SCHEDULING STATUS: S3

EMCOR 5/5 FDC tablet

EMCOR 5/10 FDC tablet

EMCOR 10/5 FDC tablet

EMCOR 10/10 FDC tablet

Bisoprolol fumarate and Amlodipine

Sugar-free

Read all of this leaflet carefully before you start taking EMCOR FDC

- Keep this leaflet. You may need to read it again.
- If you have more questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EMCOR FDC 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 Emcor FDC is and what it is used for
2. What you need to know before you take Emcor FDC
3. How to take Emcor FDC
4. Possible side effects
5. How to store Emcor FDC
6. Contents of the pack and other information

1. What Emcor FDC is and what it is used for:

Emcor FDC is a combination medicine that contains the active substances bisoprolol and amlodipine. Bisoprolol belongs to a group of medicines called beta-blockers. Amlodipine belongs to a group of medicines called calcium channel blockers. Emcor FDC lowers the blood pressure by decreasing the resistance of the arteries to blood flow and the volume of blood pumped per minute by your heart.

Emcor FDC 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.

Emcor FDC is indicated for the treatment of hypertension in patients whose blood pressure cannot be controlled by either bisoprolol or amlodipine monotherapy.

2. What you need to know before you take Emcor FDC

Do not take Emcor FDC range

- If you are hypersensitive (allergic) to bisoprolol, amlodipine, dihydropyridine derivates or any of the other ingredients of **Emcor FDC** (listed in section 6)
- If you suffer from acute heart failure, or worsening heart failure requiring injecting medicines into a vein, that increase the force of the contraction of the heart
- If you have serious narrowing of the outflow tract of the left ventricle (e.g. high grade aortic stenosis)
- If you have cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure
- If you suffer from certain heart conditions causing a very slow heart rate or irregular heartbeat

- If you have a slow heart rate
- If you experience symptoms of low blood pressure, like dizziness or lightheadedness
- If you have severe asthma (difficulty breathing)
- If you have untreated phaeochromocytoma, which is a rare tumour of the adrenal gland
- If you have metabolic acidosis, which is a condition where there is too much acid in the blood
- 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

Take special care with EMCOR FDC

Take **Emcor FDC** with special care if

- You are of an elderly age
- You have heart failure, as there is an increased risk of further damage to you heart pumping blood
- You have diabetes (high blood sugar) with extremely fluctuating blood sugar levels as symptoms of very low blood sugar (e.g. palpitations or sweating) may be masked.
- You are fasting
- You are receiving ongoing antiallergic (desensitisation) therapy (e.g. in order to prevent or treat allergies). **Emcor FDC** increase both the sensitivity to allergens and the severity of allergic reactions.
- You have a mild disorder of an irregular heart rhythm (first degree AV block
- You have certain heart diseases such as disturbances in heart rhythm, severe chest pain at rest (Prinzmetal's angina) or narrowing of the heart arteries
- You have bronchial asthma or other chronic obstructive lung dysfunctions for which bronchodilating therapy is indicated.
- You are undergoing general anaesthesia - inform your doctor
- You suffer from psoriasis (a chronic skin condition that causes flaky patches of skin which form scales)

- You have a thyroid problem. The tablets can hide the symptoms of an overactive thyroid.

Children and adolescents:

Emcor FDC is not recommended for the use in children or adolescents below the age of 18 years due to the lack of data on safety and efficacy.

Other medicines and Emcor FDC

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

Emcor FDC in combination with the following medicines is not recommended:

- certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (such as verapamil and diltiazem)
- certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonodine, rilmenidine. Do not stop taking these medicines before consulting your doctor.

Caution is advised when using **Emcor FDC** with the following medicines, as your doctor may need to check your condition more frequently:

- Certain medicines used to treat irregular or abnormal heartbeat (Class III antidysrhythmic medicines) such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, propaphenon, amiodarone
- Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment)
- Certain medicines are used to potentiate function of smooth muscle in diseases of stomach, small intestine, bladder and in glaucoma.
- Antidiabetic medicines used to treat sugar diabetes including insulin
- Anaesthetic agents (for example used during surgery)

- Certain medicines used to treat heart failure (digoxin)
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation, such as ibuprofen or diclofenac
- Sympathomimetics medicines are used for the treatment of serious circulation disorders in case of emergence (e.g. isoprenaline, dobutamine, norepinephrine (noradrenaline), epinephrine (adrenaline)).
- Any medicine that can lower blood pressure as a desired or undesired effect, such as blood pressure medicines, certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (barbiturates such as phenobarbitone), or certain medicines to treat mental illness characterised by a loss of contact with reality (phenothiazines such as levomepromazine)
- *Tacrolimus,* a medicine used to alter the way the immune system works.
- *Ciclosporin,* an immunosuppressant.
- *Dantrolene,* infusion for severe body temperature abnormalities during anaesthesia.
- *Simvastatin,* a cholesterol lowering medicine.

Possible effects of a coadministration of the following medicines with Emcor FDC needs to be considered by your doctor:

- Mefloquine, used to prevent or treat malaria.
- Monoamine oxidase (MAO) inhibitors (except MAO-B inhibitors), used to treat depression.
- Ergotamine derivatives, used to treat migraines or cluster headaches.

Emcor FDC with food, drink and alcohol:

Alcohol may increase the blood pressure lowering effects of Emcor FDC.

Grapefruit juice and grapefruit should not be consumed by people taking Emcor FDC. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Emcor FDC.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking Emcor FDC.

You are advised to not use Emcor FDC when you are pregnant. There is a risk that use of Emcor FDC during pregnancy may harm your baby.

There is no information available concerning the safety of Emcor FDC during breastfeeding.

Driving and using machinery:

Emcor FDC may impair driving or using machines by causing dizziness, headache, fatigue or nausea, especially when you start treatment or if your treatment has changed or when taken in combination with alcohol. Therefore, your doctor should decide individually at what kind of dosage you can drive or use machines.

3. How to take Emcor FDC

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

Your individual dose will be decided by your doctor after examinations.

Always take Emcor FDC as the doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long you should take a certain dose. Your doctor will decide to increase or decrease the dose based on how you respond clinically.

The recommended dose is one tablet daily.

Elderly:

No dosage adjustment is required however, caution is advised when the dose is increased.

Kidney impairment

No dosage adjustment is required if you have mild to moderate kidney impairment. In case of severe kidney impairment, the daily dose of the bisoprolol component of Emcor FDC must not exceed 10 mg.

Liver impairment

In case of severe liver impairment, the daily dose of the bisoprolol component of Emcor FDC must not exceed 10 mg.

Due to the amlodipine component in case of liver impairment special caution must be taken when Emcor FDC is administered.

Tablets are taken in the morning with or without food. They are swallowed with some liquid and not be chewed.

Your doctor will tell you how long your treatment with Emcor FDC will last. Do not stop treatment early without consulting your doctor or pharmacist. If you have the impression that the effect of Emcor FDC is too strong or too weak, tell your doctor or pharmacist.

If you forget to take EMCOR FDC

If you missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take Emcor FDC at the next regularly scheduled time.

Do not take a double dose to make up for the forgotten individual doses.

If you take more Emcor FDC than you should

Do not take a double dose to make up for forgotten individual doses.

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

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you stop taking Emcor FDC

Emcor FDC should not be stopped abruptly without prior discussion with your doctor. Discontinuation of therapy should be gradual, and you should limit the extent of physical activity during the period that the medicine is being discontinued.

4. Possible side effects

Emcor FDC can have side effects.

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

Visit your doctor immediately if you experience any of the following side effects after taking this medicine:

Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis) or other allergic reactions

Frequent side effects:

- Oedema
- Headache
- Dizziness
- Drowsiness (especially at the beginning of the treatment)
- Palpitation
- Bradycardia
- Flush
- Abdominal pain
- Ankle swelling
- Fatigue
- Feeling of coldness and numbness in the extremities (fingers and toes)
- Gastrointestinal complaints such as nausea, vomiting, altered bowel habits, diarrhoea, constipation, indigestion
- Visual disturbances
- Muscle cramps
- Breathing difficulties

Less frequent side effects:

- Insomnia
- Mood changes (including anxiety)
- Depression
- Temporary loss of consciousness

- Numbness
- Abnormal sense of taste
- Tremor
- Ringing in the ears
- Low blood pressure
- Allergic rhinitis
- Cough
- Dry mouth
- Hair loss
- Small bleedings in the skin and mucosa
- Skin discolouration
- Increased sweating
- Itching
- Rash
- Back pain
- Chest pain
- Pain
- Tiredness
- Weight increase
- Weight decrease
- Sleep disorders
- Heart conduction disorders
- Worsening of pre-existing heart failure
- Cardiac arrhythmia
- Slow heart rate
- Low blood pressure
- Bronchospasm in patients with bronchial asthma or a history of obstructive lung disease

- Muscle weakness
- Confusion
- Elevated level of triglyceride
- Nightmares
- Sense illusion, which is an abnormal sensation without detectable stimulus, similar to real sensation and seems real (hallucination)
- Decreased tear secretion (it must be taken into consideration if you wear contact lenses)
- Hearing impairments
- Allergic rhinitis
- Hepatitis
- Hypersensitivity reactions such as itching, flush, rash, elevated liver enzymes, decrease of number or white blood cells and platelets, allergic reactions
- Elevated level of blood sugar
- Increased muscle tone
- Nerve issues
- Heart attack
- Patchy inflammation of small blood vessels (vasculitis)
- Stomach discomfort
- Excessive growth of gum tissue around the teeth
- Inflammation of the pancreas
- Yellowing of the skin
- Acute swelling of skin or mucosa involving most frequently eyelids, lips, joints, genitals, glottis, pharynx and tongue (angio-oedema)
- Serious inflammation of skin or mucosa with red vesicles (erythema multiforme)
- Widespread erythema and scaling of the skin (exfoliative dermatitis)
- Serious blistering lesions of the skin and mucous membranes of the mouth, genital and anal regions, with fever, sore throat and fatigue (Stevens-Johnson syndrome)

- Sensitivity to the sunlight
- Inflammation of the eye
- Medicines with similar mechanism of action than bisoprolol (active ingredient of the preparation) may evoke or worsen psoriasis (chronic skin disease with itchy scaly red patches) or may cause psoriasis-like skin disorder
- Disorders combining involuntary movements, muscle rigidity and contractions, tremor (extrapyramidal syndrome)

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 pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publication: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Emcor FDC.

5. How to store Emcor FDC

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not remove from carton until ready for use.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What Emcor FDC contains

The active substances are Bisoprolol fumarate and Amlodipine

Each tablet Emcor FDC 10 + 10 contains 10 mg bisoprolol fumarate and 10 mg amlodipine (as 13.9 amlodipine besilate) as active ingredients.

Each tablet Emcor FDC 10 + 5 contains 10 mg bisoprolol fumarate and 5 mg amlodipine (as 6.95 mg amlodipine besilate) as active ingredients.

Each tablet Emcor FDC 5 + 10 contains 5 mg bisoprolol fumarate and 10 mg amlodipine (as 13.9 amlodipine besilate) as active ingredients.

Each tablet Emcor FDC 5 + 5 contains 5 mg bisoprolol fumarate and 5 mg amlodipine (as 6.95 mg amlodipine besilate) as active ingredients.

The other ingredients are:

Cellulose microcrystalline, magnesium stearate, silica colloidal anhydrous, sodium starch glycolate.

What Emcor FDC looks like and contents of the pack

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

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

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

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

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

OPA/Aluminium/Polyvinylchloride/Aluminium blister packs of 28, 30, 56 or 90 tablets in a carton box.

Holder of the certificate of registration

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