Package leaflet

Concor® 5 mg

MERCK

Active substance: bisoprolol fumarate (2:1)

Composition

One film-coated tablet contains
Medicinally active ingredient:
5 mg bisoprolol fumarate (2:1).
Other ingredients:
Colloidal silicon dioxide, magnesium (stearate, palmitate, oleate), crospovidone, microcrystalline cellulose, corn starch, calcium hydrogen phosphate, iron oxide hydrate (E172), dimethicone, macrogol 400, titanium dioxide (E171), hypromellose.

Presentation and package sizes

Film-coated tablet, light yellow, heart-shaped, with dividing score
Packof 30 tablets

Substance group

Cardioselective beta-receptor blocker

Marketing authorisation holder and manufacturer

Merck KGaA, Frankfurter Strasse 250
64293 Darmstadt, Germany

Indications

- High blood pressure (hypertension)
- Coronary heart disease (anginapectoris)

Contraindications

When must you not take Concor 5 mg?

Concor 5 mg must not be taken in
- acute myocardial insufficiency (heart failure) or during a deterioration (decompensation) of the heart failure requiring intravenous therapy with substances increasing the contractility of the heart
- shock induced by disorders of cardiac function (cardiogenic shock)
- severe disturbances of atrioventricular impulse conduction (second or third degree AV) without a pacemaker
- sick sinus syndrome
- disturbed impulse conduction between sinus node and atrium (sinoatrial block)
- markedly slowed heart beat (pulse rate less than 50 beats/min) before the start of treatment
- markedly decreased blood pressure (systolic blood pressure below 90 mmHg)
- severe bronchial asthma or severe chronic obstructive pulmonary disease
- late stages of peripheral arterial occlusive disease or vascular spasms in toes and fingers (Raynaud's syndrome)
- untreated tumours of the adrenal medulla (phaeochromocytoma)
- metabolic acidosis
- known hypersensitivity to bisoprolol or to any of the excipients.

When may Concor 5 mg only be taken after consulting your doctor?

The following section describes when you may use Concor 5 mg only under certain conditions and only with special caution. Please ask your doctor about this. This also applies if you have been affected by any of the following in the past

Patients with any of the following should be monitored particularly closely:
- bronchospasm (bronchial asthma, or obstructive airways diseases)
- concomitant treatment with inhalational anaesthetics
- diabetes mellitus with extremely fluctuating blood glucose levels; symptoms of markedly reduced blood glucose (hypoglycaemia) can be masked
- strict fasting
- ongoing desensitisation therapy
- mild disturbances of atrioventricular impulse conduction (first degree AV block)
- disturbed cardiac blood flow due to spasmodic constrictions of the coronary vessels (Prinzmetal angina)
- peripheral arterial occlusive disease (intensification of complaints may occur especially when starting therapy).

In patients with a personal or family history of psoriasis, beta-receptor blockers (e.g. Concor 5 mg) should only be used if the benefit-to-risk ratio has been carefully weighed. In patients with a tumour of the adrenal medulla (phaeochromocytoma) Concor 5 mg may only be administered after previous alpha-receptor blockade.

What must pregnant women and nursing mothers pay attention to?

During pregnancy Concor should only be used after the doctor has carefully weighed the benefit to risk ratio. In general beta-receptor blockers reduce placental blood flow and can affect the development of the unborn child. Placental and uterine blood flow as well as the growth of the unborn child must be monitored and, if required, alternative therapeutic measures considered.
The newborn child must be monitored closely after delivery. Symptoms of reduced blood glucose and slowed pulse are generally to occur within the first 3 days of life.
It is not known whether bisoprolol passes into breast milk. Therefore, breastfeeding is not recommended during Concor 5 mg therapy.

What must be especially observed in children and elderly people?

Concor 5 mg should not be administered to children as no adequate therapeutic experience in this context is available. No special notes apply to the treatment of elderly people.

Precautions for use and warnings

What precautions must be observed?

In impaired liver and kidney function the dosage instructions must be observed (see section Dosage instructions).
Therapy with Concor 5 mg necessitates regular monitoring by a physician. In bronchial asthma or other chronic obstructive pulmonary diseases that may be associated with symptoms concomitant bronchodilator therapy is indicated. An increase in airways resistance may occasionally occur in asthma patients, requiring a higher β2-sympathomimetic dose.
Like other beta-receptor blockers, bisoprolol can increase the sensitivity to allergens and the severity of anaphylactic reactions, i.e. acute general allergic reactions. Adrenaline does not always produce the desired therapeutic effect in these cases.
The symptoms of thyroid hyperfunction (thyrotoxicosis) can be masked by bisoprolol.
The therapy with bisoprolol should not be discontinued abruptly without compelling indication.

What must you pay attention to if you are driving a vehicle, operating machinery, or working without a firmhold?

In a study on patients with coronary heart disease bisoprolol did not affect the driving performance of the patients. However, due to individually different reactions to the drug, the ability to drive a vehicle, to operate machinery, or to work without a firm hold may be impaired. This is particularly the case at the start of treatment, when the dosage is increased or the medication changed, as well as in conjunction with alcohol.

Special warnings

THIS IS A MEDICAMENT
- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of the treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Drug interactions

What other drugs influence the effect of Concor 5 mg or what influence does Concor 5 mg have on the effect of other drugs?

Simultaneous administration of the following drugs is not recommended:
Increased slowering of blood pressure, delayed atrioventricular impulse conduction as well as reduced contractility of the heart muscle have been observed after simultaneous use of calciumantagonists. Especially intravenous administration of calcium antagonists of the verapamil type may lead to pronounced hypotension and AV block.
Concurrent use of bisoprolol and clonidine can lead to a stronger reduction of heart rate and to delayed impulse conduction in the heart. Discontinuation of clonidine can also bring about an excessive increase in blood pressure.
Simultaneous administration of monoamine oxidase inhibitors (except MAO-B inhibitors) can affect the blood pressure (lowering of blood pressure, but also to excessive increase in blood pressure).
The following drugs may only be used at the same time as bisoprolol under certain conditions and with particular caution:
The cardiodepressant effects of Concor 5 mg and antiarrhythmics on impulse conduction and contractility of the heart can become additive.
Parasympathomimetics (including tacrine) can prolong the atrioventricular conduction time.
Other beta-receptor blockers, even if contained in eye drops, potentiate the effect of Concor 5 mg.
Concomitant use of Concor 5 mg and insulin or other drugs lowering the blood glucose level (oral antidiabetics) can potentiate the effect of the latter. Warning signs of reduced blood glucose (hypoglycaemia) – especially accelerated pulse (tachycardia) – can be masked or suppressed.
The concurrent administration of Concor 5 mg and anaesthetics may lead to a pronounced drop in blood pressure. Counter-regulatory mechanisms, e.g. increase in heart rate (reflex tachycardia) can be impaired. Continuation of beta blockade reduces the risk of arrhythmia during initiation of anaesthesia and intubation. The anaesthetist should be informed about treatment with Concor 5 mg.
Concurrent therapy with Concor 5 mg and cardioactive glycosides (digitalis) can lead to marked slowing of the heart beat and of impulse conduction in the heart.
Simultaneous administration of mefloquine also further slows a slowing of the heart beat.
Prostaglandin synthesis inhibitors (e.g. acetylsalicylic acid) can reduce the antihypertensive effect of Concor 5 mg.
Concurrent administration of ergotamine derivatives (e.g. ergotamine containing drugs against migraine) and Concor 5 mg can lead to an increase in peripheral circulatory disturbances.
Concomitant administration of Concor 5 mg and sympathomimetics can reduce the effect of the two substances. The treatment of allergic reactions may require an increased adrenaline dose.
The antihypertensive effect of Concor 5 mg can be potentiated by tricyclic antidepressants, barbiturates, phenothiazines and other antihypertensive drugs.
Concomitant administration of rifampicin and Concor 5 mg can slightly shorten the half-life of bisoprolol. Dose adjustment is in general not required.

What food or drinks, etc. should you avoid?

The antihypertensive effect of Concor 5 mg may be potentiated by alcohol.

Dosage instructions, mode and duration of use

The following instructions apply for Concor 5 mg, unless your doctor has prescribed otherwise.
Please follow these directions carefully, otherwise Concor 5 mg cannot have the proper effect.

How much Concor 5 mg should you take and how often should you take it?

Treatment should principally be initiated gradually with low doses, which are then increased slowly. In all cases the dosage should be adjusted individually, in particular according to the pulse rate and therapeutic success.

High blood pressure (hypertension)

Unless otherwise prescribed, the recommended dose is 1 film-coated tablet of Concor 5 mg (5 mg bisoprolol fumarate (2:1)) once daily. If the effect is inadequate the dose can be increased to 2 film-coated tablets of Concor 5 mg (equivalent to 10 mg bisoprolol fumarate (2:1)) once daily. A further dosage increase is justified only in exceptional cases.

Coronary heart disease (angina pectoris)

Unless prescribed otherwise, the recommended dose is 1 film-coated tablet of Concor 5 mg (5 mg bisoprolol fumarate (2:1)) once daily. If the effect is inadequate the dose can be increased to 2 film-coated tablets of Concor 5 mg (10 mg bisoprolol fumarate (2:1)). A further increase of dosage is justified only in exceptional cases.

Dosage in impaired liver and/or kidney function

In patients with liver or kidney function disorders of mild to moderate severity no dosage adjustment is normally required. In patients with advanced renal insufficiency (creatinine clearance < 20 ml/min) and in patients with severely impaired liver function a daily dose of 10 mg bisoprolol fumarate (2:1) should not be exceeded.

How and when should you take Concor 5 mg?

You should take the film-coated tablet whole with some liquid in the morning before, during or after breakfast.

How long should you take Concor 5 mg?

The duration of treatment is not limited. It depends upon the nature and severity of the disease.
The dosage of Concor 5 mg should not be altered unless directed by the doctor. Also, treatment with Concor 5 mg should only be interrupted or discontinued prematurely if directed by the doctor.
Therapy with Concor 5 mg should not - especially in patients with disturbed blood flow in the coronary arteries (coronary heart disease: angina pectoris) - be stopped abruptly but should generally be discontinued on a gradual basis (i.e. by halving the dose at weekly intervals), since abrupt withdrawal may lead to an acute deterioration of the patient's condition.

Adverse effects

What adverse reactions may occur when you are taking Concor 5 mg?

The following data are based on the therapeutic experience obtained after approval of bisoprolol for the therapy of hypertension as well as coronary heart disease.

	Type	Frequency
Central nervous system	...tiredness*, exhaustion*, dizziness*, headache*	occasionally
	Sleep disorders, depression	rarely
	Nightmares, hallucinations	very rarely
Eyes	Reduced tear flow (to be taken into consideration in patients wearing contact lenses)	very rarely
	Conjunctivitis	single cases
Ears	Hearing disorders	very rarely
Cardiovascular system	Sensation of cold and numb extremities	occasionally
	Slowing of heart beat (bradycardia) disturbed cardiac activity disturbed atrioventricular impulse conduction (AV block) deterioration of myocardial insufficiency (heart failure) stronger drop in blood pressure (also when standing up from a supine position, orthostatic hypotension)	rarely
Respiratory system	Bronchospasm in patients with a history of bronchial asthma or obstructive airways disease	rarely
	Allergic cold (rhinitis)	very rarely
Gastrointestinal tract	Nausea, vomiting, diarrhoea, constipation	occasionally
Muscles and skeleton (musculoskeletal system)	Muscle weakness, muscle cramps	rarely
Skin	Hypersensitivity reactions (itching, temporary flush, rash)	very rarely
	Beta-receptor blockers can trigger psoriasis, aggravate the condition or lead to psoriasiform rash.	single cases
	Loss of hair	very rarely
Genito-urinary organs	Potency disorders	very rarely
Metabolism	Increased liver enzyme values (GOT, GPT), hepatitis, increased triglyceride values	very rarely

*These symptoms occur especially at the start of treatment. They are mild and usually disappear within 1 to 2 weeks after the start of treatment.

If you should experience any adverse reactions not referred to in this package leaflet, you should report these also to your doctor or pharmacist.

What countermeasures are to be taken in the case of adverse reactions?

Your doctor will decide about any possibly required countermeasures.

Notes on stability

The expiry date of the packs is printed on the folding box and on the edge of each blister strip.
Do not use this package or the expiry date has elapsed.

How should you store Concor 5 mg?

Do not store above 30 °C.

Date of issue

March 2002

Reg. N° Lebanon 23650

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