

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

ADCO BISOCOR 5 mg film-coated tablets
ADCO BISOCOR 10 mg film-coated tablets

ADCO BISOCOR 5 mg: Each film-coated tablet contains 5 mg bisoprolol hemifumarate equivalent to 4,24 mg of bisoprolol.
Sugar free.

ADCO BISOCOR 10 mg: Each film-coated tablet contains 10 mg bisoprolol hemifumarate equivalent to 8,49 mg of bisoprolol.
Sugar free.

Read all of this leaflet carefully before you start taking ADCO BISOCOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- ADCO BISOCOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ADCO BISOCOR is and what it is used for
2. What you need to know before you take ADCO BISOCOR
3. How to take ADCO BISOCOR
4. Possible side effects
5. How to store ADCO BISOCOR
6. Contents of the pack and other information

1. What ADCO BISOCOR is and what it is used for

ADCO BISOCOR contains the active substances bisoprolol. Bisoprolol belongs to a group of medicines called beta-blockers.

ADCO BISOCOR is indicated for the management of mild to moderate hypertension and angina pectoris.

2. What you need to know before you take ADCO BISOCOR

Do not take ADCO BISOCOR:

- If you are allergic to bisoprolol or any of the other ingredients of ADCO BISOCOR (listed in section 6).
- If you have severe asthma.
- If you have severe blood circulation problem in limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.

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- If you have untreated phaeochromocytoma, which is a rare tumour of the adrenal gland (medulla).
- If you have metabolic acidosis, which is a condition when there is too much acid in the blood.
- If you have heart failure.
- If you have certain heart condition (sinoarterial block) causing a very slow heart rate or irregular heartbeat.
- If you have cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.
- You have been diagnosed with a condition known as sick sinus syndrome (a group of abnormal heart rhythms presumably caused by a malfunction of the heart's primary pacemaker).
- If you are pregnant.
- If you suffer from a condition marked by excessive production of thyroid hormones.

Warnings and precautions

- Do not stop ADCO BISOCOR therapy abruptly, especially if you have coronary heart disease as this may lead to transitional worsening of your heart condition.
- If you are due to receive an anaesthetic e.g., before an operation; you should inform the hospital doctor that you are taking ADCO BISOCOR. This medicine may influence how your body react to this situation.
- If you suffer from an irregular heartbeat, you experience sudden onset of chest pain, or if you already suffer from a mild form of angina or Prinzmetal's angina.
- If you have any heart problems or first degree heart block (a condition in which nerve signals to the heart are disturbed, possibly causing it occasionally to skip a beat, or beat irregularly).
- If you have liver or kidney problems.
- If you are using medicines (verapamil or diltiazem) to treat an irregular heartbeat.
- If you suffer from diabetes mellitus (low blood sugar levels may be masked by this medicine).
- If you suffer from phaeochromocytoma (marked by high blood pressure, raised heart rate and headache); this condition should be treated first, prior to taking ADCO BISOCOR.
- If you are using a medicine that contains clonidine (used to treat high blood pressure).
- If you suffer from or have suffered from psoriasis (marked by severe skin rashes).
- If you are fasting.
- If you have a thyroid disorder. The tablets can hide symptoms of an overactive thyroid.
- If you have chronic lung disease or asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using ADCO BISOCOR.
- If you are treated for hypersensitivity (allergic) reactions. Bisoprolol may make your allergy worse or often difficult to treat.

Children and adolescents

- Safety and efficacy of ADCO BISOCOR have not been established in children.

Other medicines and ADCO BISOCOR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ADCO BISOCOR with these medicines may cause undesirable interactions. Such medicines include:

- Medicines that lower blood glucose.
- Medicines used for emotional or psychiatric conditions e.g. phenothiazines.
- Medicines that correct the rhythm of your heart.
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (known as Calcium antagonists of the verapamil type).
- Certain medicines used to treat high blood pressure such as clonidine, methyldopa etc. However, do not stop taking these without checking with your doctor first.
- Certain medicines used to treat irregular or abnormal heartbeat. Medicines such as quinidine, disopyramide, lidocaine, phenytoin, flecainides propafenone, amiodarone.
- Certain medicines used to treat high blood pressure or angina pectoris (known as Calcium antagonists of the dihydropyridine type (e.g. nifedipine).
- Parasympathomimetics medicines such as acetylcholine, methacholine, carbachol.
- Topical application of beta-blockers such as eye drops for treatment of glaucoma.
- Insulin and oral medication used to treat diabetes
- Anaesthetic agents, (for example during surgery)
- Digoxin used to treat heart failure.
- Non-steroidal anti-inflammatory medicines, used to treat arthritis, pain or inflammation.
- Medicines used to treat acute heart problems (such as isoprenaline, dobutamine) may antagonise the effects of ADCO BISOCOR.
- Sympathomimetics such as epinephrine and norepinephrine which are used in the treatment of heart attack and low blood pressure. Epinephrine is also used to treat allergic reactions. Higher doses of adrenaline may be necessary for treatment of allergic reactions if ADCO BISOCOR is taken at the same time.
- Any medicine, which can lower blood pressure as a desired or undesired effect such as antihypertensives, certain medicines for depression (tricyclic antidepressants), certain medicines used to treat epilepsy or during anaesthesia (barbiturates), or certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines).
- Mefloquine, used for prevention or treatment of malaria.
- Depression treatment medicines called monoamine oxidase inhibitors.
- Rifampicin, an antibiotic used to treat infections, including tuberculosis (TB).
- Ergotamine derivatives used in the acute treatment of migraine headaches.

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- Using certain medicines (such as reserpine or guanethidine) causing high blood pressure together with ADCO BISOCOR may cause life-threatening vasoconstriction (constricting of the blood vessels).

ADCO BISOCOR with food, drink and alcohol

ADCO BISOCOR may be taken with or without food but must be taken in the morning.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ADCO BISOCOR.

ADCO BISOCOR is not recommended during pregnancy and breastfeeding.

Driving and using machines

Bisoprolol may cause dizziness or fatigue (see section 4) and, therefore, may adversely affect your ability to drive or use machinery. It is not always possible to predict to what extent ADCO BISOCOR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ADCO BISOCOR] affects them.

3. How to take ADCO BISOCOR

Do not share medicines prescribed for you with any other person.

Always take ADCO BISOCOR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: 5 to 10 mg once a day in the morning with or without food.

The dose must be individualised according to response and tolerance. Your doctor will decide how to increase the dose.

The maximum recommended daily dose is 20 mg.

Severe renal impairment (creatinine clearance < 30 ml/min) or severe hepatic impairment:

Do not exceed the daily dose of 10 mg.

Elderly: No dose adjustment is required in these patients.

Paediatric population

There is no therapeutic experience with ADCO BISOCOR in children. Its use in children is therefore not recommended.

If you take more ADCO BISOCOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you have taken too much ADCO BISOCOR you may experience the following: a slowed heart rate, severe difficulty in breathing, wheezing, feeling dizzy, fatigue or trembling (due to decreased blood sugar which may involve feelings of hunger, sweating and palpitations). Heart problems, coma and convulsions have also been reported.

If you forget to take ADCO BISOCOR

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

If you stop taking ADCO BISOCOR

ADCO BISOCOR therapy should not be stopped abruptly.

If you have to stop ADCO BISOCOR treatment early, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

4. Possible side effects

ADCO BISOCOR can cause side effects

Not all side effects reported for ADCO BISOCOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO BISOCOR, please consult your doctor, pharmacist or health care professional for advice.

If any of the following happen, stop taking ADCO BISOCOR and tell your doctor immediately or go to the causality department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- a rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ADCO BISOCOR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the causality department at your nearest hospital if you notice any of the following:

- Slow pulse rate, irregular heartbeats or changes to your heart rate which may cause dizziness and weakness. Heart muscle cannot pump blood leads to heart failure.
- Worsening of heart failure which can cause a persistent chesty cough due to a build-up of fluid on the lungs.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Drowsiness, unusual tiredness or weakness.
- Feeling of coldness or numbness in hands or feet.
- Low blood pressure (you may feel light-headed).

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- Headache, dizziness and extreme tiredness (these may be mild especially at the beginning of therapy and may often disappear within 1-2 weeks).
- Nausea, vomiting, diarrhoea, constipation.
- Decreased sexual ability.
- Lack of energy

Less frequent side effects

- Confusion, hallucinations, depression, trouble sleeping, nightmares and vivid dreams, anxiety, memory loss and nervousness.
- Allergic runny nose, sneezing and itching, nasal congestion, breathing problems in patients with asthma, chronic lung disease or other problems of the airways.
- Dry, sore eyes, irritation and redness of the eye (conjunctivitis).
- Reduced tear flow which may lead to problems if you wear contact lenses.
- Skin rash, itching of the skin, swelling under skin (angioedema), appearance or worsening of scaly skin rash (psoriasis).
- Hair-loss (which will grow back after treatment with ADCO BISOCOR is stopped).
- Back pain, joint pain or chest pain, muscle cramps, skeletal muscle disorders, muscle weakness.
- Dizziness on standing, fainting, pins-and-needles sensation.
- Hearing problems.
- Inflammation of the liver which can cause yellowing of the skin or the whites of the eyes and skin and dark urine, toxic liver disease.
- Impaired erection.
- A decrease in the number of white blood cells
- Certain blood test results for liver function or fat levels differing from normal.
- Raynaud's syndrome (a condition where the blood supply to the tips of the fingers or toes may become restricted so as to cause tissue damage).
- Blue fingers and toes.
- Lack of energy (Asthenia).
- Build-up of fluid in body tissue (swelling).

Unknown frequency side effects

- Systemic Lupus Erythematosus (also known as 'lupus' or 'SLE') a disease characterised by inflammation and damage to various body tissues.
- Restlessness, loss of contact with reality.
- Excessive fibrous tissue forms in the area behind the stomach and intestine leading to block the tubes that carry urine from kidney to bladder. Inflammation in lining of abdomen causing pain and intestinal obstruction.
- Stomach cramps, dry mouth, weight gain, inflammation of the mouth or lips.
- Heart block (due to electrical signals intermittently fail to conduct)
- Sweating, itching of skin.

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- Inflammation, excessive fibrous connective tissue or fluid in the lungs leading to breathing difficulties or a sharp stabbing pain in the chest.
- Problem in vision (eyes)
- Temporary loss of hearing

Side effects are more common in patients with kidney problems.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO BISOCOR.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store ADCO BISOCOR

Store all medicines out of the reach of children.

Store in the original package at or below 25 °C in a dry place.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What ADCO BISOCOR contains

The active ingredient is bisoprolol fumarate

The other ingredients are:

ADCO BISOCOR 5 mg and 10 mg:

Tablet core: Calcium hydrogen phosphate, colloidal anhydrous silica, crospovidone, magnesium stearate, microcrystalline cellulose, pregelatinised starch.

Tablet coating: Hydroxypropyl methylcellulose, iron oxide red (E 172), iron oxide yellow (E 172), polyethylene glycol 400, and titanium dioxide (E171).

What ADCO BISOCOR looks like and contents of the pack

ADCO BISOCOR 5 mg film coated tablets are light pink, round, biconvex film-coated tablets. The tablets are embossed with “BSL 5” on one side and scored on both sides.

ADCO BISOCOR 10 mg film coated tablets are yellow to orange, round, biconvex film-coated tablets. The tablets are embossed with “BSL 10” on one side and scored on both sides.

ADCO BISOCOR is available in Carton boxes of PVC/PE/PVDC/Al blisters either with or without aluminium sachets containing 14, 28, 30, 50, 56 or 100 tablets.

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HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685,
Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

11 September 2025

REGISTRATION NUMBER (S):

ADCO BISOCOR 5 mg: 37/5.2/0010

ADCO BISOCOR 10 mg: 37/5.2/0011

Botswana		
	Product name	Registration number
	ADCO BISOCOR 5 mg	BOT1202249A/B/C/D/E/F
	ADCO BISOCOR 10 mg	BOT1202248A/B/C/D/E/F
Namibia		
	ADCO BISOCOR 5 mg	06/5.2/0014
	ADCO BISOCOR 10 mg	06/5.2/0015