

CONCOR AM TABLET

bisoprolol fumarate, amlodipine besilate (5mg/5mg, 5mg/10mg)

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What Concor AM is used for

Concor AM is used to treat high blood pressure.

How Concor AM works

The active substances in Concor AM are bisoprolol and amlodipine. Bisoprolol 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, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

Amlodipine prevents an inflow of calcium ions into heart. It also widens and reduces blockage of blood vessels around the heart. Thus, it does not cause abnormal rapid heart rate, myocardial energy consumption and oxygen requirement will be reduced.

Concor AM increases the antihypertensive and anti-anginal efficacy by decreasing peripheral blockage and cardiac output.

Before you use Concor AM

- When you must not take it

Do not take Concor AM if one of the following conditions applies to you:

- allergy (hypersensitivity) to bisoprolol, amlodipine or to any of the other ingredients

Severe hypotension which systolic blood pressure < 100mmHg

- severe asthma or severe chronic obstructive airway 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, which is a rare tumour of the adrenal gland
- metabolic acidosis, which is a condition when there is too much acid in the blood.

Do not take Concor AM if you have one of the following heart problems:

- acute heart failure, that is not controlled medically
- worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart
- slow heart rate that causes problems
- low blood pressure that causes problems
- certain heart conditions causing a very slow heart rate or irregular heart beat (second or third-degree AV-block, sinoatrial block, sick sinus syndrome)
- cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.

- Before you start to take it

If you have any of the following conditions tell your doctor before taking Concor AM; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- diabetes mellitus
- deficiency of glucose in bloodstream which lead to abnormal rapid heart rate, irregular heartbeat or sweating
- strict fasting
- certain heart diseases (such as disturbances in heart rhythm or Prinzmetal's angina)
- kidney or liver problems
- less severe blood circulation problems in your limbs

- less severe chronic bronchial diseases (asthma or chronic obstructive airway disease)
- history of a scaly skin rash (psoriasis)
- tumour of the adrenal gland (phaeochromocytoma)
- thyroid disorder.

In addition, tell your doctor if you are going to have:

- desensitization therapy (for example for the prevention of hay fever), because Concor AM may make it more likely that you experience an allergic reaction, or such reaction may be more severe
- anaesthesia (for example for surgery), because Concor AM may influence how your body reacts to this situation.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- Class I antiarrhythmic medicines (such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone). These medicines are used to treat irregular or abnormal heartbeat
- Certain calcium antagonists used to treat high blood pressure, angina pectoris or irregular heart beat such as verapamil and diltiazem
- Certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonidine, rilmenidine.

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

Check with your doctor before taking the following medicines with Concor AM; your doctor may need to check your condition more frequently:

- Tacrolimus is an immunosuppressive drug used to lower risk of organ rejection after allogeneic organ transplant
- Cyclosporine levels should be monitored in renal transplant patients on amlodipine
- Simvastatin is a lipid lowering drug and dose of statin needs to be limited with amlodipine
- Certain calcium antagonists used to treat high blood pressure or angina pectoris such as nifedipine (dihydropyridine type antagonists)
- Class III antiarrhythmic medicines (such as amiodarone). These medicines are used to treat irregular or abnormal heartbeat
- Beta-blockers applied locally (such as eye drops for glaucoma treatment)
- Nervous system medicines which are used to stimulate the inner organs or to treat glaucoma (parasympathomimetics) or are used in emergency settings to treat severe circulatory conditions (sympathomimetics)
- Antidiabetic medicines including insulin
- Anaesthetic agents (for example during surgery)
- Digitalis, used to treat heart failure
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac)
- Any medicine, which can lower blood pressure as a desired or undesired effect (such as tricyclic antidepressants, barbiturates, phenothiazines)
- Mefloquine, used for prevention or treatment of malaria

How to take Concor AM

- How much to take

Recommended daily dose is one tablet Concor AM 5/5mg or 5/10mg

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

Patients with liver disorder
Exact dosage recommendations of amlodipine have not been established, however, daily dose of bisoprolol must not be exceeded 10mg

Patients with kidney disorder
No dosage adjustment is required for mild to moderate kidney failure. The daily dose of bisoprolol must not be exceeded 10mg for severe kidney failure (creatinin clearance < 20ml/min)

Treatment with Concor AM requires regular monitoring by your doctor.

Depending on how well you tolerate the medicine, your doctor may also decide to lengthen the time between dose increases. If your condition gets worse or you no longer tolerate the drug, it may be necessary to reduce the dose again or to interrupt treatment.

Your doctor will tell you what to do.

Elderly: No dose adjustment is required in the elderly
Paediatric: The safety and efficacy of Concor AM in children and adolescents below the age of 18 years have not been established.

- When to take it

Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet.

- How long to take it

Treatment with Concor AM is usually long-term.

- If you forget to take it

Do not take a double dose to make up for a forgotten dose. Take your usual dose the next morning.

- If you take too much (overdose)

If you have taken more Concor AM tablets than you should, tell your doctor immediately. Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake. Your doctor will decide what measures are necessary. Symptoms of an overdose may include slowed heart rate (bradycardia), acute narrowing of the airways leading to difficulty in breathing (bronchospasm), excessive relaxation blood vessels, increased heart rate (tachycardia), marked drop in blood pressure, acute heart failure, or a decrease in blood sugar.

Never stop taking Concor AM unless on your doctor's advice. Otherwise your condition could become much worse. If you have to stop treatment, your doctor will usually advise you to reduce the dose gradually.

If you have any further questions on the use of this product, ask your doctor or pharmacist

While you are using it

- Things you must do

If you are pregnant or planning to become pregnant, tell your doctor. He or she will decide whether you can take Concor AM during pregnancy. However, Concor AM is not recommended during pregnancy unless clearly necessary. It is not known whether bisoprolol passes into human breast milk. Amlodipine passes into breast milk. Therefore, breastfeeding is not recommended during therapy with Concor AM.

- Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to. Do not give this medicine to anyone else, even if they have the same condition as you. Do not stop taking Concor AM or change the dosage, without checking with your doctor.

- Things to be careful of

Your ability to drive or use machines may be affected depending on your tolerance to the medication. Please be careful, especially at the beginning of treatment, when the dose is increased or when the drug is changed or when taken with alcohol.

Side effects

Like all medicines, Concor AM can cause side effects, although not everybody gets them. These side effects are listed below according to how frequently they may occur:

Common (affects less than 1 person in 10):

- dizziness, headache, drowsiness
- conscious awareness of rapid or irregular heartbeat (palpitations)
- feeling of coldness and numbness in hands or feet

- intestinal problems such as nausea, vomiting, diarrhea, constipation, stomachache
 - Oedema, fatigue
- Uncommon (affects less than 1 person in 100):
- insomnia, mood changes, depression, sleeping disorder
 - decreased stimuli of senses, distortion of sense of taste, tremor
 - visual disturbance including double vision
 - noise or ringing in ears (tinnitus)
 - slow heart beat (bradycardia), low blood pressure, fainting
 - shortness of breath, stuffy nose
 - upset stomach, dry mouth
 - loss of hair, discolourations on skin, increased sweating, itching
 - joint pain, muscle pain, muscular weakness, muscle cramps, back pain
 - difficulties in urinating such as frequent, abnormal urination during the day and at night
 - chest pain, weight increase or weight decrease

Tell your doctor or your pharmacist if you notice any of the side effects listed above or any other unwanted or unexpected effects. To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))).

Storage and Disposal of Concor AM

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Concor AM after the expiry date which is stated on the blister and the carton after EXP.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Concor AM 5/5mg

Film-coated tablets are white, oblong, slightly convex with a score line on one side and with embossed MS on the other side.

Concor AM 5/10mg

Film-coated tablets are white, round, flat, bevel edged with score line on one side and embossed MS on the other side.

Concor AM 5/5mg or 5/10mg

Pack sizes: 30 tablets in blister pack

- Ingredients

- Active ingredients

bisoprolol fumarate and amlodipine besilate

- Inactive ingredients

Silica, colloidal anhydrous; Magnesium stearate; Sodium starch glycolate (Type A); Cellulose, microcrystalline

- MAL number(s)

Concor AM 5/5mg
MAL16115025AZ

Concor AM 5/10mg
MAL16115026AZ

Manufacturer

EGIS Pharmaceuticals PLC
Bökényföldi út 118-120
1165 Budapest
Hungary

Product Registration Holder

Merck Sdn Bhd (178145-V)
B-23A-1, Level 23A,
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Date of Revision

30/06/2024

Serial Number

NPRA (R1/1) 08102024/191