



Australian
Rheumatology
Association

PATIENT INFORMATION ON

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; and**
- **Other precautions you should take while taking bosentan.**

Please read it carefully and discuss with your doctor.

What is bosentan?

Bosentan (brand name Tracleer) is a medicine used to treat a condition called pulmonary arterial hypertension (PAH), which means increased pressure in the arteries that carry blood from your heart to your lungs. PAH can occur in a number of rheumatological diseases such as scleroderma, which cause thickening of the blood vessel walls. Symptoms include shortness of breath during routine activity, such as climbing stairs, tiredness and chest pain.

For more information about scleroderma see Scleroderma Australia website
www.sclerodermaaustralia.com.au/what_is_scleroderma.html.

How does it work?

Bosentan helps lower blood pressure by preventing thickening of the blood vessels, especially those in the lungs and heart. This helps your heart pump blood through the blood vessels in the lungs more efficiently.

What benefit can you expect from your treatment?

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

Before bosentan can be prescribed, you should be assessed by a specialist with experience in managing PAH. You will be asked to have the following tests:

- an ultrasound scan of your heart (echocardiogram);
- a test to measure the blood pressures in your heart and lungs – this involves inserting a tube into your heart from an artery in your neck or groin; and
- 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 blood 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 a day. It is usually taken in the morning and night. It does not have to be taken with food.

Are other medicines taken with bosentan?

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 medicines such as paracetamol;
- calcium channel blockers (for Raynaud's disease);
- diuretics (fluid tablets);
- warfarin (blood-thinning medicine) - the dose of warfarin may need to be reduced if bosentan is commenced while you are on warfarin treatment; and/or
- 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 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. Below are some side effects that you might experience with your treatment. Tell your doctor if you experience any problems. A reduction in dose may minimise the side effects so that you can continue to have treatment.

Tell your doctor if you experience any side effects.

Most common possible side effects:

- stomach upset including nausea and diarrhea;
- headache;
- inflamed throat and irritated nose passages;
- flushing;
- ankle and leg swelling;
- dizziness due low blood pressure;
- irregular heart beats;
- tiredness;
- skin rash or irritation;
- low red blood cell levels (anemia).

Less common or rare possible side effects:

- Bosentan can cause severe liver problems. Symptoms include nausea, stomach pain, low fever, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin 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 uncommon side effects. It is a good idea to read the leaflet that comes with the medicine as it will list all the cautions and possible 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.

Other medicines:

- Bosentan can interact with other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines. You should also mention your treatment when you see other health professionals.

- The following medicines may interfere with bosentan. Some should not be taken with bosentan. For others, the dose may need to be adjusted.
 - cyclosporin (Sandimmune, Neoral);
 - cholesterol lowering medicines;
 - warfarin (a blood thinning medicine) – close monitoring is recommended as the warfarin dose may need to be adjusted if bosentan is commenced while you are on warfarin;
 - hormone-based birth control, such as pills, shots, patches and implants;
 - HIV/AIDS medicines lopinavir or ritonavir (Kaletra, Norvir);
 - anti-fungal medicines (ketoconazole, fluconazole, itraconazole or voriconazole);
 - tacrolimus (used to prevent rejection of liver or kidney transplants); and
 - rifampicin (used for tuberculosis).
- The risk of side effects from the low doses of aspirin used to prevent heart attack and strokes is not increased when taken with bosentan.

- Bosentan can be taken safely with anti-inflammatory drugs (NSAIDs), as long as your kidney function is normal.
- The simple pain reliever, paracetamol, and combined medicines such as Panadeine and Panadeine Forte, can be used while taking bosentan provided you take them as directed.
- Most vaccines can be given safely with bosentan. Pneumovax and yearly flu vaccinations are safe and recommended to reduce your risk of those infections. Talk with your rheumatologist before receiving any vaccines.

Pregnancy and breastfeeding:

- Bosentan is not recommended to be taken during pregnancy or during breastfeeding.
- If you are a woman of child bearing age you should use effective contraception while taking bosentan.
- If you are planning a family or become pregnant you should discuss this with your doctor as soon as possible.

All patients taking bosentan should be seen regularly by the specialist who prescribed the medicine to optimise treatment and to minimise any potential side effects.

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

Your doctor's contact details:

REMEMBER – Keep all medicines out of reach of children

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.