

Bicor

contains the active ingredient bisoprolol fumarate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Bicor.

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 Bicor against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What Bicor is used for

Bicor 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.

Bicor 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. Bicor also slows your heart rate, which in turn increases the efficiency of your heart.

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

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

Bicor is available only with a doctor's prescription.

There is no evidence that Bicor is addictive.

Before you take Bicor

When you must not take it

Do not take Bicor if you are allergic to medicines containing bisoprolol or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

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

Do not take this medicine 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.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

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

Tell your doctor if you are breastfeeding or wish to breastfeed.

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

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.

Your doctor may want to take special care if you have any of these conditions.

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

Bicor 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 Bicor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Bicor may interfere with each other.

Do not take the following medicines with Bicor 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 (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 Bicor.

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 Bicor 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 Bicor.

How to take Bicor

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 Bicor and during dose increase.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take it

Swallow the tablets with a glass of water.

Do not crush or chew the tablets.

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

When to take it

Take Bicolor 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.

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

How long to take it for

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

Keep taking Bicolor for as long as your doctor recommends.

It is very important that you do not stop taking Bicolor 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 Bicolor. 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 Bicolor

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Bicolor.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Bicolor.

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

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Bicolor.

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

Bicolor 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. Bicolor 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 Bicolor.

Bicolor may affect the results of some tests.

Visit your doctor regularly so they can check on your progress.

Your doctor may check your eyes, thyroid, lipid and blood glucose levels.

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.

Things you must not do

Do not stop taking Bicolor, or lower the dose, without checking with your doctor.

Stopping Bicolor suddenly may cause your condition to 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 use Bicolor to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how Bicolor affects you.

Bicolor may cause tiredness, dizziness or lightheadedness in some people, especially after the first dose. If any of these occur, 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.

Suggestions to help manage your condition

- * 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 Bicolor.

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

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

After taking Bicolor

Storage

Keep Bicolor 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.

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.

Bicolor 1.25 mg (Starter Pack) and 2.5 mg should be stored below 25 degrees C.

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

Do not store Bicolor or any other medicine in the bathroom or near a sink.

Do not leave Bicolor in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Bicolor, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Bicolor comes in 4 strengths of tablets:

- * Bicolor 1.25 mg (Starter Pack) - white, round film-coated tablet
- * Bicolor 2.5 mg - white, heart-shaped, film-coated tablet with a dividing score on both sides
- * Bicolor 5 mg - yellowish white, heart-shaped, film-coated tablet with a dividing score on both sides
- * Bicolor 10 mg - pale orange - light orange, heart-shaped, film-coated tablet with a dividing score on both sides

Bicolor 1.25 mg comes in pack of 10 tablets. The other packs contain 28 tablets.

Ingredients

The active ingredient in Bicolor is bisoprolol fumarate.

Each Bicolor 1.25 mg (Starter Pack) tablet contains 1.25 mg of bisoprolol fumarate.

The tablets also contain:

- * colloidal anhydrous silica
- * magnesium stearate
- * crospovidone
- * pregelatinised maize starch
- * maize starch
- * microcrystalline cellulose
- * anhydrous calcium hydrogen phosphate
- * dimethicone 100
- * purified talc
- * macrogol 400
- * titanium dioxide
- * hypromellose.

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

The tablets also contain:

- * colloidal anhydrous silica
- * magnesium stearate
- * crospovidone
- * maize starch
- * microcrystalline cellulose
- * anhydrous calcium hydrogen phosphate
- * dimethicone 100
- * macrogol 400
- * titanium dioxide
- * hypromellose.

Each Bicor 5 mg and 10 mg tablet contains 5 mg and 10 mg bisoprolol fumarate respectively.

These tablets also contain:

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

Bicor 10 mg tablets also contain:

- * iron oxide red (CI 77491).

The tablets are gluten free.

Supplier

Bicor is supplied by:
Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
Phone: (02) 9298 3999

Medical Information
Phone: 1800 028 365

www.alphapharm.com.au

Australian registration numbers:

Bicor 1.25 mg (Starter Pack)- Aust R 81603

Bicor 2.5 mg - Aust R 81604

Bicor 5 mg - Aust R 81606

Bicor 10 mg - Aust R 81608

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