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.

- 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 mediation 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.

- 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 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 hospitilisation.

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).

- 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.

- 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 debossed 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 debossed with “BSL 10” on one side and scored on both sides.

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

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

16 January 2025

REGISTRATION NUMBER (S):

ADCO BISOCOR 5 mg: 37/5.2/0010
ADCO BISOCOR 10 mg: 37/5.2/0011

Botswana		
	Product names	**Registration numbers**
	ADCO BISOCOR 5 mg	BOT1202249A/B/C/D/E/F
	ADCO BISOCOR 10 mg	BOT1202247A & BOT1202248B/C/D/E/F
Namibia		
	ADCO BISOCOR 5 mg	06/5.2/0014
	ADCO BISOCOR 10 mg	06/5.2/0015

PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: **S3**

ADCO BISOCOR 5 mg filmbedekte tablette
ADCO BISOCOR 10 mg filmbedekte tablette

ADCO BISOCOR 5 mg: Elke filmbedekte tablet bevat 5 mg bisoprololhemifumaraat gelykstaande aan 4,24 mg bisoprolol.
Suikervry.

ADCO BISOCOR 10 mg: Elke filmbedekte tablet bevat 10 mg bisoprololhemifumaraat gelykstaande aan 8,49 mg bisoprolol.
Suikervry.

Lees hierdie hele biljet noukeurig deur voordat u ADCO BISOCOR begin neem
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- ADCO BISOCOR is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat in hierdie biljet is

1. Wat ADCO BISOCOR is en waarvoor dit gebruik word
2. Wat u moet weet voordat u ADCO BISOCOR neem
3. Hoe om ADCO BISOCOR te neem
4. Moontlike newe-effekte
5. Hoe om ADCO BISOCOR te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat ADCO BISOCOR is en waarvoor dit gebruik word
ADCO BISOCOR bevat die aktiewe bestanddeel bisoprolol. Bisoprolol behoort tot 'n groep medisyne wat betablokkers genoem word.
ADCO BISOCOR is aangedui vir die hantering van ligte tot matige hipertensie en angina pectoris.

2. Wat u moet weet voordat u ADCO BISOCOR neem
Moenie ADCO BISOCOR neem nie:
- Indien u allergies is vir bisoprolol of enige van die ander bestanddele van ADCO BISOCOR (gelys in afdeling 6).
- Indien u ernstige asma het.
- Indien u ernstige bloedsomloop-probleme in ledemate het (soos Raynaud se sindroom), wat u vingers en tone kan laat prikkel of bleek of blou word.

- Indien u onbehandelde feochromositoom het, wat 'n seldsame gewas van die byniere (medulla) is.
- Indien u metaboliese asidose het, wat 'n toestand is wanneer daar te veel suur in die bloed is.
- Indien u hartversaking het.
- Indien u ‘n sekere harttoestand (sino-arteriële blok) het, wat 'n baie stadige hartklop of onreëlmatige hartklop veroorsaak.
- Indien u kardiogene skok het, wat 'n akute ernstige harttoestand is wat lae bloeddruk en bloedsomloopversaking veroorsaak.
- U gediagnoseer is met 'n toestand bekend as siek sinussindroom ('n groep abnormale hartritmes wat vermoedelik veroorsaak word deur wanfunksionering van die hart se primêre pasaangeër).
- Indien u swanger is.
- Indien u ly aan 'n toestand wat gekenmerk word deur oormatige produksie van tiroïedhormone.

Waarskuwings en voorsorgmaatreëls

- Moenie ADCO BISOCOR terapie skielik stop nie, veral indien u koronêre hartsiektes het, aangesien dit kan lei tot oorgangsverergering van u harttoestand.
- Indien u 'n narkose moet ontvang, bv. voor 'n operasie; u moet die hospitaaldokter inlig dat u ADCO BISOCOR neem. Hierdie medisyne kan beïnvloed hoe u liggaam op hierdie situasie reageer.
- Indien u aan 'n onreëlmatige hartklop ly, u skielike aanvang van borspyn ervaar, of indien u reeds aan 'n ligte vorm van angina of Prinzmetal se angina ly.
- Indien u enige hartprobleme of eerstegraadse hartblok het ('n toestand waarin senuweeseine na die hart versteur word, wat moontlik veroorsaak dat dit af en toe 'n slag oorslaan, of onreëlmatig klop).
- Indien u lewer- of nierprobleme het.
- Indien u medisyne gebruik (verapamiel of diltiasem) om 'n onreëlmatige hartklop te behandel.
- Indien u aan diabetes mellitus ly (lae bloedsuikervlakke kan deur hierdie medisyne verdoesel word).
- Indien u aan feochromositoom ly (gekenmerk deur hoë bloeddruk, verhoogde hartspoed en hoofpyn); hierdie toestand moet eers behandel word voordat ADCO BISOCOR geneem word.
- Indien u 'n medisyne gebruik wat klonidien bevat (wat gebruik word om hoë bloeddruk te behandel).
- Indien u aan psoriase ly of gely het (gekenmerk deur ernstige veluitslag).
- Indien u vas.
- Indien u 'n skildklierversteuring het. Die tablette kan simptome van 'n ooraktiewe skildklier verberg.

- Indien u chroniese longsiekte of asma het, stel asseblief u dokter dadelik in kennis indien u nuwe probleme met asemhaling ervaar, hoes, hyg na oefening, ens., terwyl u ADCO BISOCOR neem
- Indien u behandel word vir hipersensitiwiteit (allergiese) reaksies. Bisoprolol kan u allergie erger of dikwels moeilik maak om te behandel.

Kinders en adolessente
- Veiligheid en doeltreffendheid van ADCO BISOCOR is nie by kinders vasgestel nie.

Ander medisyne en ADCO BISOCOR
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Indien u ander medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne, kan die gebruik van ADCO BISOCOR met hierdie medisyne ongewenste interaksies veroorsaak. Sulke medisyne sluit in:
- Medisyne wat bloedglukose verlaag.
- Medisyne wat gebruik word vir emosionele of psigiatriese toestande, bv. fenotiasiene
- Medisyne wat die ritme van u hart regstel.
- Sekere medisyne wat gebruik word om hoë bloeddruk, angina pectoris of onreëlmatige hartklop te behandel (bekend as kalsium-antagoniste van die verapamiel-tipe).
- Sekere medisyne wat gebruik word om hoë bloeddruk te behandel, soos klonidien, metieldopa, ens. Moet egter nie ophou om dit te neem sonder om eers u dokter te raadpleeg nie.
- Sekere medisyne wat gebruik word om onreëlmatige of abnormale hartklop te behandel. Medisyne soos kinidien, disopiramied, lidokaïen, fenitoïen, flekaïniede, propafenoon, amiodaroon.
- Sekere medisyne wat gebruik word om hoë bloeddruk of angina pectoris te behandel (bekend as kalsium-antagoniste van die dihidropiridien-tipe (bv. nifedipien)).
- Parasimpatomimetiese medisyne soos asetielcholien, metacholien, karbachol.
- Topikale toediening van betablokkers soos oogdruppels vir die behandeling van gloukoom.
- Insulien en mondelikse medikasie gebruik om diabetes te behandel.
- Narkosemiddels (byvoorbeeld tydens chirurgie).
- Digoksien gebruik om hartversaking te behandel.
- Nie-steroïed anti-inflammatoriese medisyne, wat gebruik word om artritis, pyn of inflammasie te behandel.
- Medisyne wat gebruik word om akute hartprobleme te behandel (soos isoprenalien, dobutamien) kan die effekte van ADCO BISOCOR antagoniseer.
- Simpatomimetika soos epinefrien en norepinefrien wat gebruik word in die behandeling van hartaanval en lae bloeddruk. Epinefrien word ook gebruik om allergiese reaksies te behandel. Hoër dosisse adrenalien kan nodig wees vir die behandeling van allergiese reaksies indien ADCO BISOCOR terselfdertyd geneem word.

- Enige medisyne wat bloeddruk kan verlaag as 'n gewenste of ongewenste effek, soos antihipertensiewe middels, sekere medisyne vir depressie (trisikliese antidepressante), sekere medisyne wat gebruik word om epilepsie te behandel of tydens narkose (barbiturate), of sekere medisyne vir die behandeling van geestesongesteldheid wat gekenmerk word deur 'n verlies aan kontak met die werklikheid (fenotiasiene).
- Meflokien, wat gebruik word vir die voorkoming of behandeling van malaria.
- Depressie-behandeling medisyne genoem monoamienoksidase remmers.
- Rifampisien, 'n antibiotikum wat gebruik word om infeksies te behandel, insluitend tuberkulose (TB).
- Ergotamienderivate wat gebruik word in die akute behandeling van migraine-hoofpyn.
- Die gebruik van sekere medisyne (soos reserpien of guanetidien) wat hoë bloeddruk saam met ADCO BISOCOR veroorsaak, kan lewensgevaarlike vasokonstriksie (vernouing van die bloedvate) veroorsaak.

ADCO BISOCOR saam met kos, drank en alkohol
ADCO BISOCOR kan met of sonder kos geneem word, maar moet soggens geneem word.

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u ADCO BISOCOR neem.
ADCO BISOCOR word nie aanbeveel tydens swangerskap en borsvoeding nie.

Bestuur en gebruik van masjinerie
Bisoprolol kan duiseligheid of moegheid veroorsaak (sien afdeling 4) en kan dus u vermoë om te bestuur of masjinerie te gebruik nadelig beïnvloed.
Dit is nie altyd moontlik om te voorspel in watter mate ADCO BISOCOR die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle bewus is van die mate waartoe ADCO BISOCOR hulle raak nie.

3. Hoe om ADCO BISOCOR te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd ADCO BISOCOR presies soos u dokter u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Die algemene dosis is:
Volwassenes: 5 tot 10 mg een keer per dag in die oggend met of sonder kos.
Die dosis moet geïndividualiseer word volgens reaksie en verdraagsaamheid. U dokter sal besluit hoe om die dosis te verhoog.
Die maksimum aanbevole daaglikse dosis is 20 mg.

Ernstige nierinkorting (kreatinienopruiming < 30 ml/min) of ernstige lewerinkorting:

Moenie die daaglikse dosis van 10 mg oorskry nie.

Bejaardes: Geen dosisaanpassing is nodig by hierdie pasiënte nie.

Pediatriese bevolking
Daar is geen terapeutiese ervaring met ADCO BISOCOR by kinders nie. Die gebruik daarvan by kinders word dus nie aanbeveel nie.

Indien u meer ADCO BISOCOR neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.
Indien u te veel ADCO BISOCOR geneem het, kan u die volgende ervaar: 'n vertraagde hartklop, ernstige asemhalingsprobleme, hygende asemhaling, voel duiselig, moegheid of bewing (as gevolg van verlaagde bloedsuiker wat gevoelens van honger, sweet en hartkloppings kan behels). Hartprobleme, koma en stuiptrekkings is ook aangemeld.

Indien u vergeet om ADCO BISOCOR te neem
Moenie 'n dubbele dosis neem om op te maak vir 'n vergete dosis nie. Indien u vergeet om 'n dosis te neem, neem dit sodra u dit onthou en neem dan die volgende dosis op die regte tyd.

Indien u ophou om ADCO BISOCOR te neem
Behandeling met ADCO BISOCOR moet nie skielik gestaak word nie.
Indien u behandeling met ADCO BISOCOR vroegtydig moet stop, sal u dokter u gewoonlik aanraai om die dosis geleidelik te verminder, aangesien u toestand andersins kan vererger.

4. Moontlike newe-effekte
ADCO BISOCOR kan newe-effekte veroorsaak
Nie alle newe-effekte wat vir ADCO BISOCOR aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u ADCO BISOCOR neem, raadpleeg asseblief u dokter, apteker of gesondheidswerker vir advies.

Indien enige van die volgende gebeur, hou op om ADCO BISOCOR te neem en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme kan veroorsaak om te sluk of asem te haal
- 'n veluitslag of jeuk

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op ADCO BISOCOR gehad. U sal dalk dringende mediese hulp of hospitalisering benodig.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- Stadige polsslag, onreëlmatige hartklop of veranderinge aan u hartklop wat duiseligheid en swakheid kan veroorsaak. Hartspier wat nie bloed kan pomp nie, lei tot hartversaking.
- Verergering van hartversaking wat 'n aanhoudende aamborstige hoes kan veroorsaak as gevolg van 'n opbou van vloeistof op die longe.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Gereelde newe-effekte

- Slaperigheid, ongewone moegheid of swakheid.
- Gevoel van koue of gevoelloosheid in hande of voete.
- Lae bloeddruk (u kan lighoofdig voel).
- Hoofpyn, duiseligheid en uiterste moegheid (dit kan veral aan die begin van die terapie minder ernstig wees en kan dikwels binne 1-2 weke verdwyn).
- Naarheid, braking, diarree, hardlywigheid.
- Verminderde seksuele vermoë.
- Gebrek aan energie

Minder gereelde newe-effekte

- Verwarring, hallusinasies, depressie, slaapprobleme, nagmerries en helder drome, angs, geheueverlies en senuweeagtigheid.
- Allergiese loopneus, nies en jeukerigheid, neusverstopping, asemhalingsprobleme by pasiënte met asma, chroniese longsiekte of ander probleme van die lugweë.
- Droë, seer oë, irritasie en rooiheid van die oog (konjunktivitis).
- Verminderde traanvloei wat tot probleme kan lei indien u kontaklense dra.
- Veluitslag, jeukerigheid van die vel, swelling onder die vel (angio-edeem), voorkoms of verergering van skubberige veluitslag (psoriase).
- Haarverlies (wat sal teruggroei na behandeling met ADCO BISOCOR gestaak word).
- Rugpyn, gewrigspyn of borspyn, spierkrampe, skeletspierafwykings, spierswakheid.
- Duiseligheid wanneer u opstaan, floute, naalde-en-spelde sensasie.
- Gehoorprobleme.
- Inflammasie van die lewer wat vergeling van die vel of die wit van die oë en vel en donker urien kan veroorsaak; vergiftigde lewersiekte.
- Ingeperkte ereksie.
- 'n Afname in die aantal witbloedselle
- Sekere bloedtoetsresultate vir lewerfunksie of vetvlakke verskil van normaal.
- Raynaud se sindroom ('n toestand waar die bloedtoevoer na die punte van die vingers of tone beperk kan word en so weefselskade veroorsaak).
- Blou vingers en tone.
- Gebrek aan energie (Astenie).
- Opbou van vloeistof in liggaamsweefsel (swelling).

Newe-effekte met onbekende frekwensie

- Sistemiese Eritematose Lupus (ook bekend as 'lupus' of 'SLE'), 'n siekte wat gekenmerk word deur inflammasie en skade aan verskeie liggaamsweefsels.
- Rusteloosheid, verlies aan kontak met die werklikheid.
- Oormatige veselagtige weefsel vorm in die area agter die maag en ingewande wat lei tot die blokkering van die buise wat urien van die nier na die blaas vervoer. Inflammasie in die voering van die buik wat pyn en dermobstruksie veroorsaak.
- Maagkrampe, droë mond, gewigstoename, inflammasie van die mond of lippe.
- Hartblok (as gevolg van elektriese seine wat af en toe versuim om te gelei)
- Sweet, jeukerigheid van die vel.
- Inflammasie, oormatige veselagtige bindweefsel of vloeistof in die longe wat lei tot asemhalingsprobleme of 'n skerp steekpyn in die bors.
- Probleem in visie (oë)
- Tydelike gehoorverlies

Newe-effekte kom meer voor by pasiënte met nierprobleme.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie biljet gelys word nie. U kan ook newe-effekte by die SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op die SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ADCO BISOCOR te verskaf.
Vir die aanmelding van newe-effekte direk aan die HSR, kontak +27 11 635 0134 of e-pos Adcock.aereports@adcock.com.

5. Hoe om ADCO BISOCOR te bêre
Bêre alle medisyne buite die bereik van kinders.
Bêre in die oorspronklike verpakking teen of benede 25 °C op 'n droë plek.
Moenie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie

6. Inhoud van die verpakking en ander inligting
Wat ADCO BISOCOR bevat
Die aktiewe bestanddeel is bisoprololfumaraat

Die ander bestanddele is:
ADCO BISOCOR 5 mg en 10 mg:

Tabletkern: Kalsiumwaterstoffosfaat, kolloïdale watervrye silika, kruispovidoon, magnesiumstearaat, mikrokristallyne sellulose, voorgegelatiniseerde stysel.
Tabletbedekking: Hidroksipropielmetielsellulose, ysteroksied-rooi (E 172), ysteroksied-geel (E 172), poliëtileenglikol 400 en titaandioksied (E 171).

Hoe ADCO BISOCOR lyk en die inhoud van die verpakking
ADCO BISOCOR 5 mg filmbedekte tablette is ligpienk, ronde, bikonvekse filmbedekte tablette. Die tablette is aan die een kant met "BSL 5" gegraveer en aan beide kante gekeep.
ADCO BISOCOR 10 mg filmbedekte tablette is geel tot oranje, ronde, bikonvekse filmbedekte tablette. Die tablette is aan die een kant met "BSL 10" gegraveer en aan beide kante gekeep.
ADCO BISOCOR is beskikbaar in kartonboksies met PVC/PE/PVDC/Al-stulpstroke, hetsy met of sonder aluminiumsakkies wat 14, 28, 30, 50, 56 of 100 tablette bevat.

HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
Adcock Ingram Limited
New Road 1
Erand Gardens
Midrand, 1685,
Kliëntediens: 0860 ADCOCK / 232625

Hierdie biljet is mees onlangs hersien op
16 Januarie 2025

REGISTRASIENOMMER(S):
ADCO BISOCOR 5 mg: 37/5.2/0010
ADCO BISOCOR 10 mg: 37/5.2/0011

Botswana		
	Produkname	**Registrasienommers**
	ADCO BISOCOR 5 mg	BOT1202249A/B/C/D/E/F
	ADCO BISOCOR 10 mg	BOT1202247A & BOT1202248B/C/D/E/F
Namibië		
	ADCO BISOCOR 5 mg	06/5.2/0014
	ADCO BISOCOR 10 mg	06/5.2/0015

adcock ingram

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