Koreg®

Carvedilol INN

Presentation
Koreg® 6.25 : Each film coated tablet contains carvedilol INN 6.25 mg
Koreg® 12.5 : Each film coated tablet contains carvedilol INN 12.5 mg
Koreg® 25 : Each film coated tablet contains carvedilol INN 25 mg

Properties and effects
Carvedilol is a multiple-action neurohormonal antagonist consisting of non-selective beta blockade, alpha 1-blockade.

Absorption
Following oral administration, maximum serum concentration is reached after approximately 1h. Approximately 98 to 99% of carvedilol is bound to plasma protein

Metabolism
Carvedilol is extensively metabolized into a variety of metabolites which are mainly eliminated in bile. The first pass effect after oral administration amounts to about 60-75%.

Elimination
The average elimination half-life of carvedilol ranges from 6 to 10 hours. Plasma clearance is approximately 590 ml/minute.
The primary route of excretion is via the feces. A minor part is eliminated via the kidneys.

Bioavailability
The absolute bioavailability of carvedilol in human is approximately 25%. Food does not affect the extent of bioavailability.

Indications and uses
Essential hypertension: Koreg® is indicated for the management of essential hypertension. It can be used alone or in combination with other anti hypertensive agents, especially thiazide type diuretics.

Treatment of angina pectoris
The recommended doses for initiation therapy is 12.5mg twice a day for the first two days. Thereafter the recommended dosage is 25 mg twice a day. The maximum daily dose for elderly patients is 50 mg in divided doses (twice daily).
Treatment of congestive heart failure: Dosage must be individualized and closely monitored by a physician during up-titration. Prior to initiation of Koreg®, it is recommended that fluid retention be minimized. The recommended starting dose of carvedilol is 3.125mg,twice daily for 2 weeks. Patients who tolerate a dose of 3.125 mg twice daily may have their dose increased to 6.25,12.5, and 25mg twice daily over successive intervals of at least 2 weeks. A maximum dose of 50 mg twice daily has been administered to patients with mild to moderate heart failure weighing over 85 kg (187 lbs).
If carvedilol treatment is discontinued for more than two weeks,therapy should be recommended at 3.125 mg twice daily and up-titrated in line with the above dosing recommendation.

Contraindications
Koreg® is contraindicated in patients with bronchial asthma or related bronchospastic conditions, second-or third degree AV block, sick sinus syndrome or severe bradycardia or in patients with cardiogenic shock.
Use of Koreg® in patients with clinically manifest hepatic impairment is not recommended.
Koreg® is contraindicated in patients with hypersensitivity to any compotent of the product.

Pregnancy, nursing mother
There is no adequate experience with koreg® in pregnant women. Koreg® should be used during pregnancy only if the potential benefit justifies the risk. Carvedilol and/or its metabolites are excreted in breast milk.

Adverse effect
Body as a whole : Allergy,malaise,hypovolaemia,fever,leg oedema.

Cardiovascular : Fluid overload,postural hypotension,aggravated angina pectoris, AV block, palpitation, hypertension.

Central and peripheral nervous system : Hypesthesia, vertigo, paresthesia.

Gastrointestiinal : Melena, periodontitis.

Liver and biliary system : SGPT increased, SGOT increased.

Metabolic and nutritional : Hyperuricemia,hypoglycemia,hyponatremia,increased alklaline phosphatase,glycosuria,hypervolemia,diabetes mellitus,GGT increased,weight loss, Hyperkalaemia, creatinine increased.

Musculoskeletal : Muscle cramps.

Interactions
Koreg® may potentiate the effect of other concomitantly administered drugs that are antihypertensive in action (e.g. alpha-receptor antagonists) or have hypotension as part of their adverse effect profile.
Careful monitoring of ECG and blood pressure should be undertaken when concomitantly administering calcium channel blockers of the verapamil or diltiazem type, or class 1 anti arrhythmic drug.
The effects of insulin or oral hypoglycemics may enhance, the signs and symptoms of hypoglycemia may be masked or attenuated (especially tachycardia) Regular monitoring of blood glucose is therefore recommended.
Care may be required in those patients receiving Inducers of mixed function oxidases. Careful attention must be paid during anesthesia to the synergistic negative inotropic and hypotensive effects of Koreg® and anesthetic drugs.
Concomitant administration of carvedilol and cardiac glycosides may prolong AV conduction time.

Special remarks
In patients who have congestive heart failure controlled with digitalis, diuretics and/or an ACE inhibitor, Koreg should be used with caution.
In CHF patients, renal function should be monitored during up-titration of Koreg®.
In congestive heart failure patients, worsening cardiac failure or fluid retention may occur during up-titration of Koreg.® Koreg® should only be used in patients with chronic obstructive pulmonary disease (COPD) with a bronchospastic component not receiving oral or inhaled medication if the potential benefit out-weighs the potential risk.
Koreg® treatment should not be discontinued abruptly, particularly in patients suffering from Ischemic heart disease. The withdrawal of Koreg® in these patients should be gradual (I - 2 weeks).
Koreg® like other agents with beta-blocking properties, may obscure the symptoms of thyrotoxicosis.
Patients with a history of psoriasis associated with beta-blocker therapy should take carvedilol only after consideration of the risk-benefit ratio.
Caution should be taken in the administration of Koreg® to patients suspected of having pheochromocytoma.
Koreg® should be used with caution in patients with peripheral vascular disease as beta-blockers can be precipitate or aggravate symptoms of arterial insufficiency.
Caution should be exercised inpatients undergoing general surgery. Because of the synergistic negative ionotropic and hypotensive effects of Koreg® and anesthetic drugs.
Medicine : keep out of children

Commercial pack
Koreg® 6.25 : 30 tablets in blister pack
Koreg® 12.5 : 30 tablets in blister pack
Koreg® 25 : 30 tablets in blister pack

Manufactured by :
Silva
Pharmaceuticals Limited
Maijdee, Noakhali, Bangladesh