

CONCOR[®] FILM COATED TABLETS

Bisoprolol fumarate (2.5mg, 5mg, 10mg)

What is in this leaflet

1. What Concor is used for
2. How Concor works
3. Before you use Concor
4. How to take Concor
5. While you are using Concor
6. Side effects
7. Storage and Disposal of Concor
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Concor is used for

Concor 2.5 mg is used to treat chronic stable heart failure

Concor 5 mg and 10mg is used to treat high blood pressure, angina pectoris and chronic stable heart failure
In adults:

How Concor works

The active substance in Concor 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.

Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs. Heart failure may begin with no symptoms, but as the condition progresses, you may feel shortness of breath. You may experience palpitations (initially during ordinary exercise, but later on also at rest), feel tired, and notice swelling of the feet and ankles due to fluid buildup.

Before you use Concor

- When you must not take it

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

- allergy (hypersensitivity) to bisoprolol or to any of the other ingredients
- 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 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 heartbeat (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; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- diabetes
- 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 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 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 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 heartbeat 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; your doctor may need to check your condition more frequently:

- Certain calcium antagonists used to treat high blood pressure or angina pectoris such as felodipine and amlodipine (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
- Monoamine oxidase inhibitors (except MAO-B inhibitors)

How to take Concor

- How much to take

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

Treatment of hypertension or angina pectoris:

For both indications the usual dosage is one tablet Concor 5 mg or ½ tablet Concor 10 mg (equivalent to 5 mg bisoprolol fumarate) once daily.

If necessary, the dose may be increased to one tablet Concor 10 mg or 2 tablets Concor 5 mg (equivalent to 10 mg bisoprolol fumarate) once daily.

The maximum recommended dose is 20 mg bisoprolol fumarate once daily.

Treatment with Concor requires regular monitoring by your doctor. This is particularly necessary at the start of treatment and during dose increase.

Treatment of chronic heart failure: Treatment with bisoprolol must be started at a low dose and increased gradually.

Your doctor will decide how to increase the dose, and this will normally be done in the following way:

- 1.25 mg bisoprolol fumarate once daily for one week
- 2.5 mg bisoprolol fumarate once daily for one week
- 3.75 mg bisoprolol fumarate once daily for one week
- 5 mg bisoprolol fumarate once daily for four weeks
- 7.5 mg bisoprolol fumarate once daily for four weeks
- 10 mg bisoprolol fumarate once daily for maintenance (on-going) therapy.

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. In some patients a maintenance dose lower than 10 mg bisoprolol fumarate may be sufficient. Your doctor will tell you what to do. The maximum recommended daily dose is 10 mg bisoprolol fumarate for chronic stable heart failure and 20 mg bisoprolol fumarate for high blood pressure and angina pectoris

Elderly: No dose adjustment is required in the elderly.

Children: Concor is not recommended for use in children.

- 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 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 tablets than you should, tell your doctor

immediately. 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), marked drop in blood pressure, acute heart failure, or a decrease in blood sugar.

Never stop taking Concor 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 Concor

- 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 during pregnancy. It is not known whether bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with Concor.

- 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 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 can cause side effects, although not everybody gets them. These side effects are listed below according to how frequently they may occur:

Very common (affects more than 1 person in 10):

- slowing of heart rate (bradycardia) especially in patients with chronic heart failure

Common (affects less than 1 person in 10):

- tiredness, dizziness, headache
- feeling weak especially in patients with chronic heart failure
- feeling of coldness or numbness in hands or feet
- low blood pressure especially in patients with chronic heart failure
- worsening of heart failure especially in patients with chronic heart failure
- stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation.

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 calling Tel: 03-78835490, or visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))).

Storage and Disposal of Concor

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Concor 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 2.5mg

Film-coated tablets are white and heart-shaped with a break-line on both sides.

Concor 5mg

Yellowish white, heart shaped, biconvex film-coated tablets, scored on both sides.

Concor 10mg

Pale orange-light orange, heart shaped, biconvex film-coated tablets, scored on both sides.

Concor 2.5mg

Pack sizes: 28, 56 and 100 tablets

Concor 5mg

Pack sizes: 100 tablets

Concor 10mg

Pack sizes: 100 tablets

Not all pack sizes may be registered or marketed

- Ingredients

Concor 2.5mg

The active substance is bisoprolol fumarate. Each film-coated tablet contains 2.5 mg.

The other ingredients are:

Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).
Film coating: Dimethicone; macrogol 400; titanium dioxide; hypromellose.

Concor 5mg

Each film-coated tablet contains 5 mg bisoprolol fumarate as active ingredient.

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; dimethicone; macrogol 400; titanium dioxide; hypromellose.

Concor 10mg

Each film-coated tablet contains 10 mg bisoprolol fumarate as active ingredient.

The other ingredients are:

Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; microcrystalline cellulose; maize starch; calcium hydrogen phosphate (anhydrous)
Film coating: Iron oxide red; Iron oxide yellow; dimethicone; macrogol 400; titanium dioxide; hypromellose.

- MAL Number:

Concor 2.5mg: MAL20020792AZ

Concor 5mg: MAL19890389AZ

Concor 10mg: MAL19890390AZ

Manufacturer

Merck Healthcare KGaA Frankfurter Strasse 250, 64293 Darmstadt, Germany

Product Registration Holder

Merck Sdn Bhd (178145-V) B-23A-1, Level 23A, The Ascent Paradigm No.1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia

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