

**Medication Guide**  
**Tracleer (tra-KLEER)**  
**(bosentan)**  
**Tablets**

Read the Medication Guide that comes with Tracleer before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

**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
  - 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. These methods can be used alone.**

**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.

### **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.

#### **Tracleer is only:**

- prescribed by healthcare providers who are enrolled in T.A.P.
- available to people who understand and agree to enroll in T.A.P.

It is not known if Tracleer is safe and works in children below 12 years of age.

### **Who should not take Tracleer?**

#### **Do not take Tracleer if you:**

- **are pregnant, plan to become pregnant, or become pregnant during Tracleer treatment. Tracleer can cause serious birth defects.** All females should read the **birth defects** section of “What is the most important information I should know about Tracleer?”
- have a blood test that shows possible liver injury.
- take one of these medicines:
  - cyclosporine A used for psoriasis and rheumatoid arthritis, and to prevent rejection of heart or kidney transplants
  - glyburide used for diabetes
- you are allergic to any of the ingredients in Tracleer. See the end of this Medication Guide for a list of the ingredients in Tracleer. If you have a rash, hives or your lips swell after taking Tracleer, it may be a sign of allergy. You should stop taking your Tracleer and talk to your healthcare provider.

### **What should I tell my healthcare provider before taking Tracleer?**

Tracleer may not be right for you. **Tell your healthcare provider about all your medical conditions, including if you:**

- **have liver problems.**
- **are breast-feeding or plan to breast feed.** It is not known if Tracleer passes into your milk. You and your healthcare provider should decide if you will take Tracleer or breast-feed. You should not do both.
- **Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Tracleer and other medicines may affect how each other works and cause side effects. Especially tell your healthcare provider if you take:
  - hormone-based birth control, such as pills, shots, patches, and implants. These birth control methods may not work as well when taken with Tracleer.
  - simvastatin or other “-statin” medicines used to lower cholesterol
  - rifampin used for tuberculosis
  - tacrolimus used to prevent rejection of liver or kidney transplant
  - ketoconazole, fluconazole, itraconazole, or voriconazole used for fungal infections
  - warfarin sodium used to prevent blood clots
  - ritonavir used to treat HIV

There may be more than one brand name medicine. Ask your healthcare provider if you are not sure if your medicine is one that is listed above.

### **How should I take Tracleer?**

Your healthcare provider will give you detailed information about T.A.P..

- Tracleer will be mailed to you by a specialty pharmacy. You will only receive a 30-day supply of Tracleer at one time.
- Take Tracleer exactly as prescribed.
- Your healthcare provider will tell you how much Tracleer to take and when to take it.
- In most cases, you will take 1 tablet in the morning and 1 in the evening.
- You can take Tracleer with or without food.
- If you take more than the prescribed dose of Tracleer, call your healthcare provider right away.
- If you miss a dose of Tracleer, take your tablet as soon as you remember. Do not take 2 doses at the same time. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time.
- Do not stop taking Tracleer unless your healthcare provider tells you to. Suddenly stopping your treatment may cause your symptoms to get worse. If you need to stop taking Tracleer, speak with your healthcare provider about the right way to stop.

### **What are the possible side effects of Tracleer?**

Tracleer can cause serious side effects, including:

- **See “What is the most important information I should know about Tracleer?”**
- **Fluid retention and swelling of your ankles and legs.** Tracleer can cause your body to hold too much water, and you may get swelling of your ankles and legs. Tell your healthcare provider if you have swelling of your ankles and legs that happens either with or without weight gain, or if you have more trouble with your breathing than normal. Your healthcare provider will look for the cause of this.
- **Lower Sperm Count.** Some men who take Tracleer may have lower sperm counts. This may affect your ability to father a child. Tell your healthcare provider if fertility is a concern for you.
- **Low red blood cell levels (anemia).** Your healthcare provider will do blood tests to check your red blood cells during treatment with Tracleer.

The most common side effects of Tracleer are:

- respiratory tract infection
- headache
- fainting
- flushing
- low blood pressure
- inflamed nose passages (sinusitis)
- joint pain
- irregular heart beats

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Tracleer. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **How should I store Tracleer?**

- Store Tracleer at 68°F to 77°F (20°C-25°C).
- **Keep Tracleer and all medicines out of the reach of children.**

### **General information about Tracleer**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Tracleer for a condition for which it was not prescribed. Do not give Tracleer to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Tracleer. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Tracleer that is written for health professionals. For more information, go to [www.TRACLEER.com](http://www.TRACLEER.com) or call 1-866-228-3546.

**What are the ingredients in Tracleer?**

Active ingredient: bosentan

Inactive ingredients: corn starch, pregelatinized starch, sodium starch glycolate, povidone, glyceryl behenate, magnesium stearate, hydroxypropylmethylcellulose, triacetin, talc, titanium dioxide, iron oxide yellow, iron oxide red, ethylcellulose.

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

Distributed by:

Actelion Pharmaceuticals US, Inc.  
South San Francisco, CA 94080, USA

ACT20090730

Revised August 2009

This Medication Guide has been approved by the U.S. Food and Drug Administration.