

**SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET**

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 1.25 mg film-coated tablets
Emconcor CHF 2.5 mg film-coated tablets
Emconcor CHF 3.75 mg film-coated tablets
Emconcor CHF 5 mg film-coated tablets
Emconcor CHF 7.5 mg film-coated tablets
Emconcor CHF 10 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Emconcor CHF 1.25 mg:	Each tablet contains 1.25 mg bisoprolol fumarate
Emconcor CHF 2.5 mg:	Each tablet contains 2.5 mg bisoprolol fumarate
Emconcor CHF 3.75 mg:	Each tablet contains 3.75 mg bisoprolol fumarate
Emconcor CHF 5 mg:	Each tablet contains 5 mg bisoprolol fumarate
Emconcor CHF 7.5 mg:	Each tablet contains 7.5 mg bisoprolol fumarate
Emconcor CHF 10 mg:	Each tablet contains 10 mg bisoprolol fumarate

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Emconcor CHF 1.25 mg	white, round film-coated tablets
Emconcor CHF 2.5 mg	white, heart-shaped, scored and film-coated tablets
Emconcor CHF 3.75 mg	off-white, heart-shaped, scored and film-coated tablets
Emconcor CHF 5 mg	yellowish white, heart-shaped, scored and film-coated tablets
Emconcor CHF 7.5 mg	pale yellow, heart-shaped, scored and film-coated tablets
Emconcor CHF 10 mg	pale orange - light orange, heart-shaped, scored and film-coated tablets

The scored tablets can be divided into two equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides (for additional information see section 5.1).

4.2 Posology and method of administration

Standard treatment of CHF consists of an ACE inhibitor (or an angiotensin receptor blocker in case of intolerance to ACE inhibitors), a beta-blocker, diuretics, and when appropriate cardiac glycosides. Patients should be stable (without acute failure) when bisoprolol treatment is initiated.

It is recommended that the treating physician should be experienced in the management of chronic heart failure.

Transient worsening of heart failure, hypotension, or bradycardia may occur during the titration period and thereafter.

Posology

Titration phase

The treatment of stable chronic heart failure with bisoprolol requires a titration phase
The treatment with bisoprolol is to be started with a gradual uptitration according to the following steps:

- 1.25 mg once daily for 1 week, if well tolerated increase to
- 2.5 mg once daily for a further week, if well tolerated increase to
- 3.75 mg once daily for a further week, if well tolerated increase to
- 5 mg once daily for the 4 following weeks, if well tolerated increase to
- 7.5 mg once daily for the 4 following weeks, if well tolerated increase to
- 10 mg once daily for the maintenance therapy.

The maximum recommended dose is 10 mg once daily.

Close monitoring of vital signs (heart rate, blood pressure) and symptoms of worsening heart failure is recommended during the titration phase. Symptoms may already occur within the first day after initiating the therapy.

Treatment modification

If the maximum recommended dose is not well tolerated, gradual dose reduction may be considered.

In case of transient worsening of heart failure, hypotension, or bradycardia reconsideration of the dosage of the concomitant medication is recommended. It may also be necessary to temporarily lower the dose of bisoprolol or to consider discontinuation.

The reintroduction and/or uptitration of bisoprolol should always be considered when the patient becomes stable again.

If discontinuation is considered, gradual dose decrease is recommended, since abrupt withdrawal may lead to acute deterioration of the patients condition.

Treatment of stable chronic heart failure with bisoprolol is generally a long-term treatment.

Patients with hepatic or renal impairment

There is no information regarding pharmacokinetics of bisoprolol in patients with chronic heart failure and with impaired hepatic or renal function. Uptitration of the dose in these populations should therefore be made with additional caution.

Older people

No dosage adjustment is required.

Paediatric population

There is no paediatric experience with bisoprolol, therefore its use cannot be recommended in paediatric patients.

Method of administration

Bisoprolol tablets should be taken in the morning and can be taken with food. They should be swallowed with liquid and should not be chewed.

4.3 Contraindications

Bisoprolol is contraindicated in chronic heart failure patients with:

- acute heart failure or during episodes of heart failure decompensation requiring i.v. inotropic therapy
- cardiogenic shock
- second or third degree AV block
- sick sinus syndrome
- sinoatrial block
- symptomatic bradycardia
- symptomatic hypotension
- severe bronchial asthma
- severe forms of peripheral arterial occlusive disease or severe forms of Raynaud's syndrome
- untreated phaeochromocytoma (see section 4.4)
- metabolic acidosis
- hypersensitivity to bisoprolol or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

The treatment of stable chronic heart failure with bisoprolol has to be initiated with a special titration phase.

Especially in patients with ischaemic heart disease the cessation of therapy with bisoprolol must not be done abruptly unless clearly indicated, because this may lead to transitional worsening of heart condition.

The initiation and cessation of treatment with bisoprolol necessitates regular monitoring.

There is no therapeutic experience of bisoprolol treatment of heart failure in patients with the following diseases and conditions:

- insulin dependent diabetes mellitus (type I)
- severely impaired renal function
- severely impaired hepatic function
- restrictive cardiomyopathy
- congenital heart disease
- haemodynamically significant organic valvular disease
- myocardial infarction within 3 months

Bisoprolol must be used with caution in:

- bronchospasm (bronchial asthma, obstructive airways diseases)
- diabetes mellitus with large fluctuations in blood glucose values; Symptoms of hypoglycaemia can be masked
- strict fasting
- ongoing desensitisation therapy. As with other beta-blockers, bisoprolol may increase both the sensitivity towards allergens and the severity of anaphylactic reactions. Epinephrine treatment does not always yield the expected therapeutic effect.
- first degree AV block
- Prinzmetal's angina; Cases of coronary vasospasm have been observed. Despite its high beta1-selectivity, angina attacks cannot be completely excluded when bisoprolol is administered to patients with Prinzmetal's angina.
- peripheral arterial occlusive disease. Aggravation of symptoms may occur especially when starting therapy.

- general anaesthesia
In patients undergoing general anaesthesia beta-blockade reduces the incidence of arrhythmias and myocardial ischemia during induction and intubation, and the post-operative period. It is currently recommended that maintenance beta-blockade be continued peri-operatively. The anaesthetist must be aware of beta-blockade because of the potential for interactions with other drugs, resulting in bradyarrhythmias, attenuation of the reflex tachycardia and the decreased reflex ability to compensate for blood loss. If it is thought necessary to withdraw beta-blocker therapy before surgery, this should be done gradually and completed about 48 hours before anaesthesia.

Combination of bisoprolol with calcium antagonists of the verapamil or diltiazem type, with Class I antiarrhythmic drugs and with centrally acting antihypertensive drugs is generally not recommended, for details please refer to section 4.5.

Although cardioselective (beta1) beta-blockers may have less effect on lung function than non-selective beta-blockers, as with all beta-blockers, these should be avoided in patients with obstructive airways diseases, unless there are compelling clinical reasons for their use. Where such reasons exist, Emconcor CHF may be used with caution. In patients with obstructive airways diseases, the treatment with bisoprolol should be started at the lowest possible dose and patients should be carefully monitored for new symptoms (e.g. dyspnea, exercise intolerance, cough). In bronchial asthma or other chronic obstructive lung diseases, which may cause symptoms, bronchodilating therapy should be given concomitantly. Occasionally an increase of the airway resistance may occur in patients with asthma, therefore the dose of beta₂-stimulants may have to be increased.

Patients with psoriasis or with a history of psoriasis should only be given beta-blockers (e.g. bisoprolol) after carefully balancing the benefits against the risks.

In patients with pheochromocytoma bisoprolol must not be administered until after alpha-receptor blockade.

Under treatment with bisoprolol the symptoms of a thyreotoxicosis may be masked.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations not recommended

Calcium antagonists of the verapamil type and to a lesser extent of the diltiazem type: Negative influence on contractility and atrio-ventricular conduction. Intravenous administration of verapamil in patients on β -blocker treatment may lead to profound hypotension and atrioventricular block.

Class I antiarrhythmic drugs (e.g. quinidine, disopyramide; lidocaine, phenytoin; flecainide, propafenone): Effect on atrio-ventricular conduction time may be potentiated and negative inotropic effect increased.

Centrally acting antihypertensive drugs such as clonidine and others (e.g. methyldopa, moxonidine, rilmenidine): Concomitant use of centrally acting antihypertensive drugs may worsen heart failure by a decrease in the central sympathetic tonus (reduction of heart rate and cardiac output, vasodilation). Abrupt withdrawal, particularly if prior to beta-blocker discontinuation, may increase risk of "rebound hypertension".

Combinations to be used with caution

Calcium antagonists of the dihydropyridine type such as felodipine and amlodipine: Concomitant use may increase the risk of hypotension, and an increase in the risk of a further deterioration of the ventricular pump function in patients with heart failure cannot be excluded.

Class-III antiarrhythmic drugs (e.g. amiodarone): Effect on atrio-ventricular conduction time may be potentiated.

Topical beta-blockers (e.g. eye drops for glaucoma treatment) may add to the systemic effects of bisoprolol.

Parasympathomimetic drugs: Concomitant use may increase atrio-ventricular conduction time and the risk of bradycardia.

Insulin and oral antidiabetic drugs: Increase of blood sugar lowering effect. Blockade of beta-adrenoreceptors may mask symptoms of hypoglycaemia.

Anaesthetic agents: Attenuation of the reflex tachycardia and increase of the risk of hypotension (for further information on general anaesthesia see also section 4.4.).

Digitalis glycosides: Reduction of heart rate, increase of atrio-ventricular conduction time.

Non-steroidal anti-inflammatory drugs (NSAIDs): NSAIDs may reduce the hypotensive effect of bisoprolol.

β -Sympathomimetic agents (e.g. isoprenaline, dobutamine): Combination with bisoprolol may reduce the effect of both agents.

Sympathomimetics that activate both β - and α -adrenoceptors (e.g. noradrenaline, adrenaline): Combination with bisoprolol may unmask the α -adrenoceptor-mediated vasoconstrictor effects of these agents leading to blood pressure increase and exacerbated intermittent claudication. Such interactions are considered to be more likely with nonselective β -blockers.

Concomitant use with antihypertensive agents as well as with other drugs with blood pressure lowering potential (e.g. tricyclic antidepressants, barbiturates, phenothiazines) may increase the risk of hypotension.

Combinations to be considered

Mefloquine: increased risk of bradycardia

Monoamine oxidase inhibitors (except MAO-B inhibitors): Enhanced hypotensive effect of the beta-blockers but also risk for hypertensive crisis.

4.6 Fertility, pregnancy and lactation

Pregnancy

Bisoprolol has pharmacological effects that may cause harmful effects on pregnancy and/or the fetus/newborn. In general, beta-adrenoceptor blockers reduce placental perfusion, which has been associated with growth retardation, intrauterine death, abortion or early labour. Adverse effects (e.g. hypoglycaemia and bradycardia) may occur in the fetus and newborn infant. If treatment with beta-adrenoceptor blockers is necessary, beta₁-selective adrenoceptor blockers are preferable.

Bisoprolol should not be used during pregnancy unless clearly necessary. If treatment with bisoprolol is considered necessary, the uteroplacental blood flow and the fetal growth should be monitored. In case of harmful effects on pregnancy or the fetus alternative treatment should be considered. The newborn infant must be closely monitored. Symptoms of hypoglycaemia and bradycardia are generally to be expected within the first 3 days.

Breast-feeding

It is not known whether this drug is excreted in human milk. Therefore, breastfeeding is not recommended during administration of bisoprolol.

4.7 Effects on ability to drive and use machines

In a study with coronary heart disease patients bisoprolol did not impair driving performance. However, due to individual variations in reactions to the drug, the ability to drive a vehicle or to operate machinery may be impaired. This should be considered particularly at start of treatment and upon change of medication as well as in conjunction with alcohol.

4.8 Undesirable effects

The following definitions apply to the frequency terminology used hereafter:

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very rare ($< 1/10,000$)

Frequency not known (cannot be estimated from available data)

Cardiac disorders:

Very common: bradycardia.

Common: worsening of heart failure.

Uncommon: AV-conduction disturbances.

Investigations:

Rare: increased triglycerides, increased liver enzymes (ALAT, ASAT).

Nervous system disorders:

Common: dizziness, headache.

Rare: syncope

Eye disorders:

Rare: reduced tear flow (to be considered if the patient uses lenses).

Very rare: conjunctivitis.

Ear and labyrinth disorders:

Rare: hearing disorders.

Respiratory, thoracic and mediastinal disorders:

Uncommon: bronchospasm in patients with bronchial asthma or a history of obstructive airways disease.

Rare: allergic rhinitis.

Gastrointestinal disorders:

Common: gastrointestinal complaints such as nausea, vomiting, diarrhoea, constipation.

Skin and subcutaneous tissue disorders:

Rare: hypersensitivity reactions (pruritus, flush, rash and angioedema).

Very rare: alopecia. Beta-blockers may provoke or worsen psoriasis or induce psoriasis-like rash

Musculoskeletal and connective tissue disorders:

Uncommon: muscular weakness and cramps.

Vascular disorders:

Common: feeling of coldness or numbness in the extremities, hypotension.

Uncommon: orthostatic hypotension.

General disorders:

Common: asthenia, fatigue.

Hepatobiliary disorders:

Rare: hepatitis.

Reproductive system and breast disorders:

Rare: erectile dysfunction.

Psychiatric disorders:

Uncommon: sleep disorder, depression.

Rare: nightmare, hallucination.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via **the national reporting system listed in Appendix V***

4.9 Overdose

Symptoms

With overdose (e.g. daily dose of 15 mg instead of 7.5 mg) third degree AV-block, bradycardia, and dizziness have been reported. In general the most common signs expected with overdosage of a beta-blocker are bradycardia, hypotension, bronchospasm, acute cardiac insufficiency and hypoglycaemia. To date a few cases of overdose (maximum: 2000 mg) with bisoprolol have been reported in patients suffering from hypertension and/or coronary heart disease showing bradycardia and/or hypotension; all patients recovered. There is a wide interindividual variation in sensitivity to one single high dose of bisoprolol and patients with heart failure are probably very sensitive. Therefore it is mandatory to initiate the treatment of these patients with a gradual uptitration according to the scheme given in section 4.2.

Management

If overdose occurs, bisoprolol treatment should be stopped and supportive and symptomatic treatment should be provided. Limited data suggest that bisoprolol is hardly dialysable. Based on the expected pharmacologic actions and recommendations for other beta-blockers, the following general measures should be considered when clinically warranted.

Bradycardia: Administer intravenous atropine. If the response is inadequate, isoprenaline or another agent with positive chronotropic properties may be given cautiously. Under some circumstances, transvenous pacemaker insertion may be necessary.

Hypotension: Intravenous fluids and vasopressors should be administered. Intravenous glucagon may be useful.

AV block (second or third degree): Patients should be carefully monitored and treated with isoprenaline infusion or transvenous cardiac pacemaker insertion.

Acute worsening of heart failure: Administer i.v. diuretics, inotropic agents, vasodilating agents.

Bronchospasm: Administer bronchodilator therapy such as isoprenaline, beta₂-sympathomimetic drugs and/or aminophylline.

Hypoglycaemia: Administer i.v. glucose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Beta blocking agents, selective
ATC Code: C07AB07

Mechanism of action

Bisoprolol is a highly beta₁-selective-adrenoceptor blocking agent, lacking intrinsic stimulating and relevant membrane stabilising activity. It only shows low affinity to the beta₂-receptor of the smooth muscles of bronchi and vessels as well as to the beta₂-receptors concerned with metabolic regulation. Therefore, bisoprolol is generally not to be expected to influence the airway resistance and beta₂-mediated metabolic effects. Its beta₁-selectivity extends beyond the therapeutic dose range.

Clinical efficacy and safety

In total 2647 patients were included in the CIBIS II trial. 83% (n = 2202) were in NYHA class III and 17% (n = 445) were in NYHA class IV. They had stable symptomatic systolic heart failure (ejection fraction $\leq 35\%$, based on echocardiography). Total mortality was reduced from 17.3% to 11.8% (relative reduction 34%). A decrease in sudden death (3.6% vs 6.3%, relative reduction 44%) and a reduced number of heart failure episodes requiring hospital admission (12% vs 17.6%, relative reduction 36%) was observed. Finally, a significant improvement of the functional status according to NYHA classification has been shown. During the initiation and titration of bisoprolol hospital admission due to bradycardia (0.53%), hypotension (0.23%), and acute decompensation (4.97%) were observed, but they were not more frequent than in the placebo-group (0%, 0.3% and 6.74%). The numbers of fatal and disabling strokes during the total study period were 20 in the bisoprolol group and 15 in the placebo group.

The CIBIS III trial investigated 1010 patients aged ≥ 65 years with mild to moderate chronic heart failure (CHF; NYHA class II or III) and left ventricular ejection fraction $\leq 35\%$, who had not been treated previously with ACE inhibitors, beta-blockers, or angiotensin receptor blockers. Patients were treated with a combination of bisoprolol and enalapril for 6 to 24 months after an initial 6 months treatment with either bisoprolol or enalapril.

There was a trend toward higher frequency of chronic heart failure worsening when bisoprolol was used as the initial 6 months treatment. Non inferiority of bisoprolol-first versus enalapril-first treatment was not proven in the per-protocol analysis, although the two strategies for initiation of CHF treatment showed a similar rate of the primary combined endpoint death and hospitalization at study end (32.4% in the bisoprolol-first group vs. 33.1% in the enalapril-first group, per-protocol population). The study shows that bisoprolol can also be used in elderly chronic heart failure patients with mild to moderate disease.

Bisoprolol is also used for the treatment of hypertension and angina.

In acute administration in patients with coronary heart disease without chronic heart failure bisoprolol reduces the heart rate and stroke volume and thus the cardiac output and oxygen consumption. In chronic administration the initially elevated peripheral resistance decreases.

5.2 Pharmacokinetic properties

Absorption

Bisoprolol is absorbed and has a biological availability of about 90% after oral administration.

Distribution

The distribution volume is 3.5 l/kg. The plasma protein binding of bisoprolol is about 30%.

Biotransformation and Elimination

Bisoprolol is excreted from the body by two routes. 50% is metabolised by the liver to inactive metabolites which are then excreted by the kidneys. The remaining 50% is excreted by the kidneys in an unmetabolised form. Total clearance is approximately 15 l/h. The half-life in plasma of 10-12 hours gives a 24 hour effect after dosing once daily.

Linearity

The kinetics of bisoprolol are linear and independent of age.

Special population

Since the elimination takes place in the kidneys and the liver to the same extent a dosage adjustment is not required for patients with impaired liver function or renal insufficiency. The pharmacokinetics in patients with stable chronic heart failure and with impaired liver or renal function has not been studied. In patients with chronic heart failure (NYHA stage III) the plasma levels of bisoprolol are higher and the half-life is prolonged compared to healthy volunteers. Maximum plasma concentration at steady state is 64 ± 21 ng/ml at a daily dose of 10 mg and the half-life is 17 ± 5 hours.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or carcinogenicity. Like other beta-blockers, bisoprolol caused maternal (decreased food intake and decreased body weight) and embryo/fetal toxicity (increased incidence of resorptions, reduced birth weight of the offspring, retarded physical development) at high doses but was not teratogenic.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emconcor CHF 1.25 mg

Tablet core: Silica, colloidal anhydrous; magnesium stearate, crospovidone, pregelatinised maize starch, maize starch, microcrystalline cellulose, calcium hydrogen phosphate, anhydrous.
Film coating: Dimethicone, talc, macrogol 400, titanium dioxide (E171), hypromellose.

Emconcor CHF 2.5 mg

Tablet core: Silica, colloidal anhydrous; magnesium stearate, crospovidone, microcrystalline cellulose, maize starch, calcium hydrogen phosphate, anhydrous.
Film coating: Dimethicone, macrogol 400, titanium dioxide (E171), hypromellose.

Emconcor CHF 3.75 mg

Tablet core: Silica, colloidal anhydrous; magnesium stearate, crospovidone, microcrystalline cellulose, maize starch, calcium hydrogen phosphate, anhydrous.
Film coating: Iron oxide yellow (E172), dimethicone, macrogol 400, titanium dioxide (E171), hypromellose.

Emconcor CHF 5 mg

Tablet core: Silica, colloidal anhydrous; magnesium stearate, crospovidone, microcrystalline cellulose, maize starch, calcium hydrogen phosphate, anhydrous.
Film coating: Iron oxide yellow (E172), dimethicone, macrogol 400, titanium dioxide (E171), hypromellose.

Emconcor CHF 7.5 mg

Tablet core: Silica, colloidal anhydrous, magnesium stearate, crospovidone, microcrystalline cellulose, maize starch, calcium hydrogen phosphate, anhydrous.

Film coating: Iron oxide yellow (E172), dimethicone, macrogol 400, titanium dioxide (E171), hypromellose.

Emconcor CHF 10 mg

Tablet core: Silica, colloidal anhydrous; magnesium stearate, crospovidone, microcrystalline cellulose, maize starch, calcium hydrogen phosphate, anhydrous.

Film coating: Iron oxide red (E172), iron oxide yellow (E172), dimethicone, macrogol 400, titanium dioxide (E171), hypromellose.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life for PVC/Alu blister

Emconcor CHF 1.25 mg, 2.5 mg and 3.75 mg

3 years.

Emconcor CHF 5 mg, 7.5 mg and 10 mg

5 years.

Shelf life for Alu/Alu blister

Emconcor CHF 1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg and 10 mg

3 years.

6.4 Special precautions for storage

Storage conditions for PVC/Alu blister

Emconcor CHF 1.25 mg, 2.5 mg and 3.75 mg

Do not store above 25 °C.

Emconcor CHF 5 mg, 7.5 mg and 10 mg

Do not store above 30 °C.

Storage conditions for Alu/Alu blister

Emconcor CHF 1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg and 10 mg

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The container is a blister, which is made of a polyvinylchloride base film and an aluminium cover foil.
The container is a blister, which is made of an aluminium forming foil and an aluminium sealing foil.

Pack sizes: 20, 28, 30, 50, 56, 60, 90 and 100 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBERS

Emconcor CHF 1.25 mg	15371
Emconcor CHF 2.5 mg	15229
Emconcor CHF 3.75 mg	15372
Emconcor CHF 5 mg	15373
Emconcor CHF 7.5 mg	15230
Emconcor CHF 10 mg	15231

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4 June 1999

Date of latest renewal: 4 June 2009

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTERPACK

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 1.25 mg film-coated tablets
Bisoprolol fumarate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 1.25 mg bisoprolol fumarate.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
56 film-coated tablets
60 film-coated tablets
90 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Storage conditions for PVC/Alu blister
Do not store above 25°C.

Storage conditions for Alu/Alu blister
This medicinal product does not require any special storage conditions.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

15371

[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 1.25 mg film-coated tablets
Bisoprolol fumarate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTERPACK

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 2.5 mg film-coated tablets
Bisoprolol fumarate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 2.5 mg bisoprolol fumarate.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
56 film-coated tablets
60 film-coated tablets
90 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Storage conditions for PVC/Alu blister
Do not store above 25°C.

Storage conditions for Alu/Alu blister
This medicinal product does not require any special storage conditions.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

15229

[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 2.5 mg film-coated tablets
Bisoprolol fumarate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTERPACK

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 3.75 mg film-coated tablets
Bisoprolol fumarate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 3.75 mg bisoprolol fumarate.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
56 film-coated tablets
60 film-coated tablets
90 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Storage conditions for PVC/Alu blister
Do not store above 25°C.

Storage conditions for Alu/Alu blister
This medicinal product does not require any special storage conditions.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

15372
[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 3.75 mg film-coated tablets
Bisoprolol fumarate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTERPACK

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 5 mg film-coated tablets
Bisoprolol fumarate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 5 mg bisoprolol fumarate.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
56 film-coated tablets
60 film-coated tablets
90 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Storage conditions for PVC/Alu blister
Do not store above 30°C.

Storage conditions for Alu/Alu blister
This medicinal product does not require any special storage conditions.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

15373

[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 5 mg film-coated tablets
Bisoprolol fumarate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTERPACK

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 7.5 mg film-coated tablets
Bisoprolol fumarate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 7.5 mg bisoprolol fumarate.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
56 film-coated tablets
60 film-coated tablets
90 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Storage conditions for PVC/Alu blister
Do not store above 30°C.

Storage conditions for Alu/Alu blister
This medicinal product does not require any special storage conditions.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

15230

[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 7.5 mg film-coated tablets
Bisoprolol fumarate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTERPACK

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 10 mg film-coated tablets
Bisoprolol fumarate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 10 mg bisoprolol fumarate.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
56 film-coated tablets
60 film-coated tablets
90 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Storage conditions for PVC/Alu blister
Do not store above 30°C.

Storage conditions for Alu/Alu blister
This medicinal product does not require any special storage conditions.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

15231

[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Emconcor CHF 10 mg film-coated tablets
Bisoprolol fumarate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PACKAGE LEAFLET

Package leaflet: Information for the user

Emconcor CHF 1.25 mg film-coated tablets
Emconcor CHF 2.5 mg film-coated tablets
Emconcor CHF 3.75 mg film-coated tablets
Emconcor CHF 5 mg film-coated tablets
Emconcor CHF 7.5 mg film-coated tablets
Emconcor CHF 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 your pharmacist.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Emconcor CHF is and what it is used for

The active substance in Emconcor CHF 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. Emconcor CHF is used to treat stable chronic heart failure. It is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides).

2. What you need to know before you take Emconcor CHF

Do not take Emconcor CHF

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

- allergy (hypersensitivity) to bisoprolol or to any of the other ingredients (see section 6 'What Emconcor CHF 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 when there is too much acid in the blood.

Do not take Emconcor CHF if you have one of the following heart problems:

- acute heart failure
- worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart
- slow heart rate
- low blood pressure
- certain heart conditions causing a very slow heart rate or irregular heartbeat
- cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.

Warnings and precautions

If you have any of the following conditions tell your doctor before taking Emconcor CHF; 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 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 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 Emconcor CHF may make it more likely that you experience an allergic reaction, or such reaction may be more severe
- anaesthesia (for example for surgery), because Emconcor CHF 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 Emconcor CHF.

Children and adolescents

Emconcor CHF is not recommended for use in children or adolescents.

Other medicines and Emconcor CHF

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

Do not take the following medicines with Emconcor CHF without special advice from your doctor:

- certain medicines used to treat irregular or abnormal heartbeat (Class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone)
- certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (calcium antagonists such as verapamil and diltiazem)
- certain medicines used to treat high blood pressure such as clonidine, methyl dopa, 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 Emconcor CHF; your doctor may need to check your condition more frequently:

- certain medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonists such as felodipine and amlodipine)
- certain medicines used to treat irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone)
- beta-blockers applied locally (such as timolol eye drops for glaucoma treatment)
- certain medicines used to treat for example Alzheimer's disease or glaucoma (parasympathomimetics such as tacrine or carbachol) or medicines that are used to treat acute heart problems (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)
- 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 Emconcor CHF 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 Emconcor CHF during pregnancy.

Breast-feeding

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

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 Emconcor CHF

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

Treatment with Emconcor CHF requires regular monitoring by your doctor. This is particularly necessary at the start of treatment, during dose increase, and when you stop treatment.

Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet. The scored tablets can be divided into two equal doses.

Treatment with Emconcor CHF is usually long-term.

Adults including the elderly

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

The maximum recommended daily dose is 10 mg bisoprolol.

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 may be sufficient.

Your doctor will tell you what to do.

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.

If you take more Emconcor CHF than you should

If you have taken more Emconcor CHF 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, severe difficulty in breathing feeling dizzy, or trembling (due to decreased blood sugar).

If you forget to take Emconcor CHF

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

If you stop taking Emconcor CHF

Never stop taking Emconcor CHF 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, this medicine can cause side effects, although not everybody gets them.

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

The most serious side effects are related to the heart function:

- slowing of heart rate (may affect more than 1 in 10 people)
- worsening of heart failure (may affect up to 1 in 10 people)
- slow or irregular heartbeat (may affect up to 1 in 100 people)

If you feel dizzy or weak, or have breathing difficulties please contact your doctor as soon as possible.

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

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

- tiredness, feeling weak, 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):

- sleep disturbances
- depression
- dizziness when standing up
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps.

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

- hearing problems
- allergic runny nose
- reduced tear flow
- inflammation of the liver which can cause yellowing of the skin or 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. You should see your doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.
- 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report the side effects directly [via the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emconcor CHF

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last date of that month.

Storage conditions for PVC/Alu blister

Emconcor CHF 1.25 mg film-coated tablets:

Emconcor CHF 2.5 mg film-coated tablets:

Emconcor CHF 3.75 mg film-coated tablets:

- Do not store above 25°C.

Emconcor CHF 5 mg film-coated tablets:

Emconcor CHF 7.5 mg film-coated tablets:

Emconcor CHF 10 mg film-coated tablets:

- Do not store above 30°C.

Storage conditions for Alu/Alu blister

Emconcor CHF 1.25 mg film-coated tablets:

Emconcor CHF 2.5 mg film-coated tablets:

Emconcor CHF 3.75 mg film-coated tablets:

Emconcor CHF 5 mg film-coated tablets:

Emconcor CHF 7.5 mg film-coated tablets:

Emconcor CHF 10 mg film-coated tablets:

- This medicine does not require any special storage conditions.

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 Emconcor CHF contains

Emconcor CHF 1.25 mg film-coated tablets

- The active substance is bisoprolol fumarate. Each film-coated tablet contains 1.25 mg.
- The other ingredients are:

Tablet core: Silica, colloidal anhydrous; magnesium stearate; crospovidone; pregelatinised maize starch; maize starch; microcrystalline cellulose; calcium hydrogen phosphate (anhydrous).

Film coating: dimethicone; talc; macrogol 400; titanium dioxide (E171); hypromellose.

Emconcor CHF 2.5 mg film-coated tablets

- 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 (E171); hypromellose.

Emconcor CHF 3.75 mg film-coated tablets

- The active substance is bisoprolol fumarate. Each film-coated tablet contains 3.75 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.

Emconcor CHF 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.

Emconcor CHF 7.5 mg film-coated tablets

- The active substance is bisoprolol fumarate. Each film-coated tablet contains 7.5 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.

Emconcor CHF 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 Emconcor CHF looks like and contents of the pack

Emconcor CHF 1.25 mg film-coated tablets are white and round.
Emconcor CHF 2.5 mg film-coated tablets are white and heart-shaped with a break-line on both sides.
Emconcor CHF 3.75 mg film-coated tablets are off-white and heart-shaped with a break-line on both sides.
Emconcor CHF 5 mg film-coated tablets are yellowish-white and heart-shaped with a break-line on both sides.
Emconcor CHF 7.5 mg film-coated tablets are pale yellow and heart-shaped with a break-line on both sides.
Emconcor CHF 10 mg film-coated tablets are pale orange – light orange and heart-shaped with a break-line on both sides.
Each pack contains 20, 28, 30, 50, 56, 60, 90, or 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt, Germany
P&G Health Austria GmbH & Co. OG, Hösslgasse 20, 9800 Spittal/Drau, Austria
Merck S.L., Polígono Merck, Mollet del Vallés, 08100 Barcelona, Spain
[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Concor COR
Croatia:	Concor COR
Finland:	Emconcor CHF
France:	Cardensiel
Germany:	Concor COR
Ireland:	Cardicor
Italy:	Sequacor
Luxembourg:	Concor Cor
Netherlands:	Emcor Deco
Portugal:	Concor IC
Spain:	EMCONCOR COR
Sweden:	Emconcor CHF
United Kingdom:	Cardicor

This leaflet was last revised in.