

Bispro

contains the active ingredient bisoprolol fumarate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Bispro.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Bispro is used for

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.

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

Your doctor may have prescribed Bispro for another reason.

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

Bispro is available only with a doctor's prescription.

Bispro is not addictive.

Before you take Bispro

When you must not take it

Do not take Bispro if you have an allergy 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.

Do not take Bispro if 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.

Do not take Bispro if 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 pheochromocytoma, a rare tumour of the adrenal gland
- * metabolic acidosis, a condition when there is too much acid in the blood.

Do not take Bispro after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- * asthma, difficulty breathing or other lung problems
- * certain 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
- * pheochromocytoma, a rare tumour of the adrenal gland.

Tell your doctor if you are pregnant or plan 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.

Tell your doctor if you are breastfeeding or wish 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.

Tell your doctor if you are going to have anaesthesia (for example for surgery).

Bispro may influence how your body reacts to this situation.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from a 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, 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.

How to take Bispro

Follow all directions given to you by your doctor or 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.

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 gets 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.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew the tablets.

When to take it

Take Bispro in the morning, with or without food.

If you forget to take it

If 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.

How long to take it for

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 tells you.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Bispro. 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.

While you are taking Bispro

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking Bispro.

If you become pregnant while taking Bispro, tell your doctor.

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 heart beat. Bispro may make hypoglycaemia last longer. Your dose of diabetic medicines, including insulin, may need to change.

If you are about to have any medical tests, tell your doctor that you are taking Bispro.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your 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.

Things you must not do

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.

Do not stop taking Bispro or lower the dosage 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.

Things to be careful of

Be careful driving or operating machinery 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.

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.

Side effects

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

This medicine helps most people with heart failure, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * tiredness, feeling weak
- * dizziness
- * headache
- * sleep disturbances, nightmares
- * nausea, vomiting
- * diarrhoea, constipation
- * feeling of coldness or numbness in hands or feet
- * allergic runny nose
- * hair loss
- * sexual problems.

Tell your doctor as soon as possible if you notice any of the following:

- * muscular weakness or cramps
- * dizziness or lightheadedness (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.

The above list includes serious side effects that may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Bispro

Storage

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.

Keep your tablets in a cool dry place.

Bispro 2.5 mg should be stored below 25 degrees C.

Bispro 5 mg and 10 mg should be stored below 30 degrees C.

Do not store Bispro or any other

medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it 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 Bispro, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Bispro comes in 3 strengths of tablets:

- * Bispro 2.5 mg - white, heart-shaped, film-coated tablet with a dividing score on both sides.
- * Bispro 5 mg - yellowish white, heart-shaped, film-coated tablet with a dividing score on both sides.
- * Bispro 10 mg - pale orange - light orange, heart-shaped, film-coated tablet with a dividing score on both sides.

Bispro 2.5 mg, 5 mg and 10 mg come in packs of 28 tablets.

Ingredients

The active ingredient in Bispro is bisoprolol fumarate.

Each Bispro 2.5 mg tablet contains 2.5 mg of bisoprolol fumarate.

The tablets also contain:

- * silica - colloidal anhydrous
- * magnesium stearate
- * crospovidone

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- * starch - maize
- * cellulose - microcrystalline
- * calcium hydrogen phosphate anhydrous
- * dimethicone 100
- * macrogol 400
- * titanium dioxide
- * hypromellose.

Each Bispro 5 mg and 10 mg tablet contains 5 mg and 10 mg of bisoprolol fumarate respectively.

These tablets also contain:

- * silica - colloidal anhydrous
- * magnesium stearate
- * crospovidone
- * starch - maize
- * cellulose - microcrystalline
- * calcium hydrogen phosphate anhydrous
- * dimethicone 100
- * macrogol 400
- * titanium dioxide
- * hypromellose
- * iron oxide yellow (CI 77492).

Bispro 10 mg tablets also contain:

- * iron oxide red (CI 77491).

This medicine does not contain gluten.

Supplier

Bispro is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Bispro 2.5 mg - Aust R 130178

Bispro 5 mg - Aust R 130180

Bispro 10 mg - Aust R 130182

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