

Bosentan (Tracleer®)

What is bosentan?

Bosentan belongs to the class of medicines called endothelin receptor antagonists. It is only available with a doctor's prescription.

What is it for?

Bosentan tablets are used for the treatment of pulmonary hypertension (high blood pressure in the blood vessels between the heart and lungs).

Bosentan works by widening these blood vessels to reduce abnormally high blood pressure.

How to take this medication

It is important that this medication is taken only as directed and not given to other people. Bosentan can be taken with or without food. It is normally prescribed twice a day and should be given at about the same time each day.

Bosentan tablets should not be crushed but if necessary, may be cut using a tablet cutter. Alternatively, bosentan tablets disintegrate rapidly (within about 5 minutes) in 5 to 25mL of water. This suspension (mixture) can be made up in a syringe and shaken immediately prior to administration to ensure dispersion of the tablet.

To make the suspension:

1. Remove the plunger and place the tablet in the syringe.
2. Replace the plunger.
3. Draw up some water and gently shake until the tablet is dissolved.

The suspension should then be used immediately, and any remaining suspension should be discarded. A new suspension must be prepared for each dose.

Bosentan should only be mixed with water and not fruit juice/cordial/soft drink. This is because bosentan will not dissolve effectively in acidic liquids such as fruit juice.

What to do if a dose is missed

If it is almost time for the next dose, skip the dose missed and give the next dose at the usual time. Otherwise, give the medication as soon as you remember and then go back to giving the medicine as usual.

Do not try to make up for missed dose(s) by giving more than one dose at a time. This can increase the risk of unwanted side effects.



Storing the medication

Store below 25°C.

Do not keep the medicine in the bathroom, near the kitchen sink or any other damp, warm place, because this may make the medication less effective.

It is important to keep bosentan locked away out of the reach of children.

Keep the tablets in the original bottle until it is time to give them.

Disposal of the medication

If your child no longer requires this medication or the medication has passed its expiry date, please return the medication to your nearest pharmacy for disposal.

Use of other medication

Bosentan can interact with various other medications so it is important to advise your doctor or pharmacist before giving any other medication. This includes medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

These include medicines that are:

- for fungal infections
- hormonal contraceptives
- for lowering blood fats
- for organ transplant rejection
- for diabetes
- for rheumatoid arthritis or psoriasis
- some anti-epileptic medications
- St John's wort.

Important information

- Bosentan is known to cause major birth defects. If your child (daughter) is sexually active, hormonal contraceptives should not be the only source of contraception as bosentan can make this method ineffective. Additional methods of contraception such as condoms must be used during bosentan treatment and for 3 months after stopping treatment. If your child is sexually active, they must have a pregnancy test prior to starting bosentan and then every month while taking bosentan.
- Bosentan is known to cause birth defects and should not be used during pregnancy or when there is a possibility of pregnancy. Pregnant women and women of childbearing potential should avoid exposure to bosentan dust particles and when handling this medication should wear disposable gloves and a face mask. The risk of exposure to bosentan dust particles during normal cutting and dissolution in a syringe is low and not a reason for concern, however it is important to take the appropriate precautions especially when pregnant or if there is a possibility of pregnancy.
- Bosentan can, in rare cases, cause liver damage; your doctor will monitor your child's liver function periodically. Bosentan may also cause anaemia (reduced

haemoglobin) in some patients; your doctor will also monitor your child's haemoglobin levels periodically.

Possible side-effects

Side effects may occur while taking bosentan. Some of these are not serious and will go away with time. Others are more serious and require you to check with your child's doctor.

Side effects may include:

- headache
- anaemia
- inflamed throat and irritated nose passages
- flushing
- ankle and leg swelling
- low blood pressure
- fast heartbeat
- itching.

Bosentan can, in rare cases, cause liver damage. If your child gets any of the following symptoms call your doctor right away:

- nausea or vomiting
- fever
- unusual tiredness
- stomach pain
- dark urine
- yellowing of the skin and/or whites of the eyes.

Commercially available dosage forms and strengths

- 62.5mg and 125mg tablets.

Your hospital pharmacy will advise you if they manufacture any additional dosage forms to the above.

If you have any concerns, contact your child's doctor or PCH Pharmacy Department

- Dispensary: 6456 0190 – select option 2
- Paediatric Medicines Information Service: 6456 0190 – select option 1

In case of overdose or poisoning contact the Poisons Information Centre on 13 11 26.



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Child and Adolescent Health Service



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