



Emcor® 5 mg film coated tablets Emcor® 10 mg film coated tablets

bisoprolol fumarate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Emcor is and what it is used for

The active substance in Emcor tablets is bisoprolol. 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.

Emcor tablets are used to treat high blood pressure (hypertension) and to help prevent chest pain (angina pectoris).

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

Do not take Emcor tablets

Do not take Emcor tablets if one of the following conditions applies to you:

- allergy (hypersensitivity) to bisoprolol or to any of the other ingredients (see section 6 'What Emcor contains')
- severe asthma
- 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 in which the blood is too acidic.

Do not take Emcor tablets if you have one of the following heart problems:

- acute heart failure
- worsening heart failure requiring an injection of medicines into a vein to increase the force of contraction of the heart
- low blood pressure
- certain heart conditions causing a very slow heart rate or irregular heartbeat and you have not been fitted with a pacemaker
- cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Emcor.

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

- heart failure (although bisoprolol can be used to treat heart failure the dosage is very different)
- 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)
- diabetes
- strict fasting
- certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina)
- kidney or liver problems
- less severe blood circulation problems in your limbs
- chronic lung disease or less severe asthma
- history of allergies
- 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 Emcor tablets may make it more likely that you experience an allergic reaction, or such a reaction may be more severe
- anaesthesia (for example for surgery), because Emcor tablets may influence how your body reacts to this situation.

If you have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using Emcor.

Other medicines and Emcor tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Do not take the following medicines with Emcor tablets without special advice from your doctor:

- certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (known as calcium antagonists, 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 Emcor tablets; your doctor may need to check your condition more frequently:

- certain medicines used to treat irregular or abnormal heartbeat (known as Class I antiarrhythmic medicines, such as quinidine and disopyramide)
- certain medicines used to treat high blood pressure or angina pectoris (known as dihydropyridine-type calcium antagonists, such as nifedipine)
- certain medicines used to treat irregular or abnormal heartbeat known as Class III antiarrhythmic medicines, such as amiodarone)
- beta-blockers applied locally (such as timolol eye drops for glaucoma treatment)
- certain medicines used to treat conditions such as Alzheimer's disease or glaucoma (known as parasympathomimetics, such as tacrine or carbachol) or medicines that are used to treat acute heart problems (known as sympathomimetics, such as isoprenaline and dobutamine)
- 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)
- sympathomimetics such as adrenaline and noradrenaline which are used in the treatment of heart attack and low blood pressure. Adrenaline is also used to treat allergic reactions. Higher doses of adrenaline may be necessary for treatment of allergic reactions if Emcor is being 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 such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (barbiturates such as phenobarbital), or certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines such as levomepromazine)
- mefloquine, used for prevention or treatment of malaria
- depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide

Pregnancy and breast-feeding

Pregnancy

There is a risk that use of Emcor tablets during pregnancy may harm the baby. If you are pregnant or planning to become pregnant, tell your doctor. He or she will decide whether you can take Emcor tablets during pregnancy.

Breast-feeding

It is not known whether bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with Emdor tablets.

Driving and using machines

Your ability to drive or use machinery may be affected depending on how well you tolerate the medicine. Please be especially cautious at the start of treatment, when the dose is increased or the medication is changed, as well as in combination with alcohol.

3. How to take Emdor Tablets

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

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

Treatment with Emdor tablets is usually long-term.

Adults including older people:

The usual daily dose is 10 mg bisoprolol.

Depending on how well you respond to the medicine, your doctor may decide to decrease the dose to 5 mg or he may decide to increase it to 20 mg. The dose should not exceed 20 mg in one day. Your doctor will tell you what to do. The label will also tell you how many tablets to take and how often to take them. Your pharmacist will help if you are unsure.

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

Children and adolescents:

Emdor tablets are not recommended for use in children or adolescents.

If you take more Emdor tablets than you should

If you have taken more Emdor tablets than you should, tell your doctor or hospital accident and emergency department immediately. Take your tablets with you. Your doctor will decide what measures are necessary.

If you have taken too many tablets you may have a slowed heart rate, severe difficulty in breathing, feeling dizzy, or trembling (due to decreased blood sugar).

If you forget to take Emdor tablets

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

If you stop taking Emdor tablets

Never stop taking Emdor unless on your doctor's advice. Otherwise your condition could become much worse.

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

4. Possible side effects

Like all medicines, Emdor tablets can cause side effects, although not everybody gets them.

To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurs suddenly or gets worse rapidly.

Known side effects are listed below according to how frequently they may occur:

Common (may affect up to 1 in 10 people):

- tiredness, dizziness, headache
- feeling of coldness or numbness in hands or feet
- low blood pressure
- stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation.

Uncommon (may affect up to 1 in 100 people):

- interference with normal heart rate
- worsening heart failure
- sleep disturbances
- depression
- breathing problems in patients with asthma or chronic lung disease
- feeling weak, muscle weakness, muscle cramps
- dizziness when standing up.

Rare (may affect up to 1 in 1,000 people):

- hearing problems
- allergic runny nose, sneezing and itching
- reduced tear flow (dry eyes)

- inflammation of the liver which can cause yellowing of the skin or the whites of the eyes
- certain blood test results for liver function or fat levels differing from normal
- allergy-like reactions such as itching, flush, rash
- impaired erection
- nightmares, hallucinations
- fainting.

Very rare (may affect up to 1 in 10,000 people):

- irritation and redness of the eye (conjunctivitis)
- hair loss
- appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emdor tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine if you notice any visible signs of deterioration. Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Emdor tablets contain

Emdor 5 mg film coated tablets

- The active substance is bisoprolol fumarate. Each film coated tablet contains 5 mg.
- The other ingredients are:
Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).
Film coating: Iron oxide yellow (E172); dimethicone; macrogol 400; titanium dioxide (E171); hypromellose.

Emdor 10 mg film coated tablets

- The active substance is bisoprolol fumarate. Each film coated tablet contains 10 mg.
- The other ingredients are:
Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).
Film coating: Iron oxide red (E172); Iron oxide yellow (E172); dimethicone; macrogol 400; titanium dioxide (E171); hypromellose.

What Emdor tablets look like and contents of the pack

Emdor 5 mg film-coated tablets are yellowish-white and heart-shaped with a break-line on both sides.

Emdor 10 mg film-coated tablets are pale orange – light orange and heart-shaped with a break-line on both sides.

Each pack contains 4, 14 or 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Merck Serono (Ireland) Ltd, 4045 Kingswood Road, Citywest BUbusiness Campus, Dublin, D24 V06K, Ireland.

Manufacturer

Merck KGaA, Frankfurter Strasse 250, 64293 Darmstadt, Germany.

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