

# 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](http://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 #:	
<b>Definitions of Reproductive Potential Status:</b>			
<u>Females of Reproductive Potential</u>			
<ul style="list-style-type: none"><li>• 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).</li><li>• 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).</li></ul>			
<u>Females of Non-Reproductive Potential</u>			
<ul style="list-style-type: none"><li>• Pre-Pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.</li><li>• Post-Menopausal Female: Females who have passed through Menopause (as defined below).</li><li>• Other medical reasons for permanent, irreversible infertility.</li></ul>			
<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.			
<b>Change in Status</b>			
<ul style="list-style-type: none"><li>• <b>Based on definitions of reproductive potential status, patient is (please check one):</b><ul style="list-style-type: none"><li><input type="checkbox"/> Female of Reproductive Potential</li><li><input type="checkbox"/> Female of Non-Reproductive Potential – Patient is pre-pubertal</li><li><input type="checkbox"/> Female of Non-Reproductive Potential – Patient is post-menopausal</li><li><input type="checkbox"/> Female of Non-Reproductive Potential – Other medical reasons for permanent, irreversible infertility</li></ul></li><li>• <b>Reason for change in classification (please check one):</b><ul style="list-style-type: none"><li><input type="checkbox"/> Physiological transition</li><li><input type="checkbox"/> Medical/surgical (please specify): _____</li><li><input type="checkbox"/> Other (please specify): _____</li></ul></li></ul>			
<b>Annual Verification</b>			
<input type="checkbox"/> Patient remains a Pre-Pubertal Female (8 years of age or older)			
<b>REQUIRED</b>	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](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.