

BOSENTAN APO

Consumer Medicine Information (CMI) summary

WARNINGS: BOSENTAN APO may cause birth defects and is contraindicated in pregnancy. See **Section 4.3 CONTRAINDICATIONS** and **Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**. Rare cases of hepatic cirrhosis and hepatic failure have been reported in patients using bosentan. See **Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**.

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

1. Why am I using BOSENTAN APO?

BOSENTAN APO contains the active ingredient bosentan (as monohydrate). BOSENTAN APO is used to treat high blood pressure in the blood vessels between the heart and the lungs. This condition is called pulmonary arterial hypertension.

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

2. What should I know before I use BOSENTAN APO?

Do not use if you have ever had an allergic reaction to BOSENTAN APO 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 BOSENTAN APO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BOSENTAN APO 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 BOSENTAN APO?

- Adults: The usual starting dose is one 62.5 mg tablet taken twice daily. Depending on how you respond to the medicine, your doctor may increase the dosage after four weeks to one 125mg tablet twice daily.
- Children aged 3 years and over: The dose will be determined by your doctor depending on the weight of the child.
- Take one tablet in the morning and one tablet in the evening, at about the same time each day. BOSENTAN APO tablets should be swallowed whole with a glass of water. BOSENTAN APO can be taken with or without food.

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

5. What should I know while using BOSENTAN APO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, surgeon, anaesthetist, dentist, or pharmacist you visit that you are using BOSENTAN APO.• It is very important that you have a liver function blood test before you start treatment and every month after that.• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• BOSENTAN APO may cause tiredness, blurred vision or dizziness. If affected, do not drive, operate machinery or do anything else that could be dangerous.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in its original packaging until it is time to take it.• Keep your medicine in a cool dry place where the temperature stays below 25°C.• Keep this medicine where children cannot reach it.

For more information, see Section [5. What should I know while using BOSENTAN APO?](#) 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.

WARNINGS: BOSENTAN APO may cause birth defects and is contraindicated in pregnancy. See **Section 4.3 CONTRAINDICATIONS** and **Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**. Rare cases of hepatic cirrhosis and hepatic failure have been reported in patients using bosentan. See **Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**.

BOSENTAN APO

Active ingredient(s): *bosentan (as monohydrate)* (BOZ-en-tan)

Consumer Medicine Information (CMI)

This leaflet provides important information about using BOSENTAN APO. **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 BOSENTAN APO.**

Where to find information in this leaflet:

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

1. Why am I using BOSENTAN APO?

BOSENTAN APO contains the active ingredient bosentan (as monohydrate). BOSENTAN APO belongs to a group of medicines called endothelin antagonists.

BOSENTAN APO 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.

This medicine acts to reduce abnormally high blood pressure by widening these blood vessels. It belongs to the class of medicines known as endothelin receptor antagonists.

Your doctor, however, may prescribe BOSENTAN APO for another purpose.

Ask your doctor if you have any questions why it has been prescribed for you.

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

2. What should I know before I use BOSENTAN APO?

Warnings

Do not use BOSENTAN APO 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:

- 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.

- you are breastfeeding or planning to breastfeed. It is not known whether BOSENTAN APO passes into breast milk.
- you have allergies to:
 - any other medicines
 - any other substances such as food, preservatives or dyes
- you have or have had any of the following medical conditions, especially the following:
 - pulmonary arterial hypertension or lung disease/condition
 - anaemia
 - hypotension
 - liver or kidney disorders
 - heart failure or disease
 - HIV infection

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking bosentan.

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.

BOSENTAN APO may harm unborn babies.

Your doctor will need evidence that you are not pregnant.

- you are allergic to bosentan, or any of the ingredients listed at the end of this leaflet.
- 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.

- BOSENTAN APO 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 BOSENTAN APO 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 BOSENTAN APO and for 3 months after stopping treatment.

BOSENTAN APO 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 BOSENTAN APO.

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 also interfere with bosentan. These include:

- hormonal contraceptives (oral, injectable, transdermal and implantable)
- simvastatin, used for lowering blood fats
- medicines for diabetes such as glibenclamide and tolbutamide.
- medicines used for fungal infections (e.g. ketoconazole, fluconazole and voriconazole)
- medicines for bacterial infections (e.g. rifampicin)
- medicines to prevent organ transplantation rejection (e.g. ciclosporin A, tacrolimus, sirolimus)
- medicines for rheumatoid arthritis or psoriasis/dermatitis
- lopinavir and ritonavir or other ritonavir-boosted protease inhibitors and nevirapine(used to treat HIV infections);
- warfarin, used to prevent blood clots
- digoxin, used to treat heart rhythm disorders
- sildenafil or tadalafil used to treat erectile dysfunction or pulmonary arterial hypertension
- phenytoin, carbamazepine or phenobarbital (medicines for seizures)
- nimodipine, a type of medication used to treat narrow blood vessels in the brain.
- St John's Wort

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with bosentan.

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

4. How do I use BOSENTAN APO?

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.

Adults

- The usual starting dose is one 62.5 mg tablet taken twice daily.

Depending on how you respond to the medicine, your doctor may increase the dosage after four weeks to one 125mg 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 take 62.5 mg 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.

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

When to take BOSENTAN APO

- BOSENTAN APO can be taken with or without food.
- Take one tablet in the morning and one tablet in the evening, at about the same time each day.
- **Take your medicine at about the same time each day.** Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take BOSENTAN APO

- **Swallow the tablet whole with a full glass of water.**

How long to take BOSENTAN APO

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

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

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

If you forget to use BOSENTAN APO

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

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 the dose you missed. This may increase the chance of you experiencing side effects.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you use too much BOSENTAN APO

If you think that you have used too much BOSENTAN APO, 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 BOSENTAN APO?

Things you should 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

If you are about to have any blood tests, tell the doctor that you are taking this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

Things you should not do

Do not become pregnant whilst taking this medicine.

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. Bosentan may harm unborn babies.

Your doctor will need evidence that you are not pregnant before prescribing the medicine again.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaints unless your doctor tells you to.

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

Driving or using machines

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

BOSENTAN APO may cause tiredness in some people. Feel dizzy or that your vision is blurred whilst taking this medicine. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

We have no information on how alcohol affects BOSENTAN APO.

Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it.
- Keep your medicine in a cool dry place where the temperature stays below 25°C

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.

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

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 printed on the pack or if the packaging is torn or shows signs of tampering .

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
<ul style="list-style-type: none">• headache• respiratory tract infection• dizziness or fainting• anaemia• abnormal liver function test or liver disorders	Speak to your doctor if you have any of these less serious side

<ul style="list-style-type: none">• inflamed throat and irritated nasal passages• joint pain• flushing (hot flushes)• swelling of ankle, leg and signs of fluid retention• low blood pressure• blood disorders• fast heart beat• tiredness• blurred vision• hypersensitivity reactions including itching, rash, skin inflammation, skin redness• blocked or runny nose• heartburn or acid reflux• diarrhoea• nosebleed• body ache and pain• worsening of existing lung disease	effects and they worry you.
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• shortness of breath or difficulty in breathing• anaphylaxis and/ or swelling, most commonly around the eyes, lips, tongue or throat• nausea or vomiting• fever• unusual tiredness• stomach pain• yellowing of your skin or the whites of your eyes (jaundice)• dark-coloured urine• chest pain	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects are uncommon.

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

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

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 BOSENTAN APO contains

Active ingredient	bosentan (as monohydrate)
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(main ingredient)	
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • ethylcellulose • glycerol dibehenate • hypromellose • iron oxide red • iron oxide yellow • magnesium stearate • maize starch • povidone • pregelatinised maize starch • purified talc • sodium starch glycollate A • titanium dioxide • triacetin
Potential allergens	-

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

What BOSENTAN APO looks like

BOSENTAN APO 62.5 mg film coated tablets are light peach to peach coloured, round shaped, biconvex and debossed with '62.5' on one side and plain on the other side.

BOSENTAN APO 125 mg film coated tablets are light peach to peach coloured, oval shaped, biconvex and debossed with '125' on one side and plain on the other side.

BOSENTAN APO 62.5 mg (bottle of 60 tablets)

AUST R 257754

BOSENTAN APO 125 mg (bottle of 60 tablets)

AUST R 257734

Who distributes BOSENTAN APO

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne 3121

Australia

www.arrotex.com.au

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