

TRACLEER® Patient Enrollment and Consent Form

Complete this form for ALL patients.

Fax this completed form to 1-866-279-0669.

Contact *Actelion Pathways®* at 1-866-228-3546 for questions.



ET3201604

FOR VA USE ONLY

1 Patient Information (please print)

_____			<input type="checkbox"/> Male	<input type="checkbox"/> Female
First name	Middle initial	Last name	Gender	
_____		_____		
Birth date	Primary language	Email address		
_____	_____	_____		
_____		_____		_____
Primary phone #	Alternate phone #	Best time to call		
_____	_____	_____		
_____		_____	_____	_____
Address	City	State	ZIP	
_____	_____	_____	_____	
_____		_____	_____	
Legal guardian	Relationship	Phone #		
_____	_____	_____		
_____		_____	_____	
Emergency contact	Relationship	Phone #		
_____	_____	_____		

2 Patient Agreement

For All Patients: I acknowledge that I understand that Tracleer is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I acknowledge that I have been counseled on the risks of Tracleer, including the risk of liver damage and serious birth defects. I have read the *Tracleer Medication Guide* and the *Tracleer REMS Guide for Patients*. I understand that I will be contacted by Actelion, its agents, and/or a healthcare provider to receive counseling and education on the Tracleer REMS Program and the risks of Tracleer treatment, to ensure that I am completing the required liver function tests before I start Tracleer and monthly before each refill. I agree to be counseled each month on the need for the monthly liver testing.

For Females Who Can Get Pregnant: I understand that I will be contacted by Actelion and/or its agents and contractors to receive counseling on the risk of serious birth defects, the need to use reliable contraception during Tracleer treatment and for one month after stopping Tracleer treatment, the importance of not becoming pregnant, and to ensure that I have completed pregnancy testing: before I start Tracleer, monthly before each refill, and for one month after stopping Tracleer. I agree to be counseled each month by the certified pharmacy on the need to use reliable contraception during Tracleer treatment and for one month after stopping Tracleer. I understand that I must immediately contact my healthcare provider if I miss a menstrual period or suspect that I am pregnant; and that I may be contacted by Actelion and/or its agents and contractors to obtain information about my pregnancy, if I become pregnant.

For Pre-pubertal Females: I acknowledge that I have received and read the *Tracleer Medication Guide* and that I understand that I must immediately contact my healthcare provider if I get my menstrual period.

For Post-menopausal Females: I acknowledge that I have received and read the *Tracleer Medication Guide*.

For Females with other medical reasons for permanent, irreversible infertility: I acknowledge that I have received and read the *Tracleer Medication Guide*.

★ _____
(REQUIRED) Patient or Parent/Guardian Signature Date

3 Prescriber Information (please print)

_____		_____	_____	_____
First name	Middle initial	Last name	City	State ZIP
_____		_____	_____	_____
_____		_____	_____	_____
Address	City	State	ZIP	
_____	_____	_____	_____	
_____		_____	_____	
Phone #	Fax #		_____	
_____	_____		_____	
_____		_____		
NPI #	Tracleer Prescriber ID			
_____	_____			
Office contact and email address				

4 VA Pharmacy Information (please print)

VA Pharmacy				

_____		_____	_____	_____
Address	City	State	ZIP	
_____	_____	_____	_____	
_____		_____	_____	
Contact	Phone #	Fax #		
_____	_____	_____		

5 Prescriber Authorization

For this patient, have you reviewed their liver function tests? Yes No

If your patient is FEMALE, check correct female patient category (please see definitions of these terms on the following page):

REQUIRED (Check one box)

Female of Reproductive Potential

If this patient is a Female of Reproductive Potential, has a negative pregnancy test been completed prior to prescribing Tracleer?

Yes No

Female of Non-Reproductive Potential

Pre-pubertal Female Post-menopausal Female

Female with other medical reasons for permanent, irreversible infertility

I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" indicated on the second page of this form. Further, I hereby authorize Actelion and/or its designated representative(s), to act on my behalf for the limited purposes of providing this prescription to the certified specialty pharmacy for patient treatment purposes.

★ _____
(REQUIRED FOR ALL PRESCRIBERS) Prescriber Signature Date

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

Prescriber Requirements

For All Patients

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Tracleer® is only available through a restricted distribution program under an FDA-required REMS
- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of Tracleer, including the risk of liver damage and serious birth defects, and that I have reviewed the *Tracleer Medication Guide* and the *Tracleer REMS Guide for Patients* with the patient (and parent/guardian when appropriate)
- I will order and review liver function tests (ALT/AST/bilirubin) prior to initiation of treatment and monthly during treatment

For Females of Reproductive Potential

- I will order and review pregnancy tests prior to initiation of Tracleer treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Tracleer REMS Program
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a *Tracleer REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change

For Pre-pubertal Females

- 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 or misclassification in reproductive potential status on a *Tracleer REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change

6 Fax this form to 1-866-279-0669

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