

Letairis Risk Evaluation and Mitigation Strategy (REMS) Program

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

FAX FORM TO: 1-888-882-4035

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 at least 8 years of age and 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 Letairis REMS ID:			
First Name:	Middle Initial:	Last Name:	
Address:		City:	State: ZIP:
Birthdate: / /		Phone: ()	
2 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 Address:	
Definitions of Reproductive Potential Status:			
Females of Reproductive Potential			
<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).			
Females of Non-Reproductive Potential			
<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.			
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.			
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: X		

Please visit www.letairisrems.com or call 1-866-664-5327 for more information about the Letairis REMS Program. This form is part of an FDA-approved REMS.



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