PATIENT ESSENTIALS

Your guide to starting, taking, and renewing Tracleer

Please also see the Medication Guide enclosed in the back pocket.
Introduction to the essentials

This booklet describes how you and your healthcare provider will work together to ensure the safe use of Tracleer. Tracleer can cause liver damage, including rare cases of liver failure. Tracleer is very likely to cause serious birth defects if taken during pregnancy. Because of these risks, Tracleer is available only through a restricted program called the Tracleer Access Program (T.A.P.), which is a component of the Tracleer Risk Evaluation and Mitigation Strategy (REMS). Before you begin taking Tracleer, you must read and agree to all the instructions in T.A.P.

What is Tracleer?

Tracleer is a prescription medicine used to treat people with certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the vessels of the lungs. Tracleer can improve your ability to exercise and can slow the worsening of your physical condition and symptoms. Tracleer lowers high blood pressure in your lungs and lets your heart pump blood more efficiently.

Starting Treatment with Tracleer

To start treatment with Tracleer, you must:
■ Review safety information with your healthcare provider
■ Complete a Tracleer Enrollment for Patients and Prescribers form
■ Agree to have important monthly tests

To continue therapy with Tracleer, you and your healthcare provider will renew your enrollment each year by completing the Tracleer Renewal form.

As a patient taking Tracleer, you may be contacted about your understanding of the risks with the use of Tracleer.

What is the most important information I should know about Tracleer?

Tracleer is only available through the Tracleer Access Program (T.A.P.). Before you begin taking Tracleer, you must read and agree to all of the instructions in T.A.P. Tracleer can cause serious side effects including:

Liver damage
■ Liver damage may not cause symptoms at first. Only a blood test can show if you have early liver damage. You must have a blood test to check your liver function before you start Tracleer and each month after that. Your healthcare provider will order these tests. Regular blood tests are important because they will help your healthcare provider adjust or stop your treatment before there is permanent damage.
■ Tell your healthcare provider if you have had liver problems, including liver problems while taking other medicines. Call your healthcare provider right away if you have any of these symptoms of liver problems while taking Tracleer: nausea, vomiting, fever, unusual tiredness, stomach area (abdominal) pain, or yellowing of the skin or the whites of your eyes (jaundice).

Serious birth defects
■ Tracleer can cause serious birth defects if taken during pregnancy. You must not be pregnant when you start taking Tracleer or during Tracleer treatment. Serious birth defects from Tracleer can happen early in pregnancy. Females who are able to get pregnant must have a negative pregnancy test before starting treatment and each month during Tracleer treatment.
■ Talk with your healthcare provider or gynecologist (a doctor who specializes in female reproduction) to find out about how to prevent pregnancy. Do not have unprotected sex. Tell your healthcare provider right away if you miss a menstrual period or think you may be pregnant.
■ Females who are able to get pregnant must use birth control (contraception) during Tracleer treatment. You must choose and use two reliable forms of birth control at the same time, unless you have had a tubal sterilization, or have a Copper T 380A IUD or LNG 20 IUS inserted. These methods can be used alone.
■ Birth control pills, shots, patches, and implants should not be used alone because they are not reliable when you are taking Tracleer. You must choose and use two reliable forms of birth control at the same time.
■ If you have had a tubal sterilization, or have an IUD, these methods can be used alone. Otherwise, you should use two forms of birth control.

Talk with your healthcare provider about which 2 methods of reliable birth control you should use. Your healthcare provider may recommend that you use a different method of birth control to help lower your risk of problems with your pulmonary arterial hypertension. See the end of this Medication Guide for more information about reliable methods of contraception during treatment with Tracleer.

See “What are the possible side effects of Tracleer?” for more information about side effects.
See the chart below for more information about reliable methods of contraception during treatment with Tracleer.

### Reliable methods of contraception during treatment with Tracleer

<table>
<thead>
<tr>
<th>Methods to use alone</th>
<th>Hormone (choose 1 and use with a barrier method)</th>
<th>Barrier (use both OR choose 1 and use with a hormone method)</th>
</tr>
</thead>
</table>
| • Intrauterine devices (IUDs)  
  —Copper T 380A IUD  
  —LNG-20 IUS (progesterone IUD)  
• Tubal sterilization  
• Male condom with spermicide  
• Diaphragm with spermicide OR  
  Cervical cap with spermicide  
• Female sterilization  
• Injection  
• Implant |
| • Estrogen and progesterone  
  —Oral contraceptives  
  —Transdermal patch  
  —Vaginal ring  
• Progestrone only  
  —Injection  
  —Implant |

A partner’s vasectomy still requires 1 additional method of contraception.

### Service and support essentials

**Tracleer Access Program (T.A.P.)**

Because of the risks of liver injury and birth defects associated with treatment, you must be enrolled in T.A.P. to receive Tracleer. This is done when you and your healthcare provider complete the Tracleer Enrollment for Patients and Prescribers form. T.A.P. is administered by PAH Pathways®. PAH Pathways counselors coordinate with your certified specialty pharmacy to make sure you receive your Tracleer. You can learn more about specialty pharmacies on page 7.

You can reach PAH Pathways, which administers T.A.P., by calling toll-free at 1-866-ACTELION (1-866-228-3546).

### Starting, taking, and renewing Tracleer

**STARTING TRACLEER**

1. Review the Medication Guide with your healthcare provider
2. Go for liver function and pregnancy tests
3. Complete the Tracleer Enrollment for Patients and Prescribers form with your healthcare provider

**TAKING TRACLEER**

1. Your healthcare provider will complete the Tracleer Renewal form every year
2. Receive Tracleer from your specialty pharmacy
3. Go for monthly liver function and pregnancy tests

### REFERENCES


Please see accompanying full prescribing information, including **BOXED WARNING** about liver damage and birth defects, and Medication Guide.
Starting Tracleer

Review the Medication Guide with your healthcare provider

The Medication Guide is in the back pocket. It covers important facts about Tracleer that you must understand before you start Tracleer, including the risks of liver injury and serious birth defects. Talk with your healthcare provider if you have any questions.

Go for your liver function and pregnancy tests

Before you start Tracleer, you must have a blood test to check your liver function. You must also have a pregnancy test before you start Tracleer, if you are able to become pregnant. You should not start Tracleer if you are pregnant.

Complete the Tracleer Enrollment for Patients and Prescribers form with your healthcare provider

Before you start Tracleer, you must consent to be enrolled in the Tracleer Access Program (T.A.P.) and agree to comply with the requirements of the program as outlined on the back of the Tracleer Enrollment for Patients and Prescribers form.

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 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) try to help find ways to pay for Tracleer, or for treatment or healthcare operations in progress. |
| I have been informed of the risks of treatment with Tracleer, including the risks of liver damage 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 understand that Actelion cannot guarantee that it will be able to find ways to pay for my Tracleer, and I know that I am responsible for the costs of my care. |
| I understand that I may be contacted by Actelion or its delegates regarding important safety surveys while I am taking Tracleer. |
| 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. |
| I consent to be in the Tracleer Access Program for as long as I am taking Tracleer. |

Taking Tracleer

Receive Tracleer from your specialty pharmacy

Tracleer is not available in your retail pharmacy; rather, it is carried by a limited network of certified specialty pharmacies that deliver Tracleer directly to you.

To reduce the risks of the use of Tracleer, you must have liver function and pregnancy tests each month (see below). Your specialty pharmacy will call you to confirm that you have had your tests before they deliver your Tracleer. The specialty pharmacies are required to document that you have had your tests each month.

If you don’t confirm with your specialty pharmacy that you have had your tests or if you become pregnant, your specialty pharmacy will not be able to ship Tracleer to you and will contact your healthcare provider. It’s important that you do not stop taking Tracleer unless your doctor tells you to do so. Suddenly stopping your treatment may cause your symptoms to get worse.

With each monthly delivery, you will receive a Medication Guide, which you should read each time because there may be new information.

Go for monthly liver function and pregnancy tests

Each month, you must have a blood test to check your liver function. If you are able to become pregnant, you must also have a monthly pregnancy test. For more details about why these monthly tests are important and how to avoid becoming pregnant while taking Tracleer, please see the Medication Guide.

Renewing Tracleer

Renew Tracleer enrollment with your healthcare provider every year

Your healthcare provider will renew your enrollment in the Tracleer Access Program every year. Your healthcare provider will review the Medication Guide with you and complete the Tracleer Renewal form.

Please see accompanying full prescribing information, including BOXED WARNING about liver damage and birth defects, and Medication Guide.
Starting, taking, and renewing Tracleer

STARTING TRACLEER

Review the Medication Guide with your healthcare provider

Go for liver function and pregnancy tests

Complete the Tracleer Enrollment for Patients and Prescribers form with your healthcare provider

RENEWING TRACLEER

Your healthcare provider will complete the Tracleer Renewal form every year

TAKING TRACLEER

Receive Tracleer from your specialty pharmacy

Go for monthly liver function and pregnancy tests

If you have questions about Tracleer enrollment and renewal, or if you would like more information about Tracleer, you can reach PAH Pathways, which administers T.A.P., by calling toll-free at 1-866-ACTELION (1-866-228-3546).

Please see accompanying full prescribing information, including BOXED WARNING about liver damage and birth defects, and Medication Guide.

© 2012 Actelion Pharmaceuticals US, Inc. All rights reserved. TRA-00055

www.TRACLEER.com