

Bosentan APOTEX

Contains the active ingredient bosentan (as monohydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about bosentan. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Bosentan APOTEX tablets. It

contains the active ingredient bosentan (as monohydrate).

It is used to treat high blood pressure in the blood vessels between the heart and the lungs. This condition is called pulmonary arterial hypertension.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Bosentan acts to reduce abnormally high blood pressure by widening the blood vessels between the heart and lungs. It belongs to the class of medicines known as endothelin antagonists.

There is no evidence that this medicine is addictive.

Use in children

There is limited experience with the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant or intend to become pregnant. You must stop taking the medicine at least 3 months before trying to become pregnant.**
Bosentan is known to cause harm to a developing baby if you take it

during pregnancy and in the three months before becoming pregnant.

- **You have a moderate to severe liver disorder.**
- **You are being treated with cyclosporin A** (a medicine used after a transplant or to treat psoriasis)
- **You are being treated with glibenclamide** (a medicine used for diabetes)
- **You are hypersensitive to, or have had an allergic reaction to, bosentan or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed. The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Bosentan may harm sperm. All men should use effective birth control while taking this medicine and for 3 months after they stop taking it.

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

This medicine may reduce the effectiveness of hormonal contraceptives such as the pill and hormone patches, implants or injections. It is important to use other contraceptives, like condoms or an intrauterine device (IUD).

Your doctor will advise you about using reliable contraceptives before taking this medicine.

Before you start taking this medicine, tell your doctor if:

1. 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. Hormonal contraceptives include 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 only on hormonal contraception. You should have a pregnancy test every month while you are taking this medicine. You must stop taking this medicine for at least 3 months prior to becoming pregnant.

2. You are currently breastfeeding or you plan to breastfeed.

It is not known whether bosentan passes into breast milk. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

3. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
4. You have or have had any medical conditions, especially the following:
 - anaemia
 - hypotension
 - liver or kidney disorders
 - pulmonary veno-occlusive disease (PVOD)
 - pulmonary arterial hypertension with heart failure
 - coronary heart disease (CHD)
 - HIV infection
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines must not be taken with bosentan, these include:

- **cyclosporin A, used to prevent organ transplantation rejection**
- **glibenclamide, used to treat diabetes.**

Some medicines may also interact with bosentan. These include:

- hormonal contraceptives (oral, injectable, transdermal and implantable)
- simvastatin, medicines for lowering blood fats
- medicines for bacterial infections such as rifampicin
- medicines to prevent organ transplantation rejection such as tacrolimus or sirolimus
- lopinavir and ritonavir or other ritonavir-boosted protease inhibitors (used to treat HIV)
- digoxin (used to treat heart rhythm disorders)
- sildenafil (used to treat erectile dysfunction and/or also pulmonary hypotension)

- warfarin used to prevent blood clots
- fluconazole used for fungal infections
- nimodipine a type of medication used to treat narrow blood vessels in the brain.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with bosentan.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

The usual starting dose is one 62.5mg tablet, twice daily for the first 4 weeks.

Depending on how you respond to the medicine, your doctor may increase the dosage after four weeks to a 125mg tablet twice daily.

If you do not think the medicine is working or you think it is working too well, talk to your doctor. Your doctor may need to change the dose you are taking.

When to take it

Take one tablet in the morning and one in the evening.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and

will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

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

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

It is very important that you have a liver function blood test before you start treatment and every month after that.

Bosentan can cause liver damage if it is not found early. As 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.

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 monthly if you are a female of childbearing age.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Do not become pregnant whilst taking this medicine.
You must have a pregnancy test every month while you are taking this medicine. Your doctor will need evidence that you are not pregnant before prescribing the medicine again.

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking bosentan or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache
- inflamed throat and irritated nose passages
- flushing (hot flushes)
- ankle and leg swelling
- low blood pressure
- blood disorders
- fast heart beat
- tiredness
- itching, rash, skin inflammation, skin redness
- diarrhoea.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- shortness of breath or difficulty in breathing.
 - nausea
 - vomiting
 - fever
 - unusual tiredness
 - stomach pain
 - yellowing of your skin or the whites of your eyes (jaundice).
- Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to bosentan, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What Bosentan APOTEX tablets looks like

62.5 mg tablets: Orange-white coloured, round shaped, biconvex film-coated tablet, engraved "APO" on one side and "62.5" on the other side.

125 mg tablets: Orange-white coloured, oval shaped biconvex film-coated tablet, engraved "APO" on one side and "125" on the other side.

* Not all strengths may be available.

Ingredients

Each tablet contains 62.5 mg or 125 mg bosentan (as monohydrate) as the active ingredient.

It also contains the following inactive ingredients:

- methylcellulose
- poloxamer
- crospovidone
- silicon dioxide
- magnesium stearate

Film coating containing:

- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- iron oxide red
- iron oxide yellow

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Bosentan APOTEX 62.5 mg tablets (Bottle of 60s): AUST R 222214.

Bosentan APOTEX 125 mg tablets (Bottle of 60s): AUST R 222215.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was last updated in: January 2015.