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Bosentan

pronounced as (boe sen' tan)

IMPORTANT WARNING:

For male and female patients:

Bosentan may cause liver damage. Tell your doctor if you have or have ever had liver disease. Your doctor will order a blood test to be sure your liver is working normally before you start taking bosentan and every month during your treatment. Keep all appointments with your doctor and the laboratory. Bosentan may damage the liver before causing symptoms. Regular blood tests are the only way to find liver damage before it becomes permanent and severe. If you experience any of the following symptoms, call your doctor immediately: nausea, vomiting, fever, stomach pain, yellowing of the skin or eyes, or extreme tiredness. Your doctor may reduce your dose, or temporarily or permanently stop your treatment with bosentan if you experience side effects or have abnormal lab results.

For female patients:

Do not take bosentan if you are pregnant or plan to become pregnant. Bosentan may harm the fetus. If you are able to become pregnant, you will need to take a pregnancy test before starting treatment, every month during treatment, and for 1 month after your treatment to show that you are not pregnant. Your doctor will order the pregnancy tests for you. You must use a reliable method of birth control during your treatment and for 1 month after your treatment. Hormonal contraceptives (birth control pills, patches, rings, shots, implants, and intrauterine devices) may not work well when used with bosentan and should not be used as your only method of birth control. Talk to your doctor about birth control methods that will work for you. In most cases you will be required to use two forms of birth control.

Call your doctor immediately if you have unprotected sex, think your birth control failed, miss a period or think that you may be pregnant while you are taking bosentan. Do not wait until your next appointment to discuss this with your doctor.

If you are a parent or guardian of a female patient who had not yet reached puberty, check your child regularly to see if she is developing any signs of puberty (breast buds, pubic hair) and let her doctor know about any changes.

Because of the risks of liver damage and birth defects, bosentan is only available through a restricted program called the Tracleer Risk Evaluation and Mitigation Strategy Program (Tracleer REMS). In order to receive bosentan you and your doctor must be registered with Tracleer REMS, and follow the programs requirements such as once a month liver function and pregnancy testing. Your doctor will register you in the program. Bosentan is only available at certain pharmacies that are registered with Tracleer REMS. Ask your doctor or pharmacist if you have any questions about how you can fill your prescription.

You will receive the manufacturer's patient information sheet (Medication Guide) when you begin treatment with bosentan and each time you refill the prescription. Read the information carefully each time and ask your doctor or pharmacist if you have any questions. You also can obtain the Medication Guide from the FDA website: <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] .

Talk to your doctor about the risks of taking bosentan.

Why is this medication prescribed?

Bosentan is used to treat pulmonary arterial hypertension (PAH, high blood pressure in the vessels that carry blood to the lungs) in adults and children 3 years of age and older. Bosentan may improve the ability to exercise and slow the worsening of symptoms in patients with PAH. Bosentan is in a class of medications called endothelin receptor antagonists. It works by stopping the action of endothelin, a natural substance that causes blood vessels to narrow and prevents normal blood flow in people who have PAH.

How should this medicine be used?

Bosentan comes as a tablet and as a dispersible tablet (tablet that can be dissolved in liquid) to take by mouth. It is usually taken with or without food twice a day in the morning and evening. To help you remember to take bosentan, take it at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take bosentan exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you are taking the dispersible tablet, place the tablet in a small amount of liquid right before you take it. If your doctor has told you to take a half tablet, break the dispersible tablet carefully on the line. Take the half tablet as directed, and put the other half back in the opened blister in the package. Use the other half tablet within 7 days. Do not break the dispersible tablet into quarters.

Your doctor will probably start you on a low dose of bosentan and increase your dose after 4 weeks.

Bosentan controls the symptoms of PAH but does not cure it. It may take 1 to 2 months or longer before you feel the full benefit of bosentan. Continue to take bosentan even if you feel well. Do not stop taking bosentan without talking to your doctor. If you suddenly stop taking bosentan, your symptoms may get worse. Your doctor may decrease your dose gradually.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking bosentan,

- tell your doctor and pharmacist if you are allergic to bosentan, any other medications, or any of the ingredients in bosentan tablets or dispersible tablets.
- do not take cyclosporine (Gengraf, Neoral, Sandimmune) or glyburide (DiaBeta, Glynase) while taking bosentan.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention any of the following: amiodarone (Nexterone, Pacerone); cholesterol-lowering medications (statins) such as atorvastatin (Lipitor, in Caduet), lovastatin (Altoprev), and simvastatin (Flolopid, Zocor, in Vytorin); diltiazem (Cardizem, Cartia, Diltzac, others); erythromycin (E.E.S., Eryc, PCE); fluconazole (Diflucan); gemfibrozil (Lopid); itraconazole (Onmel, Sporanox); ketoconazole ; rifampin (Rifadin, Rimactane, in Rifater, Rifamate); ritonavir (Norvir, in Kaletra, Viekira Pak, Technivie); voriconazole (Vfend); and warfarin (Coumadin, Jantoven). Many other medications may also interact with bosentan, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had heart failure (condition in which the heart is unable to pump enough blood to the other parts of the body).
- tell your doctor if you are breastfeeding or plan to breastfeed. Your doctor will probably tell you not to breastfeed while taking bosentan.
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent damage to your brain that can cause severe intellectual disability), you should know that the dispersible tablets are sweetened with aspartame, a source of phenylalanine.

What special dietary instructions should I follow?

Talk to your doctor about drinking grapefruit juice while taking this medication.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Bosentan may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- flushing

- runny nose, sore throat, and other cold symptoms
- joint pain

Some side effects can be serious. The following symptoms are uncommon, but if you experience any of them or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:

- hives; rash; itching; difficulty breathing or swallowing; swelling of the face, throat, tongue, lips, and eyes; hoarseness; fever; swollen lymph nodes; tiredness
- swelling of the feet, ankles, or lower legs, sudden weight gain, more trouble with breathing than normal
- new or worsening shortness of breath; new or worsening cough with or without blood; chest pain; fast, pounding, or irregular heartbeat
- fainting
- dizziness; pale skin; shortness of breath; weakness; fast, pounding, or irregular heartbeat

Male laboratory animals who were given medications similar to bosentan developed problems with their testicles and produced fewer sperm (male reproductive cells) than normal. It is not known if bosentan will damage the testicles or decrease the number of sperm produced in men. Talk to your doctor about the risks of taking bosentan if you would like to have children in the future.

Bosentan may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- headache
- nausea
- vomiting
- fast heartbeat
- fainting
- sweating
- dizziness
- blurred vision

What other information should I know?

Do not let anyone else take your medication. Ask your doctor any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Tracleer[®]

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

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