

# TRACLEER<sup>®</sup> REMS (Risk Evaluation and Mitigation Strategy) Guide for Patients

Information to help you throughout your treatment with Tracleer

*Please see accompanying full Prescribing Information, including **BOXED WARNING** for liver damage and birth defects, and Medication Guide.*

ACTELION  
Pathways<sup>®</sup>

  
Tracleer<sup>®</sup>  
BOSENTAN TABLETS

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## 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 more efficiently.

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## What are the serious risks of Tracleer?

Tracleer can cause **liver damage** and, if taken during pregnancy, can cause **serious birth defects**.

All patients—liver function must be monitored:

- When you start taking Tracleer,
- While taking Tracleer each month, and
- Any time your healthcare provider orders additional testing

Female patients—pregnancy must be avoided:

- When you start taking Tracleer,
- While taking Tracleer, and
- Within one month of stopping Tracleer

## What is the Tracleer REMS (Risk Evaluation and Mitigation Strategy) Program?

The Tracleer REMS is a program to tell patients and healthcare providers about the risk of liver damage and serious birth defects when taking Tracleer. This program is required by the Food and Drug Administration (FDA). All patients must enroll in the Tracleer REMS Program to receive Tracleer. REMS stands for **R**isk **E**valuation and **M**itigation **S**trategy.

## How do I enroll in the Tracleer REMS Program?

There are several steps you must take:

1. Read this *Tracleer REMS Guide for Patients* and the *Tracleer Medication Guide* (which comes with your medicine)
2. Ask your healthcare provider any questions you have about taking Tracleer and the Tracleer REMS Program
3. Make sure you understand:
  - The benefits and risks of Tracleer
  - How to enroll and take part in the Tracleer REMS Program
4. Complete and sign the *Tracleer Patient Enrollment and Consent Form* with your healthcare provider. Your healthcare provider will fill out most of the enrollment form for you and will send the form to *Actelion Pathways*®. *Actelion Pathways* runs the Tracleer REMS program

## What are the Tracleer® REMS Program requirements for me?

- All patients need to have liver function tests prior to starting treatment and each month for as long as you are being treated with Tracleer. Your healthcare provider will order the liver function tests for you
- Go for any additional liver tests your healthcare provider orders for you. Your healthcare provider will monitor your liver function monthly and may adjust or stop your treatment if there are signs of liver damage
- Tell your healthcare provider if you have had liver problems, including liver problems while on other medicines
- Call your healthcare provider right away if you have any of these symptoms of liver problems while you are on Tracleer:
  - Nausea, vomiting, fever, unusual tiredness, stomach area (abdominal) pain, or yellowing of the skin or the whites of your eyes (jaundice)
- Females who can get pregnant must have a negative pregnancy test before starting Tracleer, each month while taking Tracleer, and for one month after stopping Tracleer. Your healthcare provider will order the pregnancy tests for you
  - You are considered a female who can get pregnant if you:
    - Have entered puberty, even if you have not started your period, and
    - Have a uterus, and
    - Have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had your ovaries removed)
- Females who can get pregnant must use reliable birth control at all times when taking Tracleer and for one month after stopping Tracleer. Your birth control options are listed on page 6
- Do not have unprotected sex
- Talk to your healthcare provider right away if you have unprotected sex, if you think your birth control has failed, or if you think you are pregnant. If so, your healthcare provider may discuss medical options with you (e.g., emergency contraception). Do not wait until your next appointment to tell your healthcare provider if you miss your menstrual period or if you think you are pregnant
- Tracleer is not available at your local pharmacy. You must receive Tracleer through a certified pharmacy (sometimes called a specialty pharmacy)
  - Your pharmacy will call you every month to ask if you have completed the liver function tests and pregnancy test (for females who can get pregnant) before shipping your Tracleer to your home or another shipping address you choose
  - You may not receive your Tracleer refill on time if you do not confirm with the pharmacy that you have had your monthly liver test or pregnancy test (for females who can get pregnant)

## What are my birth control options?

Your healthcare provider will talk with you about your birth control options before starting Tracleer®. Ask your healthcare provider if you have any questions. Tell your healthcare provider if you want to change your birth control.

You must choose one of the 4 options listed below. More than one birth control method might be needed every time you have sex.

### Acceptable birth control options

Option 1	or	Option 2	or	Option 3	or	Option 4
<b>One method from this list:</b>		<b>One method from this list:</b>		<b>One method from this list:</b>		<b>One method from this list:</b>
Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNg 20 IUS: progesterone IUS) Tubal sterilization		Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant		Diaphragm with spermicide Cervical cap with spermicide		Partner's vasectomy
		<b>PLUS One method from this list:</b>		<b>PLUS One method from this list:</b>		<b>PLUS One method from this list:</b>
		Male condom Diaphragm with spermicide Cervical cap with spermicide		Male condom		Male condom Diaphragm with spermicide Cervical cap with spermicide Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection Progesterone implant

## How will I receive Tracleer?

Tracleer is available only through certified pharmacies (also called specialty pharmacies).

- *Actelion Pathways*® provides support and services that help patients with their PAH medicines. Once you are enrolled, a Patient Case Manager will work with you to get your Tracleer prescription filled by a pharmacy
- Before your first prescription is filled, the pharmacy will call you to schedule a shipment of Tracleer that will come right to your home
- The *Tracleer Medication Guide* will be included in the package
- Read the *Tracleer Medication Guide* each time you receive it. Important information may have been added or changed

For a list of certified pharmacies, please call *Actelion Pathways* at **1-866-ACTELION (1-866-228-3546)**.

Please see accompanying full Prescribing Information, including **BOXED WARNING** for liver damage and birth defects, and Medication Guide.

## Your steps to treatment with Tracleer®

Use this helpful checklist to get started with Tracleer and to stay on track during your treatment.

### FIRST:

- Review the *Tracleer REMS Guide for Patients* and the *Tracleer Medication Guide* with your healthcare provider
- Make sure you understand the risks and benefits of taking Tracleer
- Tell your healthcare provider if you have had liver problems, including liver problems while taking other medicines
- Go for your liver function tests and pregnancy test (for females who can get pregnant)
- Enroll in the Tracleer REMS Program

### NEXT:

- Expect a call from your Patient Case Manager. He or she will help you get your Tracleer prescription filled by one of the certified pharmacies
- Expect a call from the pharmacy to schedule your first shipment

### EVERY MONTH: All Patients

- Read the *Tracleer Medication Guide* that comes with every shipment
- Complete the monthly liver function tests ordered by your healthcare provider
- Expect your pharmacy to call you every month to ask if you had your liver function tests in the last month before it reorders your Tracleer. The refill may not be done on time if you have not had your liver test
- Tell 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)

### EVERY MONTH: Female Patients who can get pregnant

- For female patients who can get pregnant, use the reliable birth control method(s) agreed upon with your healthcare provider — during treatment and for one month after you stop taking Tracleer
- Complete the monthly pregnancy test ordered by your healthcare provider
- Expect your pharmacy to call you every month to ask if you had a pregnancy test in the last month before it reorders your Tracleer. The refill may not be done on time if you have not had your pregnancy test
- Do not get pregnant. Tell your healthcare provider right away if you:
  - Had unprotected sex
  - Think that your birth control failed
  - Miss a menstrual period
  - Think you are pregnant

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The Tracleer® REMS Program is administered by *Actelion Pathways*®.

You can reach *Actelion Pathways* by calling toll-free at 1-866-ACTELION (1-866-228-3546).

For more information about the Tracleer REMS Program, please visit [www.TracleerREMS.com](http://www.TracleerREMS.com).

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