

TRACLEER® Patient Enrollment and Consent Form

Complete this form for ALL patients.

Fax this completed form and copies of all insurance cards (front and back) to 1-866-279-0669.

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



1 Patient Information (please print)

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

Certified pharmacy preference (If left blank, this referral will be sent to the appropriate certified pharmacy based on the patient's existing benefits.)

2 Actelion Pathways Services Authorization

I allow my healthcare providers, pharmacy providers, and health plans to use and share my personal information and health information about me and my Actelion therapies ("my information") with Actelion Pharmaceuticals US, Inc. and its contractors (collectively, "Actelion") for the following purposes: 1) to establish my benefit eligibility, including benefit eligibility for laboratory services; 2) to communicate with my healthcare providers, health plans, other payers, and pharmacies about my medical care; and 3) to help provide any therapy access support services to me that will assist in my Actelion therapy. Actelion may leave messages for me on the telephone number(s) that I provide. These messages may state that I take an Actelion medication as well as provide me with additional information. I also allow the sharing of my information to specific people I have identified.

I understand that Actelion does not promise to find ways to pay for my medications. I know that I am responsible for the costs of my care. I understand that once my health information has been shared with Actelion, privacy laws may no longer protect it; however, Actelion agrees to protect my information and to use and share it only for reasons listed above or as required by law. I understand that my certified pharmacy may receive payment in connection with the use and disclosure of my information for purposes allowed under this permission. If I do not sign this form, my eligibility for health plan benefits and treatment by my healthcare provider will not change, but I will not have access to the Actelion support services. I may also cancel my permission at any time by writing a letter saying I cancel my written permission and mailing to Actelion Pharmaceuticals US, Inc.: P.O. Box 826, South San Francisco, CA 94083 or by faxing it to 1-866-279-0669 or by calling 1-866-228-3546. I am allowed a copy of this signed agreement. This written permission will expire 10 years after the date on which I sign it.

3 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 on 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 by the pharmacy 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 FOR ALL PATIENTS) Patient or Parent/Guardian Signature _____ Date _____

4 Prescriber Information

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

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

5 Diagnosis, Prescription, and Shipping Information (Check ONLY ONE Box for the Diagnosis Related to Tracleer Treatment)

Pulmonary Arterial Hypertension (PAH)

- Idiopathic PAH Heritable PAH Connective Tissue Disorder Congenital Heart Disease
 Other _____

Tracleer (bosentan) dosing: 62.5 and 125 mg tablets

Directions for use and dispensing instructions: Complete A or B below

- A. Sig: Take 62.5 mg tablet by mouth twice daily x 4 weeks, then increase to the maintenance dose of 125 mg tablet by mouth twice daily.
Disp: Tracleer 62.5 mg tablets (66215-101-06) (60 tablets). No refills.
Tracleer 125 mg tablets (66215-102-06) (60 tablets). Refill x 11.

OR

- B. Sig: _____
Disp: Tracleer 62.5 mg tablets (66215-101-06) _____ (Qty) tablets
Tracleer 125 mg tablets (66215-102-06) _____ (Qty) tablets

Ship to: Patient home Prescriber office Other

Address _____
City _____ State _____ ZIP _____

6 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
Reference ID: 3856191

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

7 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.