

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using TRACLEER?

TRACLEER contains the active ingredient bosentan. TRACLEER is used to treat pulmonary arterial hypertension.

For more information, see Section [1. Why am I using TRACLEER?](#) in the full CMI.

2. What should I know before I use TRACLEER?

Do not use if you have ever had an allergic reaction to bosentan or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use TRACLEER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRACLEER and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TRACLEER?

- The usual dose is one tablet, twice daily. For the first 4 weeks you will take a 62.5 mg tablet twice daily. Your doctor may change the dose depending on how you respond.

More instructions can be found in Section [4. How do I use TRACLEER?](#) in the full CMI.

5. What should I know while using TRACLEER?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using TRACLEER. • Keep all your doctor's appointments so your progress can be checked and monitored for side effects.
Things you should not do	• Do not become pregnant while taking this medicine. If there is any delay in getting period or any other reason to suspect pregnancy, you must tell your doctor immediately for pregnancy testing.
Driving or using machines	• If you feel dizzy, tired or have blurred vision whilst taking this medicine do not drive or operate any tools or machinery.
Looking after your medicine	• Store below 25°C. Protect from moisture.

For more information, see Section [5. What should I know while using TRACLEER?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache, respiratory tract infection, swelling of ankle, leg and joint or other signs of fluid retention, low blood pressure and anaemia. Serious side effects include shortness of breath, anaphylaxis and/ or swelling, nausea, vomiting, fever, unusual tiredness, stomach pain, jaundice, dark-coloured urine and chest pain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: TRACLEER causes birth defects and must not be used in pregnancy.

Rare cases of liver cirrhosis and liver failure have been reported in patients using TRACLEER.

TRACLEER®

Active ingredient: *bosentan*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRACLEER. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TRACLEER.**

Where to find information in this leaflet:

1. [Why am I using TRACLEER?](#)
2. [What should I know before I use TRACLEER?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use TRACLEER?](#)
5. [What should I know while using TRACLEER?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using TRACLEER?

TRACLEER contains the active ingredient bosentan. TRACLEER belongs to a class of medicines known as endothelin receptor antagonists. This medicine acts to reduce abnormally high blood pressure by widening these blood vessels.

TRACLEER is used for the treatment of high blood pressure in the blood vessels between the heart and the lungs. This condition is called pulmonary arterial hypertension.

2. What should I know before I use TRACLEER?

Warnings

Do not use TRACLEER if:

- you are allergic to bosentan, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant, think you may be pregnant or intend to become pregnant. You must have a negative pregnancy test at the time of starting treatment if you are sexually active. See additional information under [Pregnancy and breastfeeding](#).
- you are breastfeeding. See additional information under [Pregnancy and breastfeeding](#).
- you are being treated with cyclosporine A (a medicine used after a transplant or to treat psoriasis)
- you are being treated with glibenclamide (a medicine used for diabetes).
- you have moderate to severe liver disorder.

Check with your doctor if you:

- are a woman of childbearing potential and not using reliable contraceptive methods. You must have a negative pregnancy test before beginning treatment. The test should be performed on the second day of a normal menstrual period or 11 days after the last unprotected sexual intercourse, whichever is later. Your doctor will advise you about using reliable contraception before taking or whilst taking this medicine. Hormonal contraception on its own is not a reliable option because this medicine may make this method ineffective in preventing pregnancy. See additional information under [Pregnancy and breastfeeding](#).
- use hormonal contraceptives including ones you take orally (the pill), patches you put on your skin, ones that are injected and implants. You should ALWAYS use additional methods of contraception such as condoms and IUDs and not rely just on hormonal contraception. See additional information under [Pregnancy and breastfeeding](#).
- have or have had any medical conditions, including:
 - o anaemia (low levels of red blood cells)
 - o pulmonary arterial hypertension or lung disease/condition
 - o hypotension (low blood pressure)
 - o liver or kidney problems
 - o heart disease or heart problems
 - o HIV infection
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not become pregnant while taking this medicine.

TRACLEER may harm unborn babies.

Your doctor will need evidence that you are not pregnant.

- You must have a negative pregnancy test at the time of starting treatment if you are sexually active.
- You must have a pregnancy test every month while you are taking this medicine.
- If there is any delay in getting period or any other reason to suspect pregnancy, you must tell your doctor immediately for pregnancy testing.
- Your doctor will need evidence that you are not pregnant before prescribing this medicine again.

If you are sexually active, you must use a hormonal and barrier method of contraception.

- TRACLEER may reduce the effectiveness of hormone contraceptives such as the pill and hormone patches, implants or injection. It is important to use other contraceptives, like condoms or an intrauterine device.
- Your doctor will advise you about using reliable contraceptives before taking this medicine.

You must stop taking TRACLEER at least 3 months before trying to become pregnant. It is known that this medicine causes harm to the developing baby if you take it during pregnancy and in the three months before becoming pregnant.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You are advised to stop breastfeeding if this medicine is prescribed for you because it has been reported that this drug passes into the milk in a woman who was taking this medicine.

Do not father a child while taking TRACLEER and for 3 months after stopping treatment.

TRACLEER may harm sperm. Use condoms and do not donate sperm during treatment and for 3 months after your treatment has finished. Talk with your healthcare providers if you have questions about birth control. If you plan to father a child, talk to your doctor or healthcare professional before taking TRACLEER.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TRACLEER and affect how it works. These include

- hormonal contraceptives (oral, injectable, transdermal and implantable)
- simvastatin, medicines for lowering blood fats
- medicines for diabetes such as glibenclamide and tolbutamide
- medicines for fungal infections such as ketoconazole, itraconazole, fluconazole and voriconazole
- medicines for bacterial infections such as rifampicin
- medicine to prevent organ transplantation rejection such as cyclosporine A, tacrolimus and sirolimus
- medicines for rheumatoid arthritis or psoriasis / dermatitis
- lopinavir + ritonavir or other ritonavir-boosted protease inhibitors and nevirapine (used to treat HIV)
- warfarin (used as anti-clotting medicines)
- digoxin (used to treat heart rhythm disorders)
- sildenafil or tadalafil (used to treat erectile dysfunction and/or pulmonary arterial hypertension)
- phenytoin, carbamazepine or phenobarbital (medicines for seizures)
- nimodipine

- St John's Wort (a herbal medicine used for depression)

These medicines may be affected by TRACLEER or may affect how well it works. You may need to use different amounts of your medicines or take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TRACLEER.

4. How do I use TRACLEER?

How much to take

Adults

- The usual dose is one tablet, twice daily. For the first 4 weeks you will take a 62.5 mg tablet twice daily.
- Depending on how you respond to the medicine, your doctor may increase the dosage after four weeks to a 125 mg tablet twice daily.

Patients with low body weight

- If you have body weight less than 40 kg but are over 12 years old, your doctor may advise you to take a 62.5 mg tablet twice daily. The usual dose is one tablet, twice daily.

Children aged 3 years and over

- The dose will be determined by your doctor depending on the weight of the child.

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

When to take TRACLEER

- TRACLEER is taken by mouth, in the morning and evening, and can be taken with or without food.

Do not stop taking this medicine suddenly unless your doctor tells you to.

- Stopping your treatment may lead to a worsening of your symptoms. Your doctor may tell you to reduce the dose over a few days before stopping completely.

If you forget to use TRACLEER

TRACLEER should be used regularly at the same time each day. If you miss your dose at the usual time, if there is still a long time to go before your next dose, take it as soon as you remember and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much TRACLEER

If you think that you have used too much TRACLEER, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TRACLEER?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using TRACLEER.
- Be sure to keep all your doctor's appointments so your progress can be checked and to monitor for side effects.
 - o It is very important that you have a liver function blood test before you start treatment and every month after that. TRACLEER can cause liver damage if it is not found early. Because this side effect may not cause symptoms at first, only a blood test can show that you have early liver damage. Regular blood tests let your doctor change or stop your therapy before there is permanent damage.
 - o You should have a blood test for anaemia after 1 and 3 months, and then every 3 months for the rest of your treatment.
- You need to have pregnancy tests before you start treatment and monthly if you are a female of childbearing age.

Things you should not do

Do not become pregnant while taking this medicine. See additional information under [Pregnancy and breastfeeding](#).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TRACLEER affects you.

TRACLEER may cause dizziness, tiredness or blurred vision in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

We have no information on how alcohol affects TRACLEER.

Looking after your medicine

- Store below 25°C. Keep the tablets in the original container.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• headache • respiratory tract infection • dizziness or fainting • anaemia • abnormal liver function test or liver disorders • inflamed throat and irritated nasal passages • flushing (hot flashes) • swelling of ankle, leg and joint or other signs of fluid retention • joint pain • low blood pressure • blood disorders • fast heart beat • tiredness • hypersensitivity reactions including itching, rash and skin inflammation • blocked or runny nose • heartburn or acid reflux • diarrhoea • redness of the skin • blurred vision • nosebleed • body ache and pain • worsening of existing lung disease	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• shortness of breath or difficulty in breathing • anaphylaxis and/ or swelling, most commonly around the eyes, lips, tongue or throat • nausea • vomiting • fever • unusual tiredness • stomach pain	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of

Serious side effects	What to do
- yellowing of your skin or the whites of your eyes (jaundice) - dark-coloured urine - chest pain	these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TRACLEER contains

Active ingredient (main ingredient)	Bosentan
Other ingredients (inactive ingredients)	maize starch pregelatinised maize starch sodium starch glycollate povidone glyceryl behenate magnesium stearate hypromellose triacetin talc titanium dioxide iron oxide yellow iron oxide red ethylcellulose

Do not take this medicine if you are allergic to any of these ingredients.

What TRACLEER looks like

TRACLEER 62.5 mg tablets are film-coated, round, biconvex, orange-white tablets, debossed with '62.5' on one side (AUST R 91919).

TRACLEER 125 mg tablets are film-coated, oval, biconvex, orange-white tablets, debossed with '125' on one side (AUST R 91920).

TRACLEER is supplied in bottles containing 60 tablets.

Who distributes TRACLEER

JANSSEN-CILAG Pty Ltd
Macquarie Park NSW 2113 Australia
Telephone: 1800 226 334

NZ Office: Auckland New Zealand
Telephone: 0800 800 806

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