

# Bosentan Cipla

## Consumer Medicine Information (CMI) summary

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 Cipla?

Bosentan Cipla contains the active ingredient bosentan. Bosentan Cipla is used to treat pulmonary arterial hypertension.

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

### 2. What should I know before I use Bosentan Cipla?

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

### 3. What if I am taking other medicines?

Some medicines may interfere with Bosentan Cipla 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 Cipla?

- Always take this medicine exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- The usual dose is one tablet, twice daily. For the first 4 weeks you will take a 62.5 mg tablet twice daily.

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

### 5. What should I know while using Bosentan Cipla?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist when you visit that you are using Bosentan Cipla.</li><li>• Your doctor may arrange for regular blood tests to check for changes in your liver function and haemoglobin level.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take Bosentan Cipla if you have moderate to severe liver disorder.</li><li>• Do not take this medicine if you are pregnant or breastfeeding.</li><li>• Do not stop taking this medicine unless your doctor tells you to.</li><li>• 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.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• If you feel dizzy or that your vision is blurred whilst taking this medicine do not drive or operate any tools or machinery.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store this medicine in the original bottle, in a cool, dry place where the temperature stays below 25°C.</li><li>• Keep out of reach of children.</li></ul>

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

### 6. Are there any side effects?

The 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.

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

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.

# Bosentan Cipla

**Active ingredient(s):** *Bosentan* (BOZ-en-tan)

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I using Bosentan Cipla?

**Bosentan Cipla contains the active ingredient bosentan.**

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

**Bosentan Cipla 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.**

## 2. What should I know before I use Bosentan Cipla?

### Warnings

**Do not use Bosentan Cipla 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 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. 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.
- you are being treated with ciclosporin (a medicine used after a transplant or to treat psoriasis)

- you are being treated with glibenclamide (a medicine used for diabetes)
- have moderate to severe liver disorder.
- the packaging is torn or shows signs of tampering.

### 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.
- use 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 Cipla passes into breast milk.
- have allergies to any other medicines or any other substances such as foods, preservatives or dyes.
- have or have had any medical conditions, especially the following:
  - pulmonary arterial hypertension or lung disease/ condition
  - anaemia
  - hypotension
  - liver or renal disorders
  - heart failure or disease
  - HIV infection

Your doctor may arrange for regular blood tests to check for changes in your liver function and haemoglobin level.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Do not become pregnant while 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 this medicine again.

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 is not known if this drug passes into the milk in women who are taking this medicine.

### 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 Cipla and affect how it works. These includes:**

- hormonal contraceptives (oral, injectable, transdermal and implantable)
- simvastatin, medicines for lowering blood fats
- medicines for diabetes such as glibenclamide and tolbutamide
- 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 ciclosporin A, and tacrolimus and sirolimus
- medicines for rheumatoid arthritis or psoriasis/dermatitis
- lopinavir+ritonavir or other ritonavir-boosted protease inhibitors and nevirapine (used to treat HIV);
- warfarin (used as anti-clotting medicines)
- digoxin (used to treat heart rhythm disorders)
- sildenafil (used to treat erectile dysfunction and/or also pulmonary arterial hypertension)
- phenytoin, carbamazepine or phenobarbital (medicines for seizures)
- nimodipine
- St John's Wort

**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 Cipla.**

### 4. How do I use Bosentan Cipla?

#### How much to take

- Follow the instructions provided and use Bosentan Cipla until your doctor tells you to stop.
- Always take this medicine exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- **Adults:** 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.

- **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 a 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.
- 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 Bosentan Cipla

- Bosentan Cipla is taken by mouth, in the morning and evening, and can be taken with or without food.

#### If you forget to use Bosentan Cipla

Bosentan Cipla should be used regularly at the same time each day.

**If you miss your dose at the usual time and 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 there is still a long time to go before your next dose, take it as soon as you remember and then go back to taking it as you would normally.

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 Cipla

If you think that you have used too much Bosentan Cipla, 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 Cipla?

#### 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 Cipla 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.

Remind any doctor, dentist or pharmacist when you visit that you are using Bosentan Cipla.

### Things you should not do

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

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Bosentan Cipla affects you.**

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

### Looking after your medicine

- Store this medicine in the original bottle, 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.**

### 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.

Medicines should not be disposed of in wastewater or household waste.

Ask your pharmacist how to dispose of medicines you no longer require. These measures will help to protect the environment.

## 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
<b>More broad or affecting different parts of the body:</b> <ul style="list-style-type: none"><li>• Headache</li><li>• Respiratory tract infection</li><li>• Dizziness or fainting</li><li>• Anaemia</li><li>• Abnormal liver function test or liver disorders</li><li>• Inflamed throat and irritated nasal passages</li><li>• Flushing (hot flashes)</li><li>• Swelling of ankle, leg and Joint pain</li><li>• Low blood pressure</li><li>• Blood disorders</li><li>• Fast heart beat</li><li>• Tiredness</li><li>• Hypersensitivity reactions including itching, rash and skin inflammation,</li><li>• Blocked or runny nose</li><li>• Heartburn or acid reflux</li><li>• Diarrhoea</li><li>• Redness of the skin</li><li>• Blurred vision</li><li>• Nosebleed</li><li>• Body ache and pain</li><li>• Worsening of existing lung disease</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>More broad or affecting different parts of the body:</b> <ul style="list-style-type: none"><li>• shortness of breath or difficulty in breathing</li><li>• anaphylaxis and/ or swelling, most commonly around the eyes, lips, tongue or throat</li><li>• nausea</li><li>• vomiting</li><li>• fever</li><li>• unusual tiredness</li><li>• stomach pain</li><li>• yellowing of your skin or the whites of your eyes (jaundice)</li><li>• dark-coloured urine</li><li>• chest pain</li></ul>	<b>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.</b>

**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](http://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.**

### Who distributes Bosentan Cipla

Cipla Australia Pty Ltd.,  
Level 1 / 132-136 Albert Road,  
SOUTH MELBOURNE  
VIC 3205  
[drugsafety@cipla.com](mailto:drugsafety@cipla.com)  
Phone no: 1 800 569 074

This leaflet was prepared in September 2020.

## 7. Product details

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

### What Bosentan Cipla contains

<b>Active ingredient (main ingredient)</b>	Bosentan
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• maize starch</li><li>• pregelatinised maize starch</li><li>• sodium starch glycollate type B</li><li>• povidone</li><li>• glycerol dibehenate</li><li>• magnesium stearate</li><li>• OPADRY complete coating system 03K520035 YELLOW (PI 111084)</li><li>• Aquacoat ECD ethylcellulose aqueous Dispersion NF (PI 1973)</li></ul>

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

### What Bosentan Cipla looks like

Bosentan Cipla 62.5 mg film-coated tablets are cream to pale yellow coloured, circular, biconvex, film-coated tablets, debossed with "62.5" on one side and plain on other side (bottle pack AUST R 284676, blister pack AUST R 284683).

Bosentan Cipla 125 mg film-coated tablets are cream to pale yellow coloured, oblong, biconvex, film-coated tablets, debossed with "125" on one side and plain on other side (bottle pack AUST R 284686, blister pack AUST R 284690).