



PATIENT & CAREGIVER EDUCATION

Bosentan

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Tracleer

Brand Names: Canada

BIO-Bosentan [DSC]; NAT-Bosentan; PMS-Bosentan;
TARO-Bosentan; Tracleer

Warning

- Liver problems have happened. Call your doctor right away if you get signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- If you have liver problems or raised liver enzymes, talk with your doctor. This drug may not be right for you. Have your liver function checked as you have

been told by your doctor.

- This drug may cause birth defects if you take it while you are pregnant.
- Do not take this drug if you are pregnant. A pregnancy test will be done to show that you are NOT pregnant before starting this drug.
- A pregnancy test will be done every month during treatment and for 1 month after the last dose.
- If you may become pregnant, you must use birth control before starting this drug, while you are taking it, and for 1 month after you stop this drug. Talk with your doctor about what type(s) of birth control to use with this drug.
- If you get pregnant while taking this drug or within 1 month after your last dose, call your doctor right away.

What is this drug used for?

- It is used to treat high blood pressure in the lungs.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor

about the allergy and what signs you had.

- If you are taking any of these drugs: Cyclosporine or glyburide.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all patients taking this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Do not stop taking this drug all of a sudden without calling your doctor. Signs of high pressure in the lungs

like shortness of breath, dizziness, or weakness may get worse. Talk with your doctor.

- If you have phenylketonuria (PKU), talk with your doctor. Some products have phenylalanine.
- Low red blood cell levels have happened with this drug. Sometimes, this has led to anemia and the need for a blood transfusion. If you have anemia or have been told that you have a low red blood cell level, talk with your doctor.
- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Use some other kind of birth control also like a condom when taking this drug.
- This drug may lower sperm counts. This may affect being able to father a child. If you have questions, talk with the doctor.
- If you miss a period, have unprotected sex, or think that your birth control has not worked, call your doctor right away.

Children:

- If your child starts puberty while taking this drug, talk with the doctor. Your child may be able to get pregnant, even if your child's menstrual period has not started.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Feeling very tired or weak.
- Severe dizziness or passing out.
- A heartbeat that does not feel normal.
- Joint pain.
- This drug may cause you to swell or keep fluid in your body. Tell your doctor if you have swelling, weight gain, or trouble breathing.
- A severe and sometimes deadly reaction has happened. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body organs like the liver, kidney, blood, heart, muscles and joints, or lungs. If you have questions, talk with the doctor.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Flushing.
- Nose irritation.
- Signs of a common cold.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at <https://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take with or without food.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

Tablets for suspension:

- Mix with water as you have been told before drinking.
- The tablets may be broken in half. Do not break into quarters.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

All products:

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down

a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

Tablets for suspension:

- If you have broken tablets, store the tablet pieces in the opened blister for up to 7 days.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready

to tell or show what was taken, how much, and when it happened.

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Last Reviewed Date

2025-12-05

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

Bosentan - Last updated on December 12, 2022

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Last Updated

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