

PS-Ambrisentan REMS Patient Enrollment and Consent Form

FAX FORM TO: 1-888-870-1819 You may also enroll patients online (www.PSAmbrisentanREMS.com) or on the mobile app

1 Patient Information (PLEASE PRINT)								
First Name:		Middle Initial:		Last Name:				
Address:			City:		State:			
Zip:	Birthdate: / /	Gender <input type="checkbox"/> M <input type="checkbox"/> F	Home Phone: ()		Mobile Phone: ()			
Email Address:			Preferred Time of Contact: <input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening					
Preferred Method of Contact: <input type="checkbox"/> Mobile App <input type="checkbox"/> Text to Mobile # <input type="checkbox"/> Email <input type="checkbox"/> Phone Call			Alternate Contact (Parent/Guardian required if patient is under the age of 18)					
Alternate Contact First and Last Name:			Alternate Contact Phone: ()					
Alternate Contact Email:		Alternate Contact Preferred Method of Contact: <input type="checkbox"/> Phone Call <input type="checkbox"/> Email		Alternate Contact Preferred Time of Contact: <input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening				
2 Female Patient Agreement								
<p>For Females Who Can Get Pregnant: Before I begin ambrisentan treatment, I will:</p> <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. <p>Before I receive each prescription of ambrisentan, I will:</p> <ul style="list-style-type: none"> • Receive counseling from the prescriber or REMS Coordinating Center on risk of serious birth defects, 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 REMS Coordinating Center to confirm pregnancy testing. <p>During my treatment with ambrisentan and for one month after stopping treatment, I will use highly reliable contraception as described in the Guide for Female Patients.</p> <p>I will get a pregnancy test one month after I stop taking ambrisentan.</p> <p>I 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.</p> <p style="text-align: center;">Continued in next column</p>			<p>For Pre-Pubertal Females (and their guardians): Before I begin ambrisentan treatment, I will:</p> <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. <p>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.</p> <p>I will tell my prescriber if my reproductive status (ability to become pregnant) changes.</p> <p>For Post-menopausal Females or Females with other medical reasons for permanent, irreversible infertility: Before I begin ambrisentan treatment, I will:</p> <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 <p>I will tell my prescriber if my reproductive status (ability to become pregnant) changes.</p> <p>Patient or Parent/Guardian of patients under the age of 18 must sign below.</p>					
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width: 10%; padding: 5px;">Required for all patients</td> <td style="padding: 5px;">Patient or Parent/Guardian Signature: X</td> </tr> </table>				Required for all patients	Patient or Parent/Guardian Signature: X	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Date: / /</td> </tr> </table>		Date: / /
Required for all patients	Patient or Parent/Guardian Signature: X							
Date: / /								

3 Prescriber Information (PLEASE PRINT)

First Name:	Last Name:	Individual NPI #	
Address:	City:	State:	Zip:
Phone: ()	Fax: ()	State License #	

4 Statement of Medical Necessity**Diagnosis: Pulmonary Arterial Hypertension**

(the following is not to suggest approved uses or indications. Please select one category below.)

- | | |
|---|--|
| <input type="checkbox"/> Primary Pulmonary Hypertension | <input type="checkbox"/> Pulmonary Hypertension, Secondary |
| <input type="checkbox"/> Pulmonary Heart Disease, unspecified | <input type="checkbox"/> Other _____ |

5 Prescriber Authorization

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

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 this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).

Continued in next column

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 PS-Ambrisentan REMS**For All Females**

- I will determine the reproductive potential status of all female patients using the definitions provided in the **Prescriber 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 PS-Ambrisentan REMS.
- I will enroll all female patients by completing and submitting the **Patient Enrollment Form**.

For Females of Reproductive Potential

- 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.

For Pre-Pubertal Females

- I will counsel each Pre-Pubertal Female patient and her parent/guardian about 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**.

I certify that for female patients, I have provided the appropriate counseling and PS-Ambrisentan REMS materials, and I will continue to fulfill my obligations under the PS-Ambrisentan REMS as outlined on page 2 of this form.

Required
for all
prescribers**Prescriber Signature****X****Date:**

/ /

6 Fax this enrollment form to 1-888-870-1819