

# TRACLEER® TABLET

Bosentan monohydrate (62.5mg, 125mg)

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## What Tracleer is used for

Tracleer is a prescription medicine used to treat people with certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the vessels of the lungs.

## How Tracleer works

Tracleer can improve your ability to exercise and can slow the worsening of your physical condition and symptoms. Tracleer lowers high blood pressure in your lungs and lets your heart pump blood more efficiently.

## Before you use Tracleer

### When you must not use it

Do not take Tracleer if you:

- are pregnant, plan to become pregnant, or become pregnant during Tracleer treatment. Tracleer can cause serious birth defects.
- take one of these medicines:
  - cyclosporine A used for psoriasis (a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales) and rheumatoid arthritis (a long-term disease that leads to inflammation of the joints and surrounding tissues), and to prevent rejection of heart or kidney transplants
  - glyburide used for diabetes

- you are allergic to any of the ingredients in Tracleer. See the end of this Medication Guide for a list of the ingredients in Tracleer. If you have a rash, hives or your lips swell after taking Tracleer, it may be a sign of allergy. You should stop taking your Tracleer and talk to your healthcare provider.

### Before you start to use it

Tracleer may not be right for you. Tell your healthcare provider about all your medical conditions, including if you:

- have liver problems.
- are breast-feeding or plan to breastfeed. It is not known if Tracleer passes into your milk. You and your healthcare provider should decide if you will take Tracleer or breastfeed. You should not do both.

### Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Tracleer and other medicines may affect how each other works and cause side effects. Especially tell your healthcare provider if you take:

- hormone-based birth control, such as pills, shots, patches, and implants. These birth control methods may not work as well when taken with Tracleer.
- simvastatin or other “-statin” medicines used to lower cholesterol
- rifampin used for tuberculosis
- tacrolimus used to prevent rejection of liver or kidney transplant
- ketoconazole, fluconazole, itraconazole, or voriconazole used for fungal infections

- warfarin sodium used to prevent blood clots
- ritonavir used to treat HIV

There may be more than one brand name medicine. Ask your healthcare provider if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them and show it to your healthcare provider or pharmacist when you get a new medicine.

## How to use Tracleer

### How much to use

- Take Tracleer exactly as prescribed.
- Your healthcare provider will tell you how much Tracleer to take and when to take it.
- Generally, TRACLEER treatment should be initiated at a dose of 62.5 mg twice daily and then increased to the maintenance dose of 125mg twice daily. Doses above 125mg twice daily did not appear to have additional benefit.

### When to use it

- Tablet should be administered morning and evening.
- You can take Tracleer with or without food.

### How long to use it

- Do not stop taking Tracleer unless your healthcare provider tells you to. Suddenly stopping your treatment may cause your symptoms to get worse. If you need to stop taking Tracleer, speak with your healthcare provider about the right way to stop.

### If you forget to use it

- If you miss a dose of Tracleer, take your tablet as soon as you remember. Do not take 2 doses at the same time. If it is

almost time for your next dose, skip the missed dose. Just take the next dose at your regular time.

If you use too much (overdose)

- If you take more than the prescribed dose of Tracleer, call your healthcare provider right away.
- Massive overdosage may result in hypotension (low blood pressure) requiring cardiovascular support. Other overdosage symptoms include nausea, vomiting, dizziness, sweating and blurred vision.

**While you are using it**

Things you must do

- Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.
- Tell your doctor immediately if you become pregnant while taking this medication. Females who are able to get pregnant must use two forms of birth control (contraception) during Tracleer treatment because there is a possibility of birth defects.
- Liver function should be checked before the treatment and each month after that.

Things you must not do

- Do not have unprotected sex.
- Do not breastfeed.
- Do not take any new medicines without consulting your doctor.

Things to be careful of

- Tracleer can cause serious side effects, take it exactly as your doctor has told you and tell your doctor if you feel unwell.

**Side effects**

Tracleer can cause serious side effects, including:

- **Liver damage:**

- Liver damage may not cause symptoms at first. Only a blood test can show if you

have early liver damage. You must have your blood tested to check your liver function before you start Tracleer and each month after that. Your healthcare provider will order these tests. Regular blood tests are important because they will help your healthcare provider adjust or stop your treatment before there is permanent damage.

- Tell your healthcare provider if you have had liver problems, including liver problems while taking other medicines. Call your healthcare provider right away if you have any of these symptoms of liver problems while taking Tracleer:

- nausea
- vomiting
- fever
- unusual tiredness
- stomach area (abdominal) pain
- yellowing of the skin or the whites of your eyes (jaundice)

- **Serious birth defects.**

- Tracleer can cause serious birth defects if taken during pregnancy. You must not be pregnant when you start taking Tracleer or during Tracleer treatment. Serious birth defects from Tracleer can happen early in pregnancy. Females who are able to get pregnant must have a negative pregnancy test before starting treatment and each month during Tracleer treatment.
- Talk with your healthcare provider or gynecologist (a doctor who specializes in female reproduction) to find out about how to prevent pregnancy. Do not have unprotected sex. Tell your healthcare provider right away

if you miss a menstrual period or think you may be pregnant.

- Females who are able to get pregnant must use two forms of birth control (contraception) during Tracleer treatment because there is a possibility of birth defects.
- Birth control pills, shots, patches, and implants should not be used alone because they are not reliable when you are taking Tracleer. You must choose and use two reliable forms of birth control at the same time.
- If you have had a tubal sterilization or have an IUD, these methods can be used alone. Otherwise, you should use two forms of birth control.

Talk with your healthcare provider about which 2 methods of reliable birth control you should use. Your healthcare provider may recommend that you use a different method of birth control to help lower your risk of problems with your pulmonary arterial hypertension.

- **Fluid retention and swelling of your ankles and legs.**

Tracleer can cause your body to hold too much water, and you may get swelling of your ankles and legs. Tell your healthcare provider if you have swelling of your ankles and legs that happens either with or without weight gain, or if you have more trouble with your breathing than normal. Your healthcare provider will look for the cause of this.

- **Lower Sperm Count.** Some men who take Tracleer may have lower sperm counts. This may affect your ability to father a child. Tell your healthcare provider if fertility is a concern for you.
- **Low red blood cell levels (anemia).** Your healthcare provider will do blood tests to

check your red blood cells during treatment with Tracleer.

The most common side effects of Tracleer are:

- respiratory tract infection
- headache
- fainting
- flushing
- low blood pressure
- inflamed nose passages (sinusitis)
- joint pain
- irregular heart beats

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Tracleer. For more information, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

#### **Storage and Disposal of Tracleer**

#### **Storage**

- Keep out of the reach and sight of children.
- Store below 30 °C.

#### **Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help to protect the environment.

#### **Product Description**

##### **What it looks like**

Tracleer 62.5 mg film-coated tablets are orange-white, round film-coated tablets with "62.5" on one side

Tracleer 125 mg film-coated tablets are orange-white, oval film-coated tablets with "125" on one side.

##### **Ingredients**

- Active ingredient  
Bosentan monohydrate
- Inactive ingredient  
Titanium dioxide, Iron Oxide Yellow, Ethylcellulose,

Hydroxylpropyl methylcellulose, Pre-gelatinised starch, Iron Oxide Red, Triacetin, Talc, Glyceryl Behenate, Magnesium Stearate, Sodium Starch Glycolate, Corn Starch, Povidone K-90

##### **MAL numbers**

TRACLEER TABLET 62.5MG  
– MAL20041084ACR  
TRACLEER TABLET 125MG  
–MAL20041085ACR

#### **Manufacturer**

Patheon Inc.  
2100 Syntex Court,  
Mississauga,  
Ontario L5N 7K9,  
Canada.

#### **Product Registration Holder**

DKSH Malaysia Sdn Bhd  
B-11-01, The Ascent, Paradigm  
No.1, Jalan SS7/26A, Kelana Jaya  
47301 Petaling Jaya  
Selangor Darul Ehsan

#### **Date of revision**

July 2015

#### **Serial Number**

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