PART III: CONSUMER INFORMATION

IMPORTANT: PLEASE READ

PRTRACLEER®
(bosentan monohydrate)
62.5 mg and 125 mg film-coated tablets

This leaflet is part III of a three-part "Product Monograph" published when TRACLEER® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TRACLEER®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
TRACLEER® (bosentan) tablets are prescribed for the treatment of pulmonary arterial hypertension (high blood pressure in the blood vessels between the heart and the lungs).

What it does:
TRACLEER® reduces abnormally high blood pressure by relaxing these blood vessels. TRACLEER® tablets belong to the class of medicines known as endothelin receptor antagonists.

Before you take TRACLEER®:
Tests your doctor will do before treatment:

- a blood test for liver function;
- a blood test for anemia (reduction in red blood cells);
- a pregnancy test.

When it should not be used:
Do not use TRACLEER® if you:

- are hypersensitive (allergic) to bosentan or any other ingredients in the tablet (**See What the important nonmedicinal ingredients are);**
- have liver problems;
- are pregnant or planning to become pregnant (hormonal contraceptives alone are not effective when you take TRACLEER®);
- are a woman of childbearing age and not using adequate contraceptive methods;
- are being treated with cyclosporine A, or glyburide.

Tell your doctor immediately if you are pregnant or plan to become pregnant in the near future. This is because TRACLEER® may harm your unborn baby and you must not take TRACLEER® if you are pregnant. You must also not become pregnant while taking TRACLEER®. If you are a woman of childbearing age, your doctor or gynecologist will advise you about adequate contraceptive methods while taking TRACLEER®. Because TRACLEER® may make hormonal contraception (e.g., oral, injection, implant or skin patches) ineffective, this method on its own is not reliable. Therefore, if you use hormonal contraceptives you must also use a barrier method (e.g., female condom, diaphragm, contraceptive sponge or your partner must also use a condom). Monthly pregnancy tests are recommended while you are taking TRACLEER® and you are of childbearing age.

Tell your doctor immediately if you are breastfeeding. You are advised to stop breastfeeding if TRACLEER® is prescribed for you because it is not known if this drug passes into the milk in women who are taking TRACLEER®.

If you are a man taking TRACLEER®, it is possible that this medicine may lower your sperm count. It cannot be excluded that this may affect your ability to father a child. Talk to your doctor if you have any questions or concerns about this.

If you feel dizzy while taking TRACLEER®, do not drive or operate any tools or machines.

TRACLEER® is not recommended for children.

What the medicinal ingredient is:
Bosentan monohydrate.

What the important nonmedicinal ingredients are:
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.

What dosage forms it comes in:
TRACLEER® 62.5 mg film-coated bosentan (from bosentan monohydrate) tablets are orange-white, round and embossed with '62,5' on one side. TRACLEER® is also available as orange-white, oval, film-coated tablets containing 125 mg bosentan and embossed with '125' on one side.

WARNINGS AND PRECAUTIONS

Warnings and Precautions
Before you use TRACLEER® talk to your doctor or pharmacist if you are:

- **known to have liver problems;**
- **pregnant or thinking of becoming pregnant;**
- **a woman of childbearing age and not using adequate contraceptive methods;**
- **breastfeeding;**
- **hypersensitive (allergic) to bosentan or any other ingredients of TRACLEER®.**

Before starting TRACLEER® treatment, tell your doctor and your pharmacist if you are taking or have recently taken any other medicines, even those you have bought yourself. It is especially important to tell your doctor if you are taking:

- hormonal contraceptives (as these may not be effective as the sole method of contraception when you take TRACLEER®);
- glyburide (for diabetes);
- cyclosporine A (a medicine used after transplants and to treat psoriasis), or any other drugs used to prevent rejection of transplanted organs;
- fluconazole (to treat fungal infections);
- rifampicin (to treat tuberculosis);
- vasodilators (drugs used to treat high blood pressure).

Tests during treatment:
Some patients taking TRACLEER® were found to have abnormal liver function values (increase in liver enzymes) and some patients developed anemia (reduction in red blood cells). Because these findings may not cause symptoms you can feel or observe yourself, your doctor will do regular blood tests to assess any changes in your liver function and hemoglobin level.

Liver function:
This blood test will be done:

- every month or more frequently, if needed.

If you develop abnormal liver function, your doctor may decide to reduce your dose or stop treatment with TRACLEER®. When your blood test results for liver function return to normal, your doctor may decide to restart treatment with TRACLEER®.

Anemia:
This blood test will be done:

- after 1 month and after 3 months of treatment;
- every 3 months during treatment thereafter.

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

Your regular blood tests, both for liver function and anemia, 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 (ask your doctor for the date) to help you remember when your next test is due.

Pregnancy tests for women of childbearing age:
Due to the risk of failure of hormonal contraception when taking TRACLEER® and the risk in patients with pulmonary hypertension of rapid and severe deterioration of the disease, monthly pregnancy tests are recommended before and during treatment with TRACLEER®.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with TRACLEER® include: warfarin, simvastatin and other statins, glyburide, ketoconazole, cyclosporine A, tacrolimus, sirolimus and hormonal contraceptives.

PROPER USE OF THIS MEDICATION

Always take TRACLEER® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Usual dose:
The usual dose is one tablet, swallowed twice daily (morning and evening), consistently with or without food. Swallow the tablet with water. For the first 4 weeks, you will take a 62.5 mg tablet twice daily, from then on, your doctor will advise you to take a 125 mg tablet twice daily, depending on how you react to TRACLEER®.

Overdose:
If you take more tablets than you have been told to take, see a doctor or go to a hospital immediately.

Missed Dose:
If you forget to take TRACLEER®, take a dose as soon as you remember, then continue to take your tablets at the usual time. Do not take a double dose to make up for forgotten tablets.

Stopping treatment:
Suddenly stopping your treatment with TRACLEER® may lead to a worsening of your symptoms. Do not stop taking TRACLEER® unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, TRACLEER® can have side effects even when used as directed.

If you notice yellowing of the skin or eyes (jaundice) or other symptoms such as nausea, vomiting, fever, abdominal pain or unusual tiredness, see your doctor immediately because this may be related to abnormal liver function.

Headaches were the most common side effect in clinical studies.

You may also notice one or more of the following side effects

- flushed appearance, inflammation of the throat and nasal passages, swelling of the legs and ankles, or other signs of fluid retention, low blood pressure, irregular heartbeat, heartburn, tiredness, itching, nasal congestion, nausea. If these side effects become bothersome, contact your doctor.

Other less common side effects that you might notice:

- vomiting, abdominal pain, diarrhea, skin rash.

If you notice any other side effects or signs of allergic reaction (e.g. swelling of the face or tongue, rash, pruritus) while you are taking TRACLEER® or if any of the side effects mentioned above worries you, please inform your doctor or pharmacist.

SERIOUS SIDE EFFECTS: HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharmacist**
		Only if severe	**In all cases**	
Common	**Abdominal pain**		√	
	Itching	√		
	Nausea	√		
	Other signs of fluid retention	√		
	Swelling of the legs and ankles		√	
	Tiredness	√		
	Vomiting		√	
Uncommon	**Rash**	√		
	Swelling of the face, throat or tongue		√	
Rare	**Asthma like symptoms (wheezing)**		√	
	Yellowing of the skin and eyes (jaundice)		√ Call your doctor immediately	

This is not a complete list of side effects. For any unexpected effects while taking TRACLEER®, contact your doctor or pharmacist.

HOW TO STORE IT

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

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.janssen.com/canada or by contacting the sponsor, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario, M3C 1L9.

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