

BOSENTAN RBX

Consumer Medicine Information (CMI) summary

BoSENTAN 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 bositentan. See Section **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**.

1. Why am I using BOSENTAN RBX?

BOSENTAN RBX contains the active ingredient bositentan (as monohydrate). BOSENTAN RBX is used to 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.

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

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

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

3. What if I am taking other medicines?

Some medicines may interfere with BOSENTAN RBX 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 RBX?

BOSENTAN RBX is taken by mouth, in the morning and evening, and can be taken with or without food.

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

5. What should I know while using BOSENTAN RBX?

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. You need to have pregnancy tests monthly if you are a female of childbearing age.
Things you should not do	Do not give the tablets to anyone else even if they have the same symptoms as you.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how BOSENTAN RBX affects you.
Looking after your medicine	Store below 25°C.

For more information, see Section [5. What should I know while using BOSENTAN RBX?](#) in the full CMI.

6. Are there any side effects?

Common side effects include shortness of breath or difficulty in breathing; anaphylaxis and/ or swelling, most commonly around the eyes, lips, tongue or throat; nausea; vomiting; fever; unusual tiredness; stomach pain; yellowing of your skin or the whites of your eyes (jaundice); dark-coloured urine; 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.

WARNING: Bosentan 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 RBX

Active ingredient(s): *Bosentan (as monohydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bosentan RBX. **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 RBX.**

Where to find information in this leaflet:

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

1. Why am I using BOSENTAN RBX?

BOSENTAN RBX contains the active ingredient bosentan (as monohydrate). BOSENTAN RBX belongs to the class of medicines known as endothelin receptor antagonists.

BOSENTAN RBX is used to 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.

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

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

Warnings

Do not use BOSENTAN RBX 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.
- Being treated with ciclosporine A (a medicine used after a transplant or to treat psoriasis).

- Being treated with glibenclamide (a medicine used for diabetes).
- You have moderate to severe liver disorder.
- After the expiry date (EXP) printed on the pack. If you take it after the expiry date has passed, it may not work as well.
- The packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions:
 - pulmonary arterial hypertension
 - anaemia
 - hypotension
 - liver or renal disorders
 - heart failure
 - HIV infection
- 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 just 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 RBX passes into breast milk.

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 take BOSENTAN RBX if you are:

- **Pregnant or intend to become pregnant**

You must stop taking the medicine 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.

- **You are breastfeeding**

Tell your doctor immediately if you are breastfeeding. You are advised to stop breastfeeding if this medicine is prescribed for you because it is not known if this drug passes into the milk in women who are taking this medicine.

Before you start to take BOSENTAN RBX

BOSENTAN RBX 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 barrier method of contraception.

This medicine 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 have a negative pregnancy test at the time of starting treatment if you are sexually active.

Your doctor will need evidence that you are not pregnant.

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 interfere with BOSENTAN RBX. These include:

- hormonal contraceptives (oral, injectable, transdermal and implantable)
- simvastatin, medicines for lowering blood fats
- medicines for diabetes such as glibenclamide
- medicines for fungal infections such as ketaconazole, itraconazole, fluconazole and voriconazole
- medicines for bacterial infections such as rifampicin
- medicine to prevent organ transplantation rejection such as Ciclosporine A, tacrolimus and sirolimus
- medicines for rheumatoid arthritis or psoriasis/dermatitis
- lopinavir+ritonavir or other ritonavir-boosted protease inhibitors (used to treat HIV);
- warfarin (used as anti-coagulant medicine)
- digoxin (used to treat heart rhythm disorders)

- sildenafil or tadalafil (used to treat erectile dysfunction and/or also pulmonary hypertension)
- phenytoin, carbamazepine or phenobarbital (medicines for seizures)
- nimodipine
- nevirapine (an HIV medicine)
- St John Wort

These medicines may be affected by BOSENTAN RBX or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

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 RBX.

4. How do I use BOSENTAN RBX?

How much to take / use

- The usual dose is one tablet, twice daily. For the first 4 weeks you will take a 62.5 mg tablet twice daily. Depending on how you respond to the medicine, your doctor may increase the dosage after four weeks to a 125 mg 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.
- Follow the instructions provided and use BOSENTAN RBX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

When to take BOSENTAN RBX

BOSENTAN RBX should be taken in the morning and evening.

How to take/use BOSENTAN RBX

BOSENTAN RBX is taken by mouth, in the morning and evening, and can be taken with or without food.

How long to take it

Do not stop taking this medicine unless your doctor tells you to.

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.

If you forget to use BOSENTAN RBX

BOSENTAN RBX should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember and then go back to taking it as you would normally.

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

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

This may increase the chance of getting an unwanted side effect.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you use too much BOSENTAN RBX

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

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 RBX can cause liver damage if it is not found early. Because 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.

Things you should not do

Do not give the tablets to anyone else even if they have the same symptoms as you.

Driving or using machines

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

If you feel dizzy or your vision is blurred whilst taking this medicine, do not drive or operate any tools or machinery.

Looking after your medicine

Store 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.

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.

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• inflamed throat and irritated nose passage• flushing (hot flashes)• swelling of ankle, leg and joint or other signs of fluid retention• joint pain• low blood pressure• blood disorders• fast heart beat• tiredness• hypersensitivity reactions including itching, rash, skin inflammation,• skin redness• blocked or runny nose• heartburn or acid reflux• diarrhoea• blurred vision• nosebleed• body ache and pain• worsening of existing lung disease	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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• 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.

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

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

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 RBX contains

Active ingredient (main ingredient)	BOSENTAN RBX 62.5 mg: contains 62.5 mg bosentan (as monohydrate) per tablet. BOSENTAN RBX 125 mg: contains 125 mg bosentan (as monohydrate) per tablet.
Other ingredients (inactive ingredients)	maize starch, pregelatinised maize starch, sodium starch glycollate type A, povidone, glycerol dibehenate, magnesium stearate, hypromellose, glycerol triacetate, purified talc, titanium dioxide, iron oxide yellow, iron oxide red and ethylcellulose.
Potential allergens	-

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

What BOSENTAN RBX looks like

BOSENTAN RBX 62.5 mg (AUST R 257757) is 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 RBX 125 mg (AUST R 257753) is 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.

Supplied in PVC/PE/PVdC/Al blister packs containing 56 and 60 tablets.

Not all pack sizes are marketed in Australia.

Who distributes BOSENTAN RBX

Sun Pharma ANZ Pty Ltd

Macquarie Park NSW 2113 Australia

customerservice.aus@sunpharma.com

Tel: 1800 726 229

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