COMPOSITION :

Each film coated tablet contains :
Carvedilol BP 3.125 mg
Excipients q.s.
Colours : Quinoline Yellow & Titanium Dioxide BP

Dosage : As directed by the Physician.
Storage : Store below 30°C, Protect from light & moisture.
Keep the medicine out of reach of children .

Manufactured for :
Tamar & Pharez Nig. Ltd.
No. 2 Nyerere Street Narayi High Cost,
Barnawa, Kaduna (NIGERIA)

Manufactured in India by :
MAXTAR BIO-GENICS
Khasra No. 705, Vill. Malku Majra, Nalagarh Road,
Baddi, Distt. Solan-173205 (H.P.)-India

Mfg. Lic. No. : MNB/07/509
Batch No. :
Mfg. Date :
Exp. Date :

Carvebloc-3.125
Carvedilol Tablets BP

Carvebloc-3.125
Carvedilol Tablets BP

8 906041 276928

Carvebloc-3.125
Carvedilol Tablets BP

Carvebloc-3.125
Carvedilol Tablets BP

2 x 14 Tablets

PRESCRIPTION ONLY MEDICINE
KEEP THE MEDICINE OUT OF REACH OF CHILDREN

NAFDAC REG. NO. :

Carvebloc-3.125
Carvedilol Tablets BP

SIZE : 75 X 180 MM FRONT

SIZE : 75 X 180 MM BACK

Carvebloc-3.125

Carvedilol Tablets BP

COMPOSITION:
Each film coated tablet contains:
Carvedilol BP 3.125 mg
Excipients q.s.
Colours : Quinoline Yellow & Titanium Dioxide BP

PHARMACOLOGICAL CLASSIFICATION:
Alpha and beta blocking agent
Pharmacological Action: Carvedilol is a vasodilatory non-selective beta-blocker, which reduces the peripheral vascular resistance by selective alpha 1- receptor blockade and suppresses the renin-angiotensin system through non-selective beta-blockade. Plasma renin activity is reduced and fluid retention is rare.
Pharmacokinetics:
Absorption: Carvedilol is rapidly absorbed after oral administration. In healthy subjects, maximum serum concentration is achieved approximately 1 hour after administration. The absolute bioavailability of carvedilol in humans is approximately 25%.
There is a linear relationship between dose and serum concentrations of carvedilol. Food intake did not affect the bioavailability or the maximum serum concentration, although the time needed to reach maximum serum concentration is prolonged.
Distribution: Carvedilol is highly lipophilic. The plasma protein binding is about 98 to 99%. The volume of distribution is approximately 2 l / kg and increases in patients with liver cirrhosis.
Biotransformation: In humans and in animal species studied, carvedilol is extensively metabolized to several metabolites which are excreted primarily in bile. The first pass effect after oral administration is about 60-75%. The enterohepatic circulation of the parent substance was demonstrated in animals. Carvedilol is extensively metabolized in the liver, glucuronidation being one of the main reactions. The demethylation and hydroxylation at the phenol ring produce 3 active metabolites with blocking activity of beta-adrenergic receptors.
Elimination: The average half-life of elimination of carvedilol is approximately 6 hours. The plasma clearance is approximately 500-700 ml / min. Elimination is mainly via the bile, and excretion mainly via the faeces. A minor part is eliminated renally in the form of various metabolites.

INDICATIONS:
Essential hypertension, Chronic stable angina pectoris, Adjunctive treatment of moderate to severe stable chronic heart failure.

DOSAGE:
Essential Hypertension
Adults: The recommended initial dose is 12.5 mg once a day for the first two days. Thereafter, the treatment is continued at the dose 25 mg/day. If necessary, the dose may be further increased gradually at intervals of two weeks or more rarely.
Elderly: The recommended initial dose in hypertension is 12.5 mg once a day which may also be sufficient for continued treatment. However, if the therapeutic response is inadequate at this dose, the dose may be further increased gradually at intervals of two weeks or more rarely.
Chronic stable angina pectoris
Adults: The recommended initial dosage is 12.5 mg twice a day for the first two days. Thereafter, the treatment is continued at the dose 25 mg twice a day.
Elderly: The recommended initial dose is 12.5 mg twice daily for two days. Thereafter, the treatment is continued at the dose 25 mg twice daily, which is the recommended maximum daily dose.
Heart Failure: The initial dose is 3.125 mg twice a day for two weeks. If this dose is tolerated, the dose may be increased slowly with intervals of not less than two weeks up to 6.25 mg twice a day, then up to 12.5 mg twice a day and finally up to 25 mg twice a day. The dosage should be increased to the highest tolerable level. The recommended maximum dosage is 25 mg twice a day for patients with a body weight of less than 85 kg, and 50 mg twice a day for patients with a body weight above 85 kg, provided that the heart failure is not severe. A dose increase to 50 mg twice daily should be performed carefully under close medical supervision of the patient.

WARNING:
Warnings to be considered particularly in heart failure patients: In chronic heart failure patients carvedilol should be administered principally in addition to diuretics, ACE inhibitors, digitalis and/or vasodilators. Initiation of therapy should be under the supervision of a hospital physician. Therapy should only be initiated, if the patient is stabilized on conventional basic therapy for at least 4 weeks.
Reversible deterioration of renal function has been observed during carvedilol therapy in heart failure patients with low blood pressure (systolic < 100 mm Hg), ischaemic heart disease and generalized atherosclerosis, and/or underlying renal insufficiency. In heart failure patients with these risk factors, renal function should be monitored during dose titration of carvedilol. If significant worsening of renal function occurs, the carvedilol dose must be reduced or therapy must be discontinued.
In patients with chronic heart failure treated with digitalis, carvedilol should be given with caution, as digitalis and carvedilol both lengthen the AV conduction time.
Other warnings as regards carvedilol and beta-blockers in general
Agents with non-selective beta-blocking activity may provoke chest pain in patients with Prinzmetal's variant angina.
Patients with a chronic obstructive pulmonary disease with a tendency towards bronchospasms who are not treated with oral or inhalation medicine should only be given carvedilol if the expected improvement outweighs the possible risk.
Carvedilol may mask symptoms and signs of acute hypoglycaemia
Carvedilol may mask features (symptoms and signs) of thyrotoxicosis.
Carvedilol may cause bradycardia.
Care should be taken in administrating carvedilol to patients with a history of serious hypersensitivity reactions and in those undergoing desensitisation therapy as beta-blockers may increase both the sensitivity towards allergens and the seriousness of anaphylactic reactions. Cautions should be exercised when prescribing beta-blockers to patients with psoriasis since skin reactions may be aggravated.
Carvedilol should be used with caution in patients with peripheral vascular diseases, as beta-blockers may aggravate symptoms of the disease.
Patients who are known as poor metabolizers of debrisoquine, should be closely monitored during initiation of therapy.

PREGNANCY AND LACTATION:
Carvedilol should not be used during pregnancy unless clearly necessary (that is if the potential benefit for the mother outweighs the potential risk for the fetus/neonate). The treatment should be stopped 2-3 days before expected birth. If this is not possible the new-born has to be monitored for the first 2-3 days of life.
Breast feeding: Carvedilol is lipophilic and according to results from studies with lactating animals, carvedilol and its metabolites are excreted in breast milk and, therefore, mothers receiving carvedilol should not breast-feed.

CONTRAINDICATIONS:
o Heart failure belonging to NYHA Class IV of the heart failure classification with marked fluid retention or overload requiring intravenous inotropic treatment.
- Chronic obstructive pulmonary disease with bronchial obstruction
- Clinically significant hepatic dysfunction.
- Bronchial asthma.
- AV block, degree II or III (unless a permanent pacemaker is in place).
- Severe bradycardia (<50 bpm).
- Sick sinus syndrome (incl. sino-atrial block).
- Cardiogenic shock.
- Severe hypotension (systolic blood pressure below 85 mmHg).
- Prinzmetal's angina.
- Untreated phaeochromocytoma.
- Metabolic acidosis.
- Severe peripheral arterial circulatory disturbances.

Concomitant intravenous treatment with verapamil or diltiazem.

ADVERSE EFFECTS:
Dizziness, lightheadedness, drowsiness, diarrhea, impotence, or tiredness may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Tell your doctor right away if you have any serious side effects, including: very slow heartbeat, severe dizziness, fainting, unusual weakness, signs of kidney problems (such as change in the amount of urine), numbness/tingling of the hands/feet, blue fingers/toes, easy bruising/bleeding, mental/mood changes (such as confusion, depression), seizures.

List of Excipients:
Microcrystalline Cellulose, Lactose, Colloidal Silicon Dioxide, Cross Povidone, Sodium starch glycolate, Sodium lauryl sulphate, Magnesium Stearate, Hydroxy Propyl Methyl Cellulose E-15, Polyethylene Glycol 6000, Titanium dioxide, Quinoline Yellow Lake, Isopropyl Alcohol, Methylene Dichloride & Purified talc.

STORAGE CONDITIONS: Store below 30°C. Protect from light & moisture.
Keep the medicine out of reach of children.

PRESENTATION: 2 x 14 Tablets in Alu-Alu Pack.

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JOB CODE : 3THL-00
DATE : 10.11.2023