

Tracleer® (bosentan) Enrollment and Renewal

 Check one: Enrollment Renewal

PO Box 826, South San Francisco, CA 94083-0826 | Phone 1-866-ACTELION (1-866-228-3546) or Fax 1-866-279-0669

Once complete, submit this form to PAH Pathways™. The information will be entered into the Tracleer Access Program (T.A.P.®) database and forwarded to the specialty pharmacy you designate below. The specialty pharmacy will follow up as needed with prescribers and patients.

Patient Information	First name:	MI:	Last name:	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female		
	SSN	DOB:		Phone #:		
	Address		City:	State:	ZIP:	
	Legal guardian/emergency contact:		Relationship	Phone #:		
	Shipping directions <input type="checkbox"/> Physician office <input type="checkbox"/> Patient's home <input type="checkbox"/> Hospital		Shipping attn:			
	Shipping address:		City:	State:	ZIP:	
Diagnosis: Pulmonary arterial hypertension (check subtypes) <input type="checkbox"/> Familial <input type="checkbox"/> Idiopathic <input type="checkbox"/> Scleroderma <input type="checkbox"/> HIV <input type="checkbox"/> Lupus <input type="checkbox"/> Portal hypertension <input type="checkbox"/> Congenital heart defects <input type="checkbox"/> Pulmonary hypertension—other etiologies: _____ <input type="checkbox"/> Other: _____						

Required: Please submit copies of patient's current medical and prescription cards with this form.

Insurance Information	Primary insurance company:		Phone #:			
	Name of insured:		Policy #:	Group/Policy #:		
	Prescription coverage name:		Phone #:	Policy #:	Group/Policy #:	
	Indicate specialty pharmacy preference: _____					
For a current list of pharmacies, call 1-866-228-3546. If no preference is indicated, this referral will be sent to the appropriate specialty pharmacy based on the patient's existing benefits.						

I have read and agreed to the Patient Agreement on the back of this form. I have reviewed the Medication Guide with my prescriber, I consent to be enrolled in the Tracleer Access Program, and I agree to comply with the program for as long as I am prescribed Tracleer.

Patient/guardian signature: _____ Date: _____

Prescriber and Prescription Information	First name:	MI:	Last name:	Degree:		
	DFA #		NPI:			
	Complete section below only if you are a new prescriber or your contact information has changed.					
	Name of facility:		Specialty	Tax ID #:	State license #:	
	Office contact (name and phone)			Phone #:	Fax #:	
	Primary address:		City:	State:	ZIP:	E-mail
	For the patient indicated on this form, please indicate whether: 1. You have reviewed pretreatment liver function tests. <input type="checkbox"/> Yes <input type="checkbox"/> No 2. If a female, she is of childbearing potential. <input type="checkbox"/> Yes <input type="checkbox"/> No 3. If a female of childbearing potential, you have confirmed a pretreatment negative pregnancy test. <input type="checkbox"/> Yes <input type="checkbox"/> No			Prescriber Certification—My signature below certifies that: 1. I have read and understood the communication and educational materials for prescribers regarding the risks of Tracleer, and agree to document that I: -Reviewed and discussed the Medication Guide and the risks of bosentan (including the risks of teratogenicity and hepatotoxicity) with my patients prior to prescribing Tracleer. -Reviewed pretreatment liver function tests (ALT/AST/bilirubin) and confirmed that my patients are not pregnant (if applicable), and I agree to order and monitor monthly liver function tests and, if applicable, pregnancy tests. -Educated and counseled females of childbearing potential (see definition on reverse side) to notify me if they suspect they may be pregnant. Educated and counseled females of childbearing potential about the need to use reliable methods of contraception (see table on reverse side) during treatment with Tracleer and for one month after treatment discontinuation. 2. I will notify Actelion Pharmaceuticals US, Inc., and/or the FDA, of any adverse events, including hepatotoxicity, and report any pregnancy during treatment with Tracleer. 3. I will counsel my patients who fail to comply with the program requirements. 4. I will renew my patients' prescriptions annually by completing and submitting a new form for patients continuing therapy.		
	<input type="checkbox"/> Tracleer 62.5 mg (66215-0101-06) Refills #: _____ <input type="checkbox"/> Tracleer 125 mg (66215-0102-06) Refills #: _____ Dispense as Written Directions for use: _____					
	Prescriber signature: _____ Date: _____			Prescriber signature: _____ Date: _____		

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Patient Agreement

- I have reviewed the Medication Guide with my healthcare provider. I understand that a Medication Guide will be provided to me each time I receive a prescription for Tracleer, and that I must read it each time because it may have new information important to my treatment.
- I have been informed of the risks of treatment with Tracleer, including the risks of liver injury and birth defects. 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 and pregnancy tests (for females of childbearing potential—see definition below) and, if I am a female who becomes pregnant, to obtain information about my pregnancy.
- I agree to notify Actelion or my specialty pharmacy if I should change prescribers.
- I agree to have monthly blood tests as ordered by my healthcare provider for as long as I take Tracleer.
- I authorize my healthcare providers, health plans, other payers, and pharmacies to disclose my personal, medical, and health information to Actelion Pharmaceuticals US, Inc., and its employees, distributors, agents, and contractors ("Actelion"), and I authorize Actelion to use and disclose this information for use in implementing T.A.P. including to 1) establish my benefit eligibility; 2) communicate with my healthcare providers, health plans, other payers, and pharmacies about my medical care; 3) provide support services, including facilitating the provision of Tracleer to me; and 4) help find ways to pay for Tracleer, or for treatment or healthcare operations in progress.
- I understand that I may be contacted by Actelion or its delegates regarding important safety surveys while I am taking Tracleer.
- I understand that Actelion does not promise to find ways to pay for my Tracleer, and I know that I am responsible for the costs of my care.
- I understand that once my health information has been disclosed to Actelion, privacy laws may no longer restrict its use or disclosure; however, Actelion agrees to protect my information by using and disclosing it only for the purposes described above or as required by law.
- I acknowledge and agree that, although Actelion will have access to my personal health information, Actelion will not be providing counseling or medical advice regarding my condition. I further understand that all questions regarding my medical and health conditions should be discussed with my healthcare provider.

Definition of Female of Childbearing Potential (FCBP)

Female patients who are physically capable of becoming pregnant include those who are pubertal and have not yet had menses (premenarchal, Tanner stage 3, 11.5 to 13 years of age), perimenopausal and have had spontaneous menses in the last 24 months, and nonmenopausal who have not had a hysterectomy, bilateral oophorectomy, or medically documented ovarian failure.

Female patients who are not considered to be of childbearing potential are surgically sterile (both ovaries and/or uterus removed), postmenopausal (no menstrual period for longer than 24 consecutive months, confirmed by their healthcare provider), or incapable of pregnancy (confirmed by their healthcare provider).

Reliable methods of contraception during treatment with Tracleer

Methods to use alone	Hormone (choose 1 and use with a barrier method)	Barrier (use both OR choose 1 and use with a hormone method)
<ul style="list-style-type: none"> • Intrauterine devices (IUDs) <ul style="list-style-type: none"> —Copper T 380A IUD —LNg-20 IUS (progesterone IUD) • Tubal sterilization 	<ul style="list-style-type: none"> • Estrogen and progesterone <ul style="list-style-type: none"> —Oral contraceptives —Transdermal patch —Vaginal ring • Progesterone only <ul style="list-style-type: none"> —Injection —Implant 	<ul style="list-style-type: none"> • Male condom with spermicide • Diaphragm with spermicide OR Cervical cap with spermicide
A partner's vasectomy still requires 1 additional method of contraception.		