

Consumer Medicine Information (CMI) summary

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

1. Why am I taking BISPRO?

BISPRO contains the active ingredient bisoprolol fumarate. BISPRO is used to treat heart failure. For more information, see Section [1. Why am I taking BISPRO?](#) in the full CMI.

2. What should I know before I take BISPRO?

Do not take if you have ever had an allergic reaction to bisoprolol fumarate 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 take BISPRO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BISPRO 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 take BISPRO?

- BISPRO should be taken in the morning, with or without food.
- Swallow the tablets with a glass of water. Do not crush or chew the tablets.

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

5. What should I know while taking BISPRO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking BISPRO.• If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.• Visit your doctor regularly so they can check on your progress.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking BISPRO, or lower the dose, without checking with your doctor.• Do not take BISPRO to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how BISPRO affects you.• BISPRO may cause tiredness, dizziness or lightheadedness in some people, especially after the first dose.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol. Effects of alcohol should be considered particularly at the start of treatment and upon change of medication.
Looking after your medicine	<ul style="list-style-type: none">• BISPRO 2.5 mg should be stored below 25°C.• BISPRO 5 mg and 10 mg should be stored below 30°C.• Keep your tablets in a cool dry place.

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

6. Are there any side effects?

Speak to your doctor or pharmacist if you have any of these: sleep disturbances; nausea, vomiting; diarrhoea, constipation; feeling of coldness or numbness in hands or feet; allergic runny nose; hair loss or sexual problems. **Tell your doctor as soon as possible if you notice any of these:** muscular weakness or cramps; dizziness or light-headedness (sometimes with fainting); a very slow heart beat; hallucinations; depression; irritation or redness of the eye; skin reactions such as rash, flush, itching, worsening of psoriasis; difficulty hearing or fainting. **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these:** swelling of the face, lips, tongue, throat which may cause difficulty breathing or swallowing; signs of worsening heart failure; chest tightness, wheezing, rattly breathing; yellowing of the skin or eyes, dark coloured urine, itching, generally feeling unwell or irregular heart beating. **This is not a complete list of all possible side effects.**

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking BISPRO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking BISPRO.**

Where to find information in this leaflet:

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

1. Why am I taking BISPRO?

BISPRO contains the active ingredient bisoprolol fumarate.

BISPRO is used to treat heart failure. It is usually used in combination with other medicines.

Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs. Heart failure may start off with no symptoms, but as the condition progresses patients may feel short of breath and notice swelling of the feet and ankles due to fluid build up.

BISPRO belongs to a group of medicines called beta blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. BISPRO also slows your heart rate, which in turn increases the efficiency of your heart.

BISPRO can help to reduce the number of heart failure episodes needing hospital admission and also the risk of sudden death.

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

BISPRO is not recommended for use in children, as the safety and efficacy in children have not been established.

There is no evidence that BISPRO is addictive.

2. What should I know before I take BISPRO?

Warnings

Do not take BISPRO if:

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

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can take this medicine.

- you have any of the following heart problems:
 - severe heart failure that is not controlled medically
 - worsening heart failure requiring injection of medicines into a vein
 - cardiogenic shock, a serious heart condition causing low blood pressure and circulatory failure
 - certain heart conditions where the electrical activity controlling your heart rate does not work properly, causing a very slow heart rate or uneven heart beating
 - low blood pressure.
- you have any of the following medical conditions:
 - severe asthma or severe chronic obstructive lung disease
 - severe blood circulation problems in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue
 - untreated phaeochromocytoma, a rare tumour of the adrenal gland
 - metabolic acidosis, a condition when there is too much acid in the blood.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives
- have or have had any of the following medical conditions:
 - asthma, difficulty breathing or other lung problems
 - heart diseases (such as disturbances in heart rhythm or Prinzmetal angina)
 - diabetes
 - any allergic conditions
 - psoriasis, a skin disease with thickened patches of red skin, often with silvery scales
 - thyroid disorder
 - any blood vessel disorder causing poor circulation in the arms and legs

- kidney problems
 - liver problems
 - phaeochromocytoma, a rare tumour of the adrenal gland.
- take any medicines for any other condition
 - are going to have anaesthesia (for example for surgery). BISPRO may influence how your body reacts to this situation.

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.

BISPRO may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking BISPRO during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Like most beta-blocker medicines, BISPRO is not recommended while you are breastfeeding. Your doctor will discuss the risks and benefits of taking BISPRO when breastfeeding.

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

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 and BISPRO may interfere with each other.

Do not take the following medicines with BISPRO without special advice from your doctor:

- certain anti-arrhythmic medicines such as disopyramide, lidocaine, phenytoin or flecainide (used to treat irregular or abnormal heartbeat)
- certain calcium antagonists such as diltiazem or verapamil (medicines used to treat high blood pressure and angina)
- certain medicines used to treat high blood pressure such as clonidine, methyldopa or moxonidine.

However, do not stop taking these medicines without checking with your doctor.

Check with your doctor before taking the following medicines with BISPRO.

Your doctor may need to check your condition more frequently.

- anti-arrhythmic medicines such as amiodarone (used to treat irregular or abnormal heartbeat)
- calcium antagonists such as felodipine or amlodipine (used to treat high blood pressure and angina)

- certain medicines used to treat arthritis, pain or inflammation, such as ibuprofen or diclofenac
- eye drops for glaucoma treatment
- insulin and oral drugs for diabetes
- anaesthetic agents used in surgery
- digoxin, a medicine used to treat heart failure
- ergot derivatives, medicines commonly used to treat migraines
- rifampicin, a medicine used to treat tuberculosis
- tricyclic antidepressants
- barbiturates, medicines used to treat epilepsy
- phenothiazines, medicines used to treat some mental conditions
- mefloquine, a medicine used to treat malaria
- adrenaline (epinephrine), a medicine used to treat allergic reactions
- certain medicines used to treat depression called monoamine oxidase inhibitors, such as phenelzine or tranylcypromine.

These medicines may be affected by BISPRO 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 BISPRO.

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

4. How do I take BISPRO?

How much to take

- The usual starting dose is 1.25 mg once daily for a week. If well tolerated, your doctor will gradually increase your dose over the next ten weeks. The usual dose for maintenance therapy is 10 mg once daily.
- If your conditions get worse or you no longer tolerate the drug, it may be necessary to reduce the dose again or to interrupt treatment. In some patients a maintenance dose lower than 10 mg may be sufficient. Your doctor will tell you what to do.
- Your doctor will monitor your blood pressure, heart rate and other vital signs carefully after you start treatment with BISPRO and during dose increase.
- Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.
- If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

When to take BISPRO

- BISPRO should be taken in the morning, with or without food.

How to take BISPRO

- Swallow the tablets whole with a glass of water.
- Do not crush or chew the tablets.

If you crush or chew BISPRO tablets, they will not work as well.

How long to take it

To properly control your condition, BISPRO must be taken every day, usually as a long-term treatment.

Continue taking BISPRO for as long as your doctor recommends.

It is very important that you do not stop taking BISPRO suddenly.

If you forget to take BISPRO

BISPRO should be taken regularly at the same time each day.

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets 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 getting an unwanted side effect.

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

If you take too much BISPRO

If you think that you or anyone else may have taken too much BISPRO, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

You may need urgent medical attention.

Symptoms of an overdose may include slowed heart rate, difficulty breathing, marked drop in blood pressure, severe heart failure, or a decrease in blood sugar.

5. What should I know while taking BISPRO?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking BISPRO.
- If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking BISPRO.
- If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking BISPRO.

- If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

BISPRO may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar, called hypoglycaemia, such as fast heartbeat. BISPRO may make hypoglycaemia last longer. Your dose of diabetic medicines, including insulin, may need to change.

- If you are to have any medical tests, tell your doctor that you are taking BISPRO. It may interfere with the results of some tests.
- Keep all your doctor's appointments so that you progress can be checked.

Your doctor may check your eyes, thyroid, lipid and blood glucose levels from time to time to make sure the medicine is working and to prevent unwanted side effects.

- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Your doctor may think it is not working effectively and change your treatment unnecessarily.

Call your doctor straight away if you:

- become pregnant while taking BISPRO.

Things you should not do

- **Do not stop taking BISPRO, or lower the dose, without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen or other heart complications may occur.

If you have to stop treatment, your doctor will usually advise you to reduce the dose gradually.

- Do not take BISPRO to treat any other complaints unless your doctor tells you to.
- Do not give BISPRO to anyone else, even if they have the same condition as you.

Driving or using machines

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

BISPRO may cause tiredness, dizziness or lightheadedness in some people, especially after the first dose. 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.

Effects of alcohol should be considered particularly at the start of treatment and upon change of medication.

Things to be careful of

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Things that would be helpful for your heart failure:

- Physical activity - regular exercise when symptoms are absent or mild helps improve heart function. Before starting any exercise, ask your doctor for advice.
- Weight reduction - your doctor may suggest losing some weight to help lessen the amount of work your heart has to do.
- Diet - eat a healthy low fat diet which includes plenty of fresh fruit and vegetables, bread, cereals and fish. Also, try to eat less fat and sugar.
- Salt restriction - too much salt can make your heart failure worse. Try to avoid using salt in cooking and at the table.

Looking after your medicine

- BISPRO 2.5 mg should be stored below 25°C.
- BISPRO 5 mg and 10 mg should be stored below 30°C.
- Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

Follow the instructions on 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.

Heat and dampness can destroy some medicines.

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 take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BISPRO.

BISPRO helps most people with heart failure, but it may have unwanted side effects in some people.

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.

Do not be alarmed by the following list of the side effects. You may not experience any of them.

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"> • tiredness, feeling weak • dizziness 	Speak to your doctor or

Less serious side effects	What to do
<ul style="list-style-type: none"> • headache • sleep disturbances, nightmares • nausea, vomiting • diarrhoea, constipation • feeling of coldness or numbness in hands or feet • allergic runny nose • hair loss • sexual problems 	pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • muscular weakness or cramps • dizziness or light-headedness (sometimes with fainting), especially on standing up, which may be due to low blood pressure • a very slow heart beat • hallucinations • depression • irritation or redness of the eye • skin reactions such as rash, flush, itching, worsening of psoriasis • difficulty hearing • fainting 	<p>Tell your doctor as soon as possible if you notice any of these serious side effects.</p> <p>Medical attention may be required.</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the face, lips, tongue, throat which may cause difficulty breathing or swallowing • signs of worsening heart failure, such as shortness of breath, sometimes with tiredness or weakness, swelling of the feet or legs due to fluid build up • chest tightness, wheezing, rattly breathing • yellowing of the skin or eyes, dark coloured urine, itching, generally feeling unwell • irregular heart beating 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>You may need urgent medical attention or hospitalisation.</p>

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.

This leaflet was prepared in July 2024.

BISPRO® is a Viatris company trade mark

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7. Product details

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

What BISPRO contains

Active ingredient (main ingredient)	bisoprolol fumarate 2.5 mg, 5 mg or 10 mg per tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• colloidal anhydrous silica• magnesium stearate• crospovidone• maize starch• microcrystalline cellulose• calcium hydrogen phosphate• dimeticone 100• macrogol 400• titanium dioxide• hypromellose• iron oxide yellow (5 mg and 10 mg only)• iron oxide red (10 mg only)
Potential allergens	sulfites

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

What BISPRO looks like

BISPRO 2.5 mg is white, heart-shaped, biconvex film-coated tablet with a dividing score on both sides. (AUST R 130178).

BISPRO 5 mg is yellowish white, heart-shaped, biconvex film-coated tablet with a dividing score on both sides. (AUST R 130180).

BISPRO 10 mg is pale orange-light orange, heart-shaped, biconvex film-coated tablet with a dividing score on both sides. (AUST R 130182).

BISPRO are available in blister packs of 28 tablets.

Some strengths or pack sizes may not be marketed.

Who distributes BISPRO

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276