

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr[®]TRACLEER[®]

bosentan tablets

Read this carefully before you start taking **Tracleer** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Tracleer**.

What is Tracleer used for?

Tracleer is used in adults to treat certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the blood vessels leading to your lungs.

How does Tracleer work?

Tracleer is an endothelin receptor antagonist (ERA). It lowers high blood pressure in the lungs by relaxing the pulmonary arteries. This makes it easier for your heart to pump blood to the lungs and can help lower the chance of your disease getting worse.

What are the ingredients in Tracleer?

Medicinal ingredients: Bosentan monohydrate.

Non-medicinal ingredients: Corn starch, glyceryl behenate, magnesium stearate, povidone, pregelatinized starch, and sodium starch glycolate. The film-coating is composed of ethylcellulose, hydroxypropylmethylcellulose, iron oxide red, iron oxide yellow, talc, titanium dioxide and triacetin.

Tracleer comes in the following dosage forms:

Film-coated tablets: 62.5 mg and 125 mg bosentan (as bosentan monohydrate)

Do not use Tracleer if:

- you are allergic to bosentan or to any of the other ingredients in Tracleer.
- you were told by your healthcare professional that you have moderate to severe liver disease or abnormal liver test results.
- you are pregnant, think you are pregnant, plan to become pregnant, or could become pregnant because you are not using a reliable birth control method. Tracleer can cause serious birth defects if taken during pregnancy.
- you are taking cyclosporine A (used to treat certain autoimmune diseases and to prevent rejection of organ transplants).
- you are taking glyburide (used to treat diabetes).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Tracleer. Talk about any health conditions or problems you may have,

including if you:

- have pulmonary veno-occlusive disease (PVOD), a condition where the blood vessels that carry blood from the lungs to the heart are blocked, and are taking medicines that open your blood vessels (also known as vasodilators).
- have heart failure.
- have signs of fluid retention (buildup of fluids in the body). Your healthcare professional may prescribe you other medications to treat this condition before you start taking Tracleer.
- have low blood pressure (less than 85 mm Hg).
- have liver problems.
- are breastfeeding or plan to breastfeed.

Other warnings you should know about:

Pregnancy and birth control:

- Do **not** take Tracleer if you are pregnant. Taking Tracleer during pregnancy may harm your unborn baby. Talk to your healthcare professional **right away** if you discover that you are pregnant during your treatment.
- If you are able to get pregnant:
 - you must have a negative pregnancy test before starting Tracleer. Monthly pregnancy tests during treatment with Tracleer are also recommended to allow the early detection of pregnancy.
 - Your healthcare professional will advise you about the best birth control methods to use during your treatment. Tracleer may make hormonal birth control methods (e.g., pills, injections, implant, vaginal rings, skin patches) ineffective. These methods on their own are not reliable. Therefore, if you use hormonal birth control methods you must also use a barrier method (e.g., female or male condoms, diaphragm, contraceptive sponge).
 - Do **not** have unprotected sex. Tell your healthcare professional **right away** if you have unprotected sex, or if you think your birth control has failed.

Breastfeeding: Tracleer can pass into breast milk and may harm a breastfed baby. Therefore, Tracleer is not recommended during breastfeeding. Talk to your healthcare professional about the best way to feed your baby during this time.

Fertility in men: It is possible that Tracleer may lower your sperm count and affect your ability to have children. Speak with your healthcare professional if you plan on fathering a child, or have any questions or concerns about this.

Driving and using machines: Tracleer can cause side effects such as low blood pressure, dizziness and blurry vision. Avoid driving, using machinery, or doing dangerous activities until you know how Tracleer affects you.

Check-ups and testing: Some patients taking Tracleer were found to have abnormal liver test results (increase in liver enzymes) and some patients developed anemia (decrease in red blood cells). Because these findings may not cause symptoms you can feel or observe yourself, your healthcare professional will do regular blood tests to monitor the health of your liver and the amount of red blood cells.

The blood test to monitor **the health of your liver** will be done:

- before you start taking Tracleer;
- every month during your treatment or more frequently, if needed.

If you develop abnormal liver test results, your healthcare professional may reduce your dose or stop your treatment with Tracleer. When your blood test results return to normal, your healthcare professional may decide to restart treatment with Tracleer.

The blood test to monitor **the amount of red blood cells in your blood** will be done:

- before you start taking Tracleer;
- after 1 month and after 3 months of treatment;
- every 3 months during treatment thereafter.

If you develop anemia, your healthcare professional may decide to perform further tests to investigate the cause.

The blood tests mentioned above are an important part of your treatment. We suggest you write in a diary the date of your most recent test and also that of your next test to help you remember.

In addition, your healthcare professional should monitor you for **signs of fluid retention** (buildup of fluids in the body) during your treatment with Tracleer. Tell your healthcare professional **right away** if you experience symptoms such as swelling of the legs or weight gain. If you have signs of fluid retention, your healthcare professional may investigate further to determine the cause. Fluid retention may be a sign of underlying heart failure and your healthcare professional may stop your treatment with Tracleer.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not use Tracleer if you take:

- cyclosporine A (used to treat certain autoimmune diseases and to prevent rejection of organ transplants)
- glyburide (used to treat diabetes)

The following may also interact with Tracleer:

- medicines used to prevent the rejection of organ transplants such as tacrolimus or sirolimus.
- medicines used to treat fungal infections such as fluconazole, voriconazole, ketoconazole, or itraconazole.
- medicines used to treat HIV/AIDS such as ritonavir, lopinavir, or nevirapine.
- medicines known as “statins”, used to treat high blood cholesterol such as simvastatin, atorvastatin, lovastatin, rosuvastatin, or fluvastatin.
- medicines used to treat seizures such as carbamazepine, phenobarbital, or phenytoin.
- medicines used to treat erection problems such as sildenafil, or tadalafil.
- medicines taken by mouth to treat diabetes, such as glyburide.
- warfarin, used to treat and prevent blood clots.

- rifampicin, used to treat bacterial infections, including tuberculosis.
- hormonal birth control methods (e.g., pills, implant, injections, vaginal rings, skin patches).
- St. John's wort, a herbal remedy.

How to take Tracleer:

- Always take Tracleer exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take Tracleer twice daily (morning and evening) consistently, with or without food.
- Swallow the tablet with water.
- Suddenly stopping your treatment with Tracleer may worsen your condition. Do not stop taking Tracleer unless your healthcare professional tells you to. Your healthcare professional may tell you to reduce your dose over a few days before stopping completely.

Usual dose:

- **Weeks 1 to 4:** 62.5 mg twice daily.
- **Weeks 5 and after:** Your healthcare professional may increase your dose to 125 mg twice daily, depending on how you respond to Tracleer.

Overdose:

If you think you, or a person you are caring for, have taken too much Tracleer, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take Tracleer, take the missed dose as soon as you remember, then continue with the next dose at your usual time. Do not take a double dose to make up for the one that you missed.

What are possible side effects from using Tracleer?

These are not all the possible side effects you may have when taking Tracleer. If you experience any side effects not listed here, tell your healthcare professional.

Side effects (regardless of reporting frequency) with Tracleer may include:

- Cold or flu like symptoms (runny nose, sore throat, sneezing, coughing, fever)
- inflammation of the sinuses
- nasal congestion
- ear infection
- feeling dizzy or like you are spinning
- blurry vision
- headache
- fever

- chest pain
- nausea or vomiting, heartburn, abdominal pain, diarrhea, constipation, rectal bleeding
- mouth ulcers, dry mouth
- loss of appetite
- skin rash, redness or discoloration, itchy skin, hives, dry skin, eczema
- bruising
- feeling weak, lack of energy
- joint pain
- flushing

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness		✓	
Hypotension (low blood pressure): feeling dizzy or lightheaded, fainting, blurred vision, nausea, vomiting, fatigue		✓	
Peripheral edema (swelling of the legs or hands caused by fluid retention): swollen or puffy legs or hands, feeling heavy, achy or stiff		✓	
UNCOMMON			
Liver problems: yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, fever, nausea or vomiting, unusual dark urine, unusual tiredness, loss of appetite,		✓	
UNKNOWN FREQUENCY			
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			✓
Pulmonary edema (excess fluid in the lungs): difficulty breathing that worsens with activity or when lying down, extreme shortness of breath, wheezing or gasping for breath, cold clammy skin, irregular heartbeat, cough that produces frothy sputum, blue-tinged lips			✓

Stevens-Johnson syndrome (SJS) (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			✓
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If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature between 15°C and 25°C.
- Do not use after the expiry date stated on the blister.
- Keep out of reach and sight of children.

If you want more information about Tracleer:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.janssen.com/canada) or by calling 1-800-567-3331 or 1-800-387-8781

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