

BOSENTAN

(Brand name: Tracleer®)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **the possible side effects**
- **what tests you will have to monitor your condition**
- **other precautions you should take while you are taking bosentan.**

Please read it carefully and discuss it with your doctor.

Important things to remember:

- While taking bosentan you should see your treating specialist regularly to make sure the treatment is working and to minimise any possible side effects.
- Bosentan should be taken at the same time each day.
- You should not stop your treatment unless your doctor tells you to.
- You should not increase or reduce the dose of bosentan unless your doctor tells you to.
- Contact your doctor at once if you experience symptoms such as nausea, stomach pain, fever, loss of appetite, dark urine, clay-coloured stools or jaundice (yellowing of the skin and/or eyes).
- Tell your doctor if you are taking warfarin (blood thinning medicine) as the dose of warfarin may need to be reduced while you are taking bosentan.

For more information about SCLERODERMA and other inflammatory conditions see Arthritis Australia's website
www.arthritisaustralia.com.au

What is bosentan?

Bosentan (brand name Tracleer®) is a medicine used to treat a condition called pulmonary arterial hypertension (PAH). This is a condition where there is increased pressure in the arteries that carry blood from the heart to the lungs.

PAH can occur in a number of rheumatological diseases such as scleroderma. These diseases can cause thickening of the blood vessel walls. Symptoms include shortness of breath during routine activity (such as climbing stairs), tiredness and chest pain.

How does it work?

Bosentan helps lower blood pressure in the lungs by preventing thickening of the blood vessel walls. This helps your heart pump blood more efficiently through the blood vessels in the lungs.

What benefit can you expect from your treatment and how is it monitored?

Bosentan can reduce the symptoms of PAH and in some cases prolong life expectancy. It may take 2 months or more before your symptoms start to improve.

Before bosentan can be prescribed, a specialist will assess you. This may be a rheumatologist, immunologist, cardiologist (heart) or a respiratory (lung) physician who has experience in managing PAH.

You will be asked to have the following tests:

- an ultrasound scan of your heart (echocardiogram)

- a right heart catheter - this is a test to measure the blood pressures in your heart and lungs. It involves inserting a tube into your heart from an artery in your neck or groin
- a six minute walk test (6MWT) to measure how far you can walk in six minutes.

Every six months you will be asked to have the echocardiogram and the 6MWT to check that bosentan is still helping your condition.

How is bosentan taken?

Bosentan is a tablet. It comes in two strengths (62.5 mg and 125mg).

What is the dosage and when should it be taken?

For the first month the dose is one 62.5 mg tablet twice a day. If tests to check blood counts and liver function are satisfactory the dose is then increased to one 125mg tablet twice a day.

Bosentan should be taken at the same time each day. It is usually taken in the morning and at night. If you forget to take a dose you can take it later in the day. If it is the next day, take the normal dose (do not take a double dose). Bosentan does not have to be taken with food.

Bosentan may be taken in combination with other medicines including:

- steroid medicines such as prednisolone
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen/Nurofen)
- simple pain relieving medicines such as paracetamol or Panadeine®
- calcium channel blockers (for Raynaud's disease)
- diuretics (fluid tablets)
- other treatments for PAH.

There are a number of medicines that should **not** be taken when you are taking bosentan (see *Precautions*).

How long is the treatment continued?

Bosentan may be given on a long term basis provided it does not cause problems and continues to help your condition. It is usually given for as long as the 6-monthly tests (echocardiogram and the 6MWT) show that it is of benefit.

Do not stop taking bosentan without first talking to your doctor. If your doctor does decide to stop the treatment, you may need to reduce the dose gradually before you stop the medicine completely.

Are there any side effects?

Most people who take bosentan do not experience side effects. Tell your doctor if you are concerned about possible side effects. A reduction in dose may minimise the side effects so that you can continue to have this treatment.

Most common possible side effects

- The most common side effects include *stomach upset, nausea, diarrhea* and *headache*.
- Other side effects include *inflamed throat, irritated nose passages or skin rash*.
- *Dizziness* due to low blood pressure, *flushing, ankle and/or leg swelling* can occur.
- *Irregular heart beats* or *tiredness* have been reported.

Less common or rare possible side effects

- Bosentan can cause severe *liver problems*. Symptoms include *nausea, stomach pain, fever, loss of appetite, dark urine, clay-colored stools and jaundice* (yellowing of the skin and/or eyes). Call your doctor at once if you have any of these symptoms.
- Low haemoglobin (*anaemia*) can be detected on blood tests but rarely causes symptoms.
- There are also a number of other rare side effects.

What precautions are necessary?

Blood tests

- Your liver function and blood counts for haemoglobin will need to be tested before you start taking bosentan, and again each month during your treatment.

Use with other medicines

- Bosentan can interact with other medicines. Some should not be taken with bosentan at all. For others the dose may need to be adjusted. You should tell your doctor (including your general practitioner,

rheumatologist and other health professionals) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.

- The following are some of the medicines that may interfere with bosentan:
 - warfarin (a blood thinning medicine) – close monitoring is required if you start bosentan while taking warfarin as the warfarin dose may need to be adjusted;
 - hormone-based birth control, such as contraceptive pills, shots, patches and implants (see under 'pregnancy and breastfeeding');
 - ciclosporin
 - some cholesterol lowering medicines;
 - anti-fungal medicines;
 - HIV/AIDS medicines such as lopinavir or ritonavir (Kaletra, Norvir);
 - tacrolimus (used to prevent rejection of liver or kidney transplants);
 - rifampicin (used for tuberculosis).
- Bosentan can be taken safely with anti-inflammatory drugs (NSAIDs) provided your kidney function is normal.

- Most vaccines can be given safely with bosentan. Talk with your rheumatologist before receiving any vaccines.

Use during pregnancy and breastfeeding

- Bosentan should not be taken during pregnancy or when breastfeeding.
- If you are a woman of child bearing age you should use effective contraception while taking bosentan. Bosentan may make the contraceptive pill unreliable, therefore you should use barrier methods of contraception. It is important to discuss this with your doctor before you start bosentan.
- If you are planning a family or you become pregnant during your treatment, you should discuss this with your doctor as soon as possible.

How to store Bosentan

- Store bosentan at room temperature, away from heat, moisture and light (e.g. not in the bathroom).
- Keep all medicines out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your specialist regularly to make sure the treatment is working and to minimise any possible side effects.

How to help us help you

Sign up to the ARAD project now!

The Australian Rheumatology Association collects information on how well these drugs work and how often they cause problems. The best way to get this information is from you! **Contact us in any of the following ways:**

Email: ARAD@monash.edu
Telephone: Sydney 02 9463 1889
or Melbourne 03 9508 3424
Fax: 1-800-022-730
Visit our website: www.ARAD.org.au

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.