

# 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](http://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			
<b>For Females Who Can Get Pregnant:</b>			
Before I begin ambrisentan treatment I will:			
<ul style="list-style-type: none"><li>Review the <b>Guide for Female Patients</b>.</li><li>Get a pregnancy test.</li><li>Enroll in the REMS by completing the <b>Patient Enrollment Form</b> with the prescriber. Enrollment information will be provided to the REMS.</li><li>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 <b>Guide for Female Patients</b>.</li></ul>			
Before I receive each prescription of ambrisentan I will:			
<ul style="list-style-type: none"><li>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.</li><li>Get a pregnancy test.</li><li>Communicate with the pharmacy to confirm pregnancy testing.</li></ul>			
During my treatment with ambrisentan and for one month after stopping treatment, I will:			
<ul style="list-style-type: none"><li>Use highly reliable contraception as described in the <b>Guide for Female Patients</b>.</li><li>Get a pregnancy test monthly during treatment and for one month after I stop taking ambrisentan.</li><li>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.</li></ul>			
<b>For Pre-Pubertal Females (and their parent/guardian):</b>			
Before I begin ambrisentan treatment, I will:			
<ul style="list-style-type: none"><li>Review the <b>Guide for Female Patients</b>.</li><li>Enroll in the REMS by completing the <b>Patient Enrollment Form</b> with the prescriber. Enrollment information will be provided to the REMS.</li><li>Receive counseling from the prescriber on the risk of serious birth defects using the <b>Guide for Female Patients</b>.</li></ul>			
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.			
<b>For Post-menopausal Females or Females with other medical reasons for permanent, irreversible infertility:</b>			
Before I begin ambrisentan treatment, I will:			
<ul style="list-style-type: none"><li>Review the <b>Guide for Female Patients</b>.</li><li>Enroll in the REMS by completing the <b>Patient Enrollment Form</b> with the prescriber. Enrollment information will be provided to the REMS.</li></ul>			
I will tell my prescriber if my reproductive status (ability to become pregnant) changes.			
<b>REQUIRED FOR ALL FEMALE PATIENTS</b>	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](http://www.ambrisentanrems.us.com).

Please visit [www.ambrisentanrems.us.com](http://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.