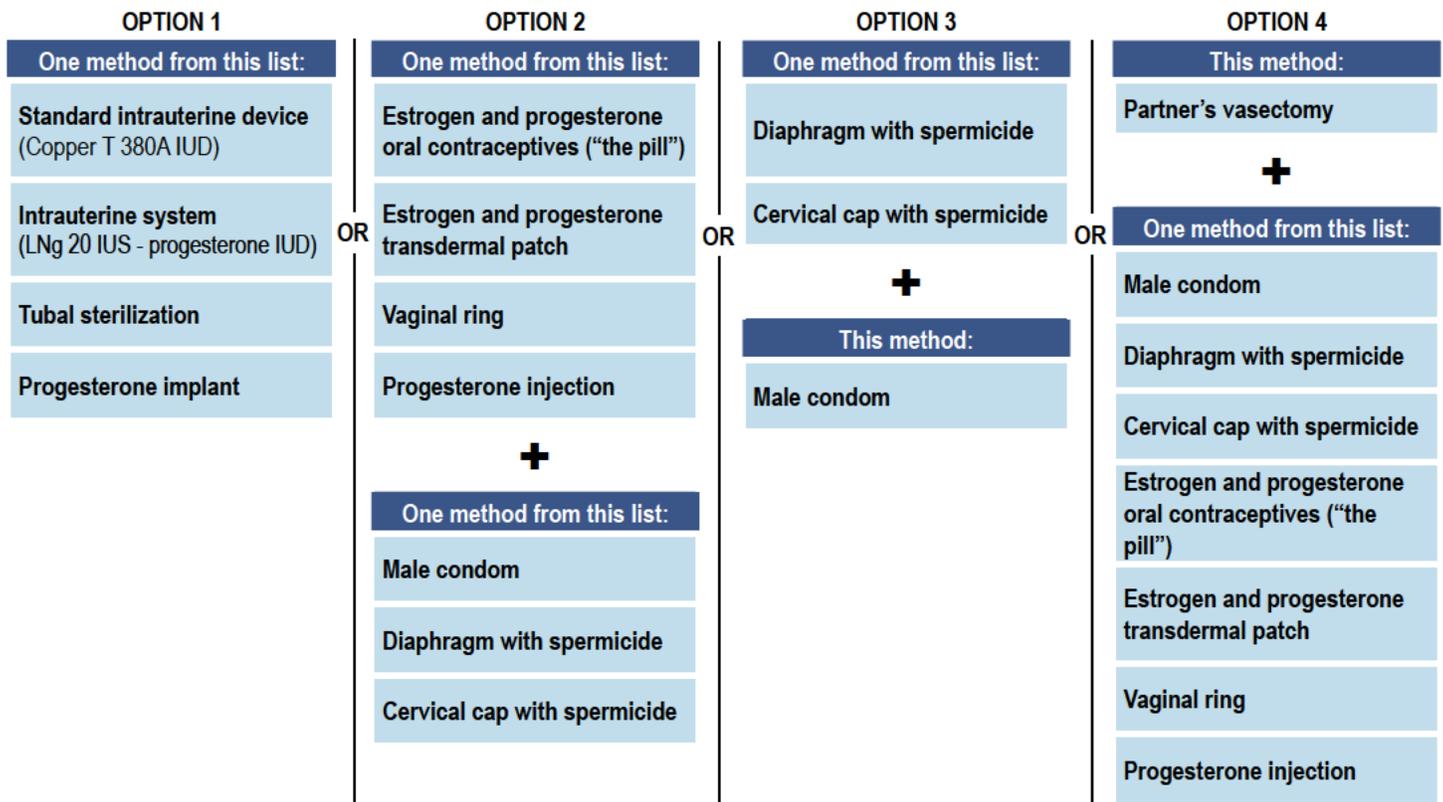
Talk to your doctor or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be pregnant. Your doctor may tell you to use emergency birth control. Do not wait until your next appointment to tell your doctor if you miss your menstrual period 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 on the next page 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 on the next page. More than one birth control method might be needed every time you have sex.

Your birth control options



How will I receive my Ambrisentan?

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 visit www.ambrisentanrems.us.com or call 1-888-417-3172 for more information about the Ambrisentan REMS.

Ambrisentan REMS Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form

Complete and fax this form to: 1-866-750-9802 or complete and submit online at www.ambrisentanrems.us.com

Complete this form to:

1. Change the reproductive status of any female patient, or
2. Complete the annual verification of reproductive potential status for Pre-Pubertal Females, 8 years of age or older

Prescriber must complete this form within 10 business days of awareness of the change in reproductive potential status.

1 Patient Information (PLEASE PRINT)			
Patient Ambrisentan REMS ID:			
First Name:	Middle Initial:	Last Name:	
Address:	City:	State:	Zip:
Birthdate: / /	Phone:		
2 Prescriber Information (PLEASE PRINT)			
Office Contact and E-mail Address:			
First Name:	Last Name:	State License #:	
Address:	City:	State:	Zip:
Phone:	Fax:	NPI #:	
Definitions of Reproductive Potential Status:			
<u>Females of Reproductive Potential</u>			
<ul style="list-style-type: none">• Females of Reproductive Potential include girls who have entered puberty and all women who have a uterus and have not passed through Menopause (as defined below).• For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).			
<u>Females of Non-Reproductive Potential</u>			
<ul style="list-style-type: none">• Pre-Pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.• Post-Menopausal Female: Females who have passed through Menopause (as defined below).• Other medical reasons for permanent, irreversible infertility.			
<u>Menopause</u>			
Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.			
3 Please select the most appropriate reason for submitting this form.			
Change in Status			
<ul style="list-style-type: none">• Based on definitions of reproductive potential status, patient is (please check one):<ul style="list-style-type: none"><input type="checkbox"/> Female of Reproductive Potential<input type="checkbox"/> Female of Non-Reproductive Potential – Patient is pre-pubertal<input type="checkbox"/> Female of Non-Reproductive Potential – Patient is post-menopausal<input type="checkbox"/> Female of Non-Reproductive Potential – Other medical reasons for permanent, irreversible infertility• Reason for change in classification (please check one):<ul style="list-style-type: none"><input type="checkbox"/> Physiological transition<input type="checkbox"/> Medical/surgical (please specify): _____<input type="checkbox"/> Other (please specify): _____			
Annual Verification			
<input type="checkbox"/> Patient remains a Pre-Pubertal Female (8 years of age or older)			
REQUIRED	By signing, I certify that the patient's reproductive potential status and reason for submitting this form are accurately noted above.		Date:
	Prescriber Signature:		

Please visit www.ambrisentanrems.us.com or call 1-888-417-3172 for more information about the Ambrisentan REMS.

This form is part of an FDA-approved REMS.

REMS Changes



The Ambrisentan REMS is a shared system REMS for approved ambrisentan products associated with this REMS, including Letairis, replacing the Letairis REMS Program. Prescribers currently certified and patients currently enrolled in the Letairis REMS Program will be transitioned from the Letairis REMS Program to the Ambrisentan REMS without the requirement to recertify or reenroll in the Ambrisentan REMS. Currently certified outpatient pharmacies in the Letairis REMS Program that are transitioning to the Ambrisentan REMS will be required to recertify in the Ambrisentan REMS.

CLOSE

The Ambrisentan REMS (Risk)

The Ambrisentan REMS is a safety program required by the Food and Drug Administration (FDA) for the safe use of ambrisentan. The Ambrisentan

- Only prescribers and pharmacies certified by the REMS are allowed to prescribe or dispense ambrisentan.
- Patients must be enrolled in the Ambrisentan REMS.

PHARMACIES

CONTACT US

RESOURCES

ng ambrisentan. The Ambrisentan

Prescribers

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

To prescribe ambrisentan:

- 1 Review the Prescribing Information and *Prescriber and Pharmacy Guide*

Female Patients

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

To receive ambrisentan:

- 1 Review the *Guide for Female Patients*

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

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

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 or will be enrolled prior to discharge
 - 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](#)
- [Spanish Ambrisentan REMS Patient Enrollment and Consent Form](#)
- [Ambrisentan REMS Guide for Female Patients](#)
- [Spanish 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](#)
- [Spanish 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
					Prescribing Information
					Prescribing Information

Generic:

Drug Name	Dosage	Company	Contact	Links
				Prescribing Information
				Prescribing Information

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](#)
- [Spanish Ambrisentan REMS Patient Enrollment and Consent Form](#)
- [Ambrisentan REMS Guide for Female Patients](#)
- [Spanish 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:

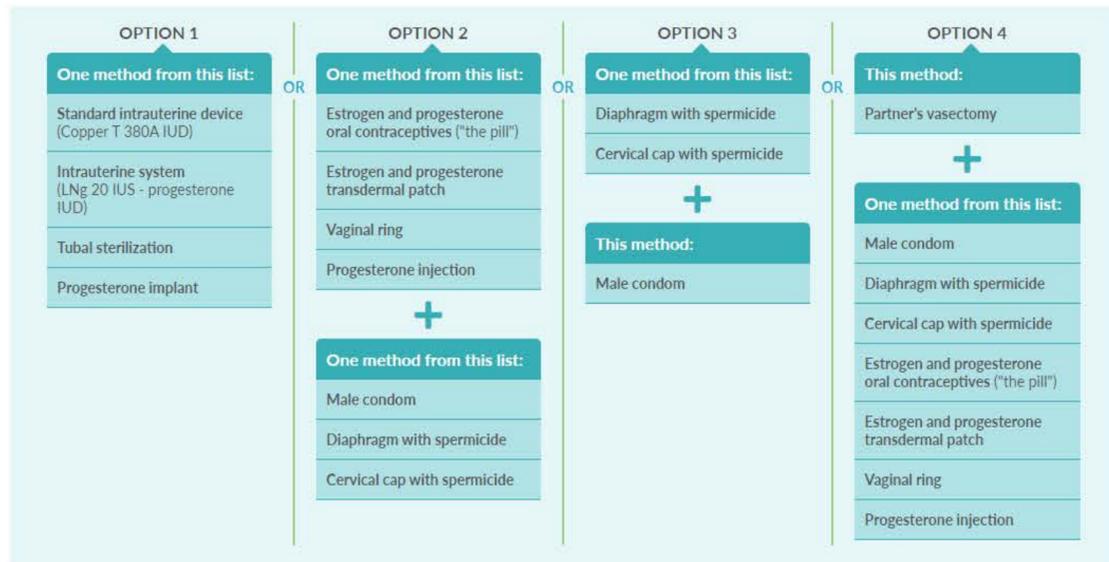
- Talk to your doctor to ensure the benefits outweigh the risks of ambrisentan.
- Review this webpage or the *Guide for Female Patients*.
- Have a negative pregnancy test before you start taking ambrisentan and before you receive your refills. Your doctor orders the pregnancy test for you.
- Enroll in 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

Spanish 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.
 - A certified prescriber may be eligible to provide the outpatient pharmacy a one time authorization to dispense a greater than 30 day supply for a FRP and the outpatient pharmacy must report the reason to the Ambrisentan REMS for approval. For information on the eligibility to dispense more than a 30 day supply and related authorization process, contact the Ambrisentan REMS at 1-888-417-3172.
- 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 female patient is enrolled or will be enrolled in the REMS prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified prescriber.
- 6 For females of reproductive potential: establish processes and procedures to verify pregnancy testing is complete, the patient has been counseled on the risk of embryo-fetal toxicity, the need to use highly reliable contraception during treatment and for one month following treatment discontinuation, 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 the female patient is under the supervision and care of a certified prescriber, her reproductive status, she is enrolled or will be enrolled in the REMS prior to discharge 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, the need to use highly reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform their prescriber of a pregnancy immediately.
- 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.
 - Maintain records that all processes and procedures are in place and are being followed.
 - 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 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

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

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Resources

Resources for Prescribers

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

Certified Outpatient Pharmacies

Below is a list of all certified outpatient pharmacies dispensing ambrisentan.

-  Download the list to spreadsheet format by clicking on the Excel icon just above the column headers
-  Search/Filter the list by entering information in the text box below any column header
-  Sort the list by clicking on any column header

					
Name	City	State	ZIP	Phone Number	Fax Number
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
ABC Pharmacy	Philadelphia	PA	12345	555-555-1212	555-555-2323

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARY R SOUTHWORTH
12/22/2020 09:14:56 AM