

Tracleer® REMS Inpatient Pharmacy Enrollment Form

Complete and fax this form to *Actelion Pathways*® at 1-866-279-0669.

You can also reach *Actelion Pathways* via phone at 1-866-ACTELION (1-866-228-3546).



HT22001502

Due to the risk of hepatotoxicity and teratogenicity, Tracleer is available only through a restricted program called the Tracleer REMS (Risk Evaluation and Mitigation Strategy) Program. In order for inpatients to receive Tracleer, all patients, as well as inpatient pharmacies that wish to stock this product, must enroll in the Tracleer REMS Program and agree to comply with the requirements of the program. An Authorized Representative must complete and submit this form on behalf of the inpatient pharmacy.

Inpatient Pharmacy Information (please print)

Name _____
 Hospital Nursing home Hospice Asylum/Mental facility Assisted Living Prison Rehabilitation
 Other (please specify): _____

Identification (please complete one of the following):
 Health Industry Number (HIN #) _____ National Provider Identifier (NPI #) _____
 Other identifier: _____

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

Ship To Address (if different from above)

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

Authorized Representative Information (please print)

Title:
 Hospital pharmacist Head of Pharmacy and Therapeutics (P&T) committee
 Other title: _____
Name _____
Authorized Representative phone # _____ Fax # _____
Authorized Representative email _____

Authorized Representative Consent

- This inpatient pharmacy will:
- Put processes and procedures in place to ensure the Tracleer REMS Program requirements are met
 - Dispense only to those patients under the supervision and care of a healthcare provider who is enrolled in the Tracleer REMS Program
 - Dispense to a patient only after he/she has been enrolled in the Tracleer REMS Program or if he/she will be enrolled prior to discharge from the healthcare facility. A patient who has not been enrolled by the certified prescriber will not have access to Tracleer in the outpatient setting until registration has been completed
 - Dispense no more than a fifteen- (15-) day temporary supply of Tracleer in a child-resistant container upon discharge of any patient
 - Notify Actelion Pharmaceuticals US, Inc. ("Actelion") or FDA of any adverse events, including hepatotoxicity, and report any pregnancy during treatment with Tracleer
 - Not transfer Tracleer to any pharmacy, practitioner, or any healthcare setting not certified by *Actelion Pathways*
 - Develop a process to track compliance with the conditions above and provide information about its compliance to Actelion

I attest that I have read the Tracleer Prescribing Information, *Medication Guide*, and the *Prescriber and Pharmacy Guide for the Tracleer REMS Program* available at www.TracleerREMS.com.

I will ensure training of dispensing staff on the Tracleer REMS Program procedures and materials, including the *Prescriber and Pharmacy Guide for the Tracleer REMS Program* prior to dispensing Tracleer.

I agree that this pharmacy may be audited by the FDA, Actelion, or a designated third party.

Note: If your inpatient pharmacy needs Tracleer and is not enrolled in the Tracleer REMS Program, contact *Actelion Pathways* at 1-866-228-3546 for assistance in obtaining a 15-day supply of Tracleer for a specific inpatient while initiating enrollment of the pharmacy.

Signature _____ Date _____