

Tracleer® REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form

**NOTE: THIS FORM SHOULD NOT BE USED TOGETHER WITH THE ENROLLMENT FORM.
USE IT ONLY TO REPORT A CHANGE IN REPRODUCTIVE STATUS OR FOR PRE-PUBERTAL ANNUAL VERIFICATION.**

Complete this form to:

- 1) Change the reproductive status of any female patient within 10 business days of awareness of the change in reproductive status
- 2) Complete the annual verification of the reproductive potential status for Pre-pubertal Females 8 years of age or older

Fax this form to *Actelion Pathways*® at 1-866-279-0669.

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

Patient Information (please print)

Patient Tracleer ID _____

First name _____ MI _____ Last name _____

Address _____

City _____ State _____ ZIP _____

Birth date _____ Phone _____

Prescriber Information (please print)

First name _____ MI _____ Last name _____

NPI # _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Tracleer Prescriber ID (if available) _____

Office contact and email address (optional) _____

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females 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. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical form bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

Select the most appropriate reason for submitting this form. (For reference, please see the Definitions of Reproductive Potential Status)

Change in Status

- Based on definitions of reproductive potential status, patient is (please check one):

- Female of Reproductive Potential
- Female of Non-Reproductive Potential—Patient is pre-pubertal
- Female of Non-Reproductive Potential—Patient is post-menopausal
- Female of Non-Reproductive Potential—Other medical reasons for permanent, irreversible infertility

- Reason for change in classification (please check one):

- Physiological transition
- Medical/surgical (please specify): _____
- Other (please specify): _____

- Annual Verification

- Patient remains a Pre-Pubertal Female (8 years of age or older)

Prescriber acknowledgement (REQUIRED)

By signing, I certify that the patient's reproductive status as noted above is accurate, and that I will comply with the REMS requirements for my patient's reproductive potential status.

Prescriber signature _____

Title (MD/PA/NP, etc) _____

Date _____

Please visit www.TracleerREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Tracleer REMS Program.

