



Bosentan (Tracleer)

To treat pulmonary arterial hypertension

This handout explains
Bosentan, a medicine
used to treat pulmonary
arterial hypertension
(PAH).

What is bosentan?

Bosentan 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.

Bosentan lowers the blood pressure in your lungs and lets your heart pump blood more efficiently. Bosentan can improve your ability to exercise and can slow the worsening of your symptoms.

Important Note

Bosentan is ONLY available through the Tracleer Access Program (T.A.P.). Before starting treatment with bosentan, you and your doctor must complete an enrollment form and you must agree to have monthly blood tests. The enrollment form must be renewed yearly.

Bosentan is only available through a limited number of certified specialty pharmacies. To learn more about the Tracleer Access Program, talk with your doctor or visit www.tracleer.com.

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

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 first dose in the morning and your second 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 it out of reach of children.

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
- 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.
- You must have a blood test to check your liver function before starting bosentan and each month after that. 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 or during your treatment with the medicine.

- Women who are able to get pregnant **MUST** have a negative pregnancy test before starting treatment and each month during treatment with bosentan.
- Women who are able to get pregnant **MUST** use birth control (contraception) during treatment with bosentan. You must use 2 reliable forms of birth control at the same time. Talk with your health care provider or gynecologist about which 2 methods of birth control you should use. Refer to the *Medicine Guide* for more information about reliable methods of contraception during treatment with bosentan. 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 retain too much water, and 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), or if you have 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.

Questions?

Your questions are important. Call your doctor or health care provider if you have questions or concerns. UWMC clinic staff are also available to help.

Interstitial Lung Disease Clinic: 206-598-4967

Warnings: Before You Take Bosentan

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

- Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. **This is especially important if you are a woman using hormonal contraceptives** (birth control pills, patches, injectable or implantable forms). Bosentan can make hormonal birth control less effective in preventing pregnancy, and you should not take bosentan if you are 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).

Please note that this list of possible drug interactions may not be complete. Review your current list of medicines with your doctor before starting bosentan.

- 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
- If you are a woman, tell your doctor if you are:
 - Pregnant
 - Planning to become pregnant
 - Breastfeeding or planning to breastfeed
- Tell your doctor if you have liver problems or have had liver problems in the past caused by certain medicines.

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