

Bosentan (Tracleer)

To treat pulmonary arterial hypertension

This handout explains bosentan (Tracleer), a medicine that is used to treat pulmonary arterial hypertension (PAH).

What is bosentan?

Bosentan is a drug that is used to treat people with certain types of *pulmonary artery hypertension* (PAH). PAH is high blood pressure in the blood vessels of the lungs. The brand name for bosentan is Tracleer.

Bosentan lowers the blood pressure in your lungs and helps your heart pump blood. It can improve your ability to exercise. It can also slow the worsening of your symptoms.

Important Note About Bosentan

You can receive bosentan **ONLY** if you are enrolled in the Tracleer Access Program (TAP). And, only a limited number of certified specialty pharmacies offer bosentan.

Before you start treatment with bosentan, you and your doctor must fill out an enrollment form. You must also agree to have monthly blood tests. The enrollment form must be renewed every year.

Read the “Medicine Guide” that comes with bosentan before you start taking it. Read it again each time you get a refill. There may be new information.

To learn more, talk with your doctor or visit www.tracleer.com.

What are the side effects?

Common Side Effects

Tell your doctor if any of these side effects bother you or do not go away:

- Respiratory tract infection
- Headache



You and your doctor must fill out an enrollment form before you can start bosentan treatment.

- Fainting
- Flushing (your face becomes red or warm)
- Low blood pressure
- Inflamed nose passages
- Joint pain
- Irregular heartbeats

Allergic Reactions

Tell your doctor **right away** if you have:

- Itching or hives
- Swelling in your face or hands
- Swelling or tingling in your mouth or throat
- Chest tightness
- Trouble breathing

Liver Damage

- Tell your doctor if you have had liver problems in the past.
- Before starting bosentan, you must have a blood test to check your liver function. You must have follow-up blood tests every month while you are taking bosentan. Your doctor will order these tests.

Liver damage may not cause symptoms at first. Regular blood tests are important because they will help your doctor adjust or stop treatment before permanent liver damage occurs.

- Call your doctor if you have any of these symptoms of liver problems while taking bosentan:
 - Nausea
 - Vomiting
 - Fever
 - Unusual tiredness
 - Stomach pain
 - Yellowing of your skin or the whites of your eyes

Serious Birth Defects

Bosentan can cause serious birth defects if taken during pregnancy. **You must not be pregnant when you start taking bosentan. You must not get pregnant during your bosentan treatment.**

- Women who are able to get pregnant **MUST** have a negative pregnancy test before starting treatment. This test must be repeated every month during treatment with bosentan.
- Women who are able to get pregnant **MUST** use birth control (contraception) while they are taking bosentan.
 - You must use 2 reliable forms of birth control at the same time. Talk with your healthcare provider or gynecologist about which 2 methods of birth control you should use.
 - Refer to the bosentan “Medicine Guide” for more information about reliable methods of contraception.
 - Tell your doctor **right away** if you miss a menstrual period or think you may be pregnant.

Fluid Retention

Bosentan can cause your body to hold onto water. This may cause swelling of your ankles and legs. Tell your doctor if you have:

- Swelling of your ankles and legs, with or without weight gain
- More trouble than normal with your breathing

Lower Sperm Count

Some men who take bosentan may have lower sperm counts. Tell your doctor if fertility is a concern for you.

Anemia

Bosentan may cause low red blood cell levels (anemia). Your doctor will do blood tests to check your red blood cell levels during treatment with the medicine.

How should I take it?

- Bosentan comes in 62.5 mg and 125 mg tablets. The usual starting dose is 62.5 mg taken by mouth 2 times a day for 4 weeks. After the first 4 weeks, your dose may be increased to 125 mg 2 times a day.
- The medicine can be taken with or without food.
- Take your 1st dose in the morning and your 2nd dose in the evening. If you miss a dose, do **not** double your next dose to make up for the missed dose. Just take your next dose at the regularly scheduled time.

How do I store the medicine?

- Store bosentan in a closed container at room temperature.
- Keep the medicine out of reach of children.

Warnings

Read this section carefully before you begin taking bosentan.
Talk with your doctor if you have any questions.

Who Should NOT Take Bosentan

Some people should **not** take bosentan. **Tell your doctor if you:**

- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Have liver problems, or if taking medicines has ever caused you to have liver problems

Drug Interactions

Some other drugs may interact with bosentan and cause problems. We are listing some of these drugs below. **This list may NOT contain all the drugs that interact with bosentan.**

Before you start taking bosentan:

- Review your current list of medicines with your doctor. This includes prescription and non-prescription drugs, vitamins, and herbal products.
- **If you are a woman, tell your doctor if you are using hormonal contraceptives** (birth control pills, patches, injectable, or implantable forms). If you take bosentan, these birth control methods will not work as well. You could become pregnant.
- Tell your doctor if you are taking:
 - Amiodarone (Cordarone), amprenavir (Agenerase), diltiazem (Cardizem), dronedarone (Multaq), erythromycin, lopinavir/ritonavir (Kaletra), rifampin (Rifadin), ritonavir (Norvir), sildenafil (Viagra or Revatio), or tacrolimus (Prograf)
 - Medicine to treat a fungus infection, such as fluconazole (Diflucan), itraconazole (Sporanox), ketoconazole (Nizoral), or voriconazole (Vfend)
 - Medicine to lower cholesterol or triglycerides, such as atorvastatin (Lipitor), lovastatin (Mevacor), simvastatin (Zocor), or pravastatin (Pravachol)
 - A blood thinner (*anticoagulant*) such as warfarin (Coumadin)
- Do **not** take bosentan if you are taking:
 - Cyclosporine (Sandimmune, Neoral), used for psoriasis and rheumatoid arthritis and to prevent rejection in some patients who have had a transplant
 - Glyburide, for diabetes

Questions?

Your questions are important. Call your doctor or healthcare provider if you have questions or concerns.

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