

**CONCOR AMLO 5+5/5+10/10+5/10+10
PROPOSED PATIENT INFORMATION LEAFLET**

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

SCHEDULING STATUS:

S3

PROPRIETARY NAME (and dosage form):

CONCOR AMLO 5+5 tablets

CONCOR AMLO 5+10 tablets

CONCOR AMLO 10+5 tablets

CONCOR AMLO 10+10 tablets

1. WHAT CONCOR AMLO CONTAINS

The active ingredients are bisoprolol fumarate and amlodipine besilate.

The other ingredients are cellulose microcrystalline, magnesium stearate, silica colloidal Anhydrous, sodium starch glycolate.

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2. WHAT CONCOR AMLO IS USED FOR

CONCOR AMLO is a combination medicine that is indicated for the treatment of high blood pressure, as substitution therapy in patients adequately controlled with the individual products given concurrently at the same dose level as in the combination, but as separate tablets.

3. BEFORE YOU USE CONCOR AMLO

Do not use CONCOR AMLO:

- If you are hypersensitive (allergic) to bisoprolol, amlodipine, dihydropyridine derivatives or any of the other ingredients.
- If you have acute heart failure
- Cardiogenic shock
- Second or third degree heart block (without a pacemaker)
- Symptomatic bradycardia with less than 50 beats/min
- Symptomatic hypotension
- Severe asthma or chronic obstructive lung dysfunction
- Untreated phaeochromocytoma
- Metabolic acidosis
- Hyperthyroidism

Take special care with CONCOR AMLO

Inform your doctor if you are taking a medicine named clonidine. When transferring from clonidine to CONCOR AMLO the withdrawal of clonidine may give rise to a hypertensive crisis.

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If CONCOR AMLO and clonidine are given concurrently, the clonidine should not be discontinued until several days after the withdrawal of the CONCOR AMLO, as severe rebound hypertension may occur.

Do not stop CONCOR AMLO therapy abruptly, especially if you have coronary heart disease as this may lead to transitional worsening of your heart condition.

If you have heart failure, you should be treated cautiously, as there is an increased risk of further deterioration of your ventricular pump function.

Use CONCOR AMLO with special care if

- You have sugar diabetes with extremely fluctuating blood glucose levels as symptoms of hypoglycaemia (e.g. palpitations or sweating) may be masked.
- You are fasting
- You are receiving ongoing desensitisation therapy. CONCOR AMLO may increase both the sensitivity to allergens and the severity of anaphylactic reactions.
- You have first degree AV block
- You have Prinzmetal's angina
- You have bronchial asthma or other chronic obstructive lung dysfunctions that may be associated with symptoms concomitant bronchodilator therapy is indicated.
- You are undergoing general anaesthesia - inform your doctor
- You suffer from psoriasis
- You have impaired liver function
- You have an hyperactive thyroid

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Pregnancy and Breast-feeding

CONCOR AMLO is not indicated if you are pregnant or are breast-feeding.

Taking other medicines with CONCOR AMLO

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CONCOR AMLO with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

CONCOR AMLO in combination with the following medicines is not recommended:

- Hypoglycaemic agents
- Phenothiazines
- Various antiarrhythmic agents
- Beta-adrenoceptor stimulating agents (e.g. isoprenaline)
- Alpha-adrenoceptor stimulants
- Calcium antagonists of the verapamil type
- Centrally acting antihypertensive medicines such as clonidine, methyldopa etc.

Caution is advised when using **CONCOR AMLO** with the following medicines:

- CYP 3A4 Inhibitors: Erythromycin, Diltiazem, Ketoconazole, Itraconazole, Rifampicin
- Eye drops used in the treatment of glaucoma
- Insulin and antidiabetic medicines
- Anaesthetic agents
- Non-steroidal anti-inflammatory medicines

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- Isoprenaline
- Clonidine

4. HOW TO USE CONCOR AMLO

Always use CONCOR AMLO exactly as your doctor has instructed you. Your doctor will decide which dose is applicable to you. You should check with your doctor or pharmacist if you are unsure.

The recommended dosage is one tablet of the given strength once daily.

The are to be swallowed whole with some liquid in the morning before, during or after breakfast.

CONCOR AMLO is not indicated for use in children.

CONCOR AMLO therapy should not be stopped abruptly.

If you have the impression that the effect of CONCOR AMLO is too strong or too weak, talk to your doctor or pharmacist, who may wish to change your treatment.

If you use more CONCOR AMLO than you should:

If you take more CONCOR AMLO than your normal dose, contact your doctor or nearest hospital immediately.

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In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take a dose:

Do not take a double dose to make up for a forgotten dose, please consult your doctor.

5. POSSIBLE SIDE EFFECTS

CONCOR AMLO can cause side effects.

Common (likely to occur in fewer than 1 in 10 patients) side effects are:

- Worsening of pre-existing heart failure, palpitations
- Dizziness, headache, somnolence
- Gastrointestinal complaints such as nausea, vomiting, diarrhoea, constipation
- Feeling of coldness or numbness in the extremities
- Hypotension
- Fatigue
- Oedema, fatigue

Uncommon (likely to occur in fewer than 1 in 100 patients) side effects are:

- AV conduction disturbances, worsening of pre-existing heart failure, bradycardia
- Bronchospasm in patients with bronchial asthma
- Muscle weakness, muscle cramps
- Depression, sleep disorders, insomnia
- Paraesthesia, dysgeusia, tremor
- Visual disturbances

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- Tinnitus (ringing in the ears)
- Hypotension (low blood pressure)
- Dry mouth, dyspepsia
- Pruritus
- Potency disorders
- Chest pain
- Weight increase, weight decrease

Rare (likely to occur in fewer than 1 in 1000 patients) side effects are:

- Increased triglycerides, increased liver enzymes
- Reduced tear flow
- Hearing disorders
- Allergic rhinitis
- Hypersensitivity reactions (itching, flush, rash)
- Hepatitis
- Potency disorders
- Nightmares, hallucinations, confusion

Very rare side effects are:

- Myocardial infarction (heart attack)
- Cough
- Gastritis
- Jaundice
- Stevens-Johnson syndrome
- psoriasis

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Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

6. STORING AND DISPOSING OF CONCOR AMLO

Keep all medicines out of the reach and sight of children.

Store below 30°C. Store in the original package in order to protect from light.

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

The medicine must be administered immediately after reconstitution.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF CONCOR AMLO

Blister packs containing 30 tablets.

8. IDENTIFICATION OF CONCOR AMLO

CONCOR AMLO 5+5: White or almost white, odourless, oblong, slightly convex tablets with score line on one side and with embossed MS on the other side.

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CONCOR AMLO 5+10: White or almost white, odourless, round, flat bevel edged tablets with score line on one side and embossed MS on the other side.

CONCOR AMLO 10+5: White or almost white, odourless, oval shaped, slightly convex tablets with score line on one side and embossed MS on the other side.

CONCOR AMLO 10+10: White or almost white, odourless, round slightly convex tablets with score line on one side and embossed MS on the other side.

9. REGISTRATION NUMBER

CONCOR AMLO 5+5: To be allocated

CONCOR AMLO 5+10: To be allocated

CONCOR AMLO 10+5: To be allocated

CONCOR AMLO 10+10: To be allocated

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

MERCK (PTY) LTD

1 Friesland Drive,

Longmeadow Business Estate South,

Modderfontein

1645

11. DATE OF PUBLICATION OF THIS PACKAGE INSERT:

REFERENCE: Proposed Scientific Package Insert.