

Medication Guide

Tracleer (tra-KLEER) Tablets (bosentan)

Read this information carefully before you start taking Tracleer tablets. Read the information you get with Tracleer each time you refill your prescription. There may be new information. This information does not take the place of talking with your doctor.

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

- **Liver damage.**

Tracleer can cause liver damage if liver problems are not found early. Therefore, you must have a blood test to check your liver function before you start Tracleer and each month after that. (See “What are the possible side effects of Tracleer?” for information about the signs of liver problems.)

- **Major birth defects.**

Tracleer can cause major birth defects if taken during pregnancy. Therefore, women must not be pregnant when they start taking Tracleer or during Tracleer treatment. Women who are sexually active must have a negative pregnancy test before beginning treatment. A negative test means you are not pregnant. The test should be during the first five days of a normal menstrual period and at least 11 days after the last unprotected sexual intercourse. **Pregnancy tests must be done each month during Tracleer treatment, if you are sexually active.**

Women who are able to get pregnant must use effective birth control while taking Tracleer. Birth control pills, shots, patches, implants, or other hormone-based birth control may not be enough when Tracleer is used. Talk with your doctor and, if needed, with a gynecologist (a doctor who specializes in female reproduction) or another doctor who knows about birth control, to find out how to avoid pregnancy. **Tell your doctor right away if you miss a period or think you may be pregnant.**

What is Tracleer?

Tracleer is a medicine to treat pulmonary arterial hypertension, which is high blood pressure in the lung arteries. You take it by mouth.

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 effectively.

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 major birth defects.** All women should read the birth defects section of “What is the most important information I should know about Tracleer?” Severe birth defects from Tracleer happen early in pregnancy. Therefore, you must not be pregnant while taking Tracleer.
- **your blood test shows possible liver injury**
- **you are taking cyclosporine-A,** (used for psoriasis and rheumatoid arthritis, and to prevent rejection of heart or kidney transplants), **glyburide** (used for diabetes), **lopinavir/ritonavir** or other **ritonavir-containing HIV regimens.**

- **you are allergic to any ingredients in Tracleer.** The active ingredient is bosentan. Ask your doctor or pharmacist if you need to know the inactive ingredients.

Tell your doctor if you have moderate or severe liver problems. Tracleer may not be right for you.

Tell your doctor about **all** the medicines you use. They may affect how Tracleer works, or Tracleer may affect how the other medicines work. Be sure to tell your doctor if you take

- ketoconazole, fluconazole, itraconazole or voriconazole (used for fungal infections)
- hormone-based birth control, such as pills, shots, patches, and implants
- cyclosporine A (used for psoriasis and rheumatoid arthritis, and to prevent rejection of heart or kidney transplants)
- tacrolimus (used to prevent rejection of liver or kidney transplants)
- rifampicin (used for tuberculosis)
- glyburide (used for diabetes)
- cholesterol lowering medicines
- warfarin (used to prevent blood clots)
- lopinavir/ritonavir or other ritonavir-containing HIV regimens.

How should I take Tracleer?

Tracleer will be mailed to you by a central pharmacy. Your doctor will give you complete details:

- In most cases, you will take 1 tablet in the morning and 1 in the evening.
- You can take it with or without food.
- Your doctor will tell you how much to take.
- It will be easier to remember to take Tracleer if you do it at the same time each morning and evening. If you have trouble remembering, ask a family member to remind you, or put written notes where you will be sure to see them.
- If you take more than the prescribed dose of Tracleer, call your doctor right away.
- If you miss a dose, take your tablet as soon as you remember. However, do not take 2 doses to make up for a missed dose. Take your next tablet at the regular time.
- Do not stop taking Tracleer unless your doctor tells you to do so. Suddenly stopping your treatment may cause your symptoms to get worse. If you need to stop taking Tracleer, your doctor may tell you to reduce the dose over a few days before stopping completely.

During treatment your doctor will test your blood for signs of side effects to your liver and red blood cells.

What should I avoid while taking Tracleer?

- **Do not get pregnant** while taking Tracleer. (See the birth defect section of “What is the most important information I should know about Tracleer?”) If you miss a period, call your doctor.
- **Breast feeding is not recommended** while taking Tracleer. It is not known if Tracleer can pass through your milk and harm the baby.
- **Do not use hormone-based birth control (pills, shots, patches, implants) as your only method of birth control.** These may not work when used with Tracleer. Ask your doctor about effective birth control choices.
- **Do not take cyclosporine-A.** This medicine can cause too much Tracleer in your blood and increase your chance of side effects.

- **Do not take glyburide.** This medicine can increase your chance of liver damage.
- **Do not take lopinavir/ritonavir or other ritonavir-containing HIV regimens.** They can cause too much Tracleer in your blood and increase your chance of side effects.

What are the possible side effects of Tracleer?

Tracleer can have serious side effects:

- **Liver damage.** Tracleer can cause liver damage if it is not found early. Because this side effect may not cause symptoms at first, only a blood test can show that you have early liver damage. Regular blood tests let your doctor change or stop your therapy before there is permanent damage. **Therefore, it is very important that you have a liver function blood test before you start treatment and every month after that.**

Call your doctor right away if you have any of these symptoms of liver problems: nausea, vomiting, fever, unusual tiredness, abdominal (stomach area) pain, or yellowing of the skin or the whites of your eyes (jaundice).

- **Major birth defects.** All females should read the birth defects section of “What is the most important information I should know about Tracleer?”
- **Sperm Count Reduction.** Reduced sperm counts have been observed in some men on Tracleer, which might impair ability to father a child. Tell your doctor if remaining fertile is important to you.

Other possible side effects

The most common side effects of Tracleer are:

- low red blood cell levels (anemia)
- headache
- inflamed throat and irritated nose passages
- flushing (hot flashes)
- ankle and leg swelling
- low blood pressure
- irregular heart beats
- upset stomach
- tiredness
- rash
- itching

General advice about prescription medicines

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any concerns or questions about Tracleer, ask your doctor or other healthcare provider. This Medication Guide is only a summary of some important information about Tracleer. Your doctor can give you information about Tracleer that was written for healthcare professionals. Do not use Tracleer for a condition for which it was not prescribed. Do not share Tracleer with other people.

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

March 2009

©2008 Actelion Pharmaceuticals US, Inc.