

Bosentan

This information from Lexicomp® 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 the doctor right away if your child gets 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 your child has liver problems or raised liver enzymes, talk with the doctor. This drug may not be right for your child. Have your child's liver function checked as you have been told by the doctor.
- This drug may cause birth defects if your child takes it during pregnancy.
- Do not let your child take this drug during pregnancy. A pregnancy test will be done to show that your child is 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 your child may become pregnant, birth control must be used before starting this drug, while taking it, and for 1 month after stopping it. Talk with your child's doctor about what type(s) of birth control to use with this drug.
- If your child gets pregnant while taking this drug or within 1 month after the last dose, call the 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 the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child is taking any of these drugs: Cyclosporine or glyburide.

If your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug.

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

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

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Do not stop giving this drug to your child all of a sudden without calling the doctor. Signs of high pressure in the lungs like shortness of breath, dizziness, or weakness may get worse. Talk with the doctor.
- If your child has phenylketonuria (PKU), talk with your child's 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 your child has anemia or you have been told that your child has a low red blood cell level, talk with

the doctor.

- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Be sure your child uses 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 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.

If your child is or may be sexually active:

- If your child misses a period, has unprotected sex, or thinks that their birth control has not worked, call the doctor right away.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 your child to swell or keep fluid in the body. Tell your child's doctor if swelling, weight gain, or trouble breathing happens after this drug is given.

- 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 child's doctor or get medical help if any of these side effects or any other side effects bother your child 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 child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

All products:

- Give this drug with or without food.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.

Tablets for suspension:

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

What do I do if my child misses a dose?

- Give a missed dose as soon as you think about it.
- If it is close to the time for your child's next dose, skip the missed dose and go back to your child's normal time.
- Do not give 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any

questions about this drug, please talk with your child's doctor, nurse, 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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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.

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