PATIENT INFORMATION LEAFLET
(CARVILIN) CARVEDILOL USP 6.25 MG & 12.5 MG TABLETS
[Carvedilol USP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others.

It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. WHAT CARVEDILOL TABLETS IS AND WHAT IT IS USED FOR

It contain active ingredient Carvedilol, medicines known as alpha and beta blocking agent. It has no intrinsic sympathomimetic activity and reduces the peripheral vascular resistance by selective alpha1-receptor blockade and suppresses renin angiotensin through non-selective beta-blockade. It is indicated for treatment of mild-to-severe chronic heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis. It is also indicated in left ventricular dysfunction following myocardial infarction and for the management of essential hypertension as alone or in combination with other antihypertensive agents, especially thiazide-type diuretics.

2. BEFORE YOU USE CARVEDILOL TABLETS

It is contraindicated in patient history of serious hypersensitivity to carvedilol or to any of excipients. In patient with bronchial asthma or related bronchospastic conditions, Second-or third-degree AV block, Sick sinus syndrome, severe bradycardia, hypotension & metabolic acidosis. In patients with severe hepatic impairment, cardiogenic shock or who have decompensated heart failure requiring use of intravenous inotropic therapy.

Take special care with carvedilol tablets: Warnings and Precautions: Talk to your physician before taking carvedilol tablets. It should be discontinued over 1 to 2 weeks whenever possible. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias upon abrupt cessation of therapy were observed. It may cause bradycardia, heart failure, hypotension and postural hypotension, syncope, worsening heart failure/fluid retention. Starting with low dose of carvedilol, administration with food, and gradual up-titration of carvedilol should decrease likelihood of syncope or excessive hypotension. Plasma levels of carvedilol average about 50% higher in elderly compared with young subjects. Avoid carvedilol in patients with bronchospastic disease (e.g., chronic bronchitis and emphysema However, if deemed necessary, use with caution and at lowest effective dose. In diabetic patients, monitor glucose as carvedilol may mask symptoms of hypoglycemia or worsen hyperglycemia. **Using other medicines:** Tell your physician if you are taking inhibitors of CYP2D6 iso-enzyme, such as quinidine, fluoxetine, paroxetine, and propafenone, may increase

blood levels of R(+) enantiomer of carvedilol. Patients taking carvedilol with reserpine and MAO inhibitors should be observed closely for signs of hypotension and/or severe bradycardia. Cyclosporine concentrations be monitored closely after initiation of carvedilol therapy due to modest increases in mean trough cyclosporine concentrations. Concomitant use of digitalis glycosides and carvedilol can increase the risk of bradycardia. Rifampicin reduced plasma concentrations of carvedilol by about 70%. Amiodarone, and its metabolite desethyl amiodarone, inhibitors of CYP2C9 and P-glycoprotein increased concentrations of S(-)-enantiomer of carvedilol by at least 2fold. Concomitant administration of amiodarone or other CYP2C9 inhibitors such as fluconazole with carvedilol may enhance β-blocking properties of carvedilol resulting in further slowing of heart rate or cardiac conduction. Conduction disturbance has been observed when carvedilol is co-administered with diltiazem. It may enhance blood-sugar-reducing effect of insulin and oral hypoglycemics. **Using carvedilol tablets with food and drink:** It may be taken with or without food or as directed by physician. **Pregnancy and breast-feeding:** Before taking any medicine for advice consult to direction of **physician. Pregnancy: Pregnancy:** It should be used during pregnancy only if potential benefit justifies the potential risk to the fetus. **Use in breast-feeding:** It is not recommended in nursing mothers receiving carvedilol. **Driving and using machines:** It may cause dizziness, tiredness or faintness. It is advisable not to drive a car, use machinery, or do anything that needs the patient to be alert if these symptoms are observed. **Important information about some of the ingredients of carvedilol tablets contains excipients with known effects:** lactose monohydrate: patients with rare hereditary problems of galactose intolerance, total-lactase deficiency or glucose-galactose malabsorption should not take this medicine, colour sunset yellow supra: May cause allergic reactions. Talk to your physician.

3. HOW TO USE CARVEDILOL TABLETS

It should be taken as directed by physician. Take your normal dose immediately and continue taking your tablets at the usual time of day, do not take a double dose to make up for the missed dose. Do not change your usual dose without talking to physician.

Method of administration: *For oral use only*. It may be taken with or without food or as directed by physician. It should be swallowed with a glass of water. Break line found on one side of the tablets is not meant to facilitate dosing of the product. Dose must be individualise. Patients should be maintained on lower doses if higher doses are not tolerated.

The usual recommended doses: Heart Failure: Recommended starting dose of carvedilol is 3.125 mg twice a day for two weeks. If well tolerated, 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. Fluid retention should be treated by diuretics. Reduce the dose if patients experience bradycardia. **Left Ventricular Dysfunction following Myocardial Infarction:** Recommended starting dose of carvedilol is 6.25 mg twice daily and increased after 3 to 10 days, based on tolerability, to 12.5 mg twice daily, then again to the target dose of 25 mg twice daily. A lower starting dose may be used (3.125 mg twice daily) and/or the rate of up-titration may be slowed if clinically indicated (e.g., due to low blood pressure or heart rate, or fluid retention). **Hypertension:** Recommended starting dose of carvedilol is 6.25 mg twice daily. If this dose is tolerated, using standing systolic pressure measured about 1 hour after dosing as a guide, the dose should be maintained for 7 to 14 days, and then increased to 12.5 mg twice daily if needed, based on trough blood pressure, again using standing systolic pressure 1 hour after dosing as a guide for tolerance. This dose should also be maintained for 7 to 14 days and can then be adjusted upward to 25 mg twice daily if tolerated and needed. Total daily dose should not exceed 50 mg. Concomitant administration with a diuretic can

be expected to produce additive effects and exaggerate the orthostatic component of carvedilol action.

If you more carvedilol tablets than you should: If you accidentally take too many tablets, contact your Physician immediately. Hypotension, bradycardia, cardiac insufficiency, cardiogenic shock, and cardiac arrest. Respiratory problems, bronchospasms, vomiting, lapses of consciousness, and generalized seizures. supportive treatment should be instituted. Administer Atropine 2 mg IV for excessive bradycardia. To support cardiovascular function, administer glucagon, 5 to 10 mg IV rapidly over 30 seconds, followed by continuous infusion of 5 mg/hour and sympathomimetics (dobutamine, isoprenaline, adrenaline) at doses according to body weight and effect. Supportive treatment should be continued for a sufficiently long period of time.

If you forget to carvedilol tablets: If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Asthenia, fatigue, increased digoxin level, generalized edema, dependent edema, allergy, malaise, hypovolemia, fever, leg edema, dry mouth, sweting. Bradycardia, hypotension, syncope, angina pectoris, fluid overload, postural hypotension, aggravated angina pectoris, AV block, palpitation, hypertension, peripheral ischemia, tachycardia. Dizziness, headache, hypesthesia, vertigo, paresthesia, somnolence, insomnia, hypokinesia, nervousness, sleep disorder, aggravated depression, impaired concentration, abnormal thinking, paroniria, emotional lability. Diarrhea, nausea, vomiting, melena, periodontitis, bilirubinemia, increased hepatic enzymes. Hyperglycemia, weight increase, increased BUN, increased NPN, hypercholesterolemia, peripheral edema, hyperuricemia, hypoglycemia, hyponatremia, increased alkaline phosphatase, glycosuria, hypervolemia, diabetes mellitus, GGT increased, weight loss, hyperkalemia, increased creatinine. Arthralgia, muscle cramps. Increased cough, rales, asthma. Decreased prothrombin, purpura, thrombocytopenia. Abnormal vision, blurred vision, tinnitus. Urinary and Reproductive system: Decreased libido, Impotence, renal insufficiency, albuminuria, hematuria, increased micturition. Pruritus, rash erythematous, rash maculopapular, rash psoriaform, photosensitivity reaction.

5. HOW TO STORE CARVEDILOL TABLETS

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light.. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as carvedilol USP. Each film coated tablet contains: carvedilol USP 6.25 mg/12.5 mg. **Excipients:** Lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, crospovidone, magnesium stearate, colour sunset yellow orange SC-SP-2029, dichloromethane, isopropyl alcohol. **Pack size:** Orange coloured, round shaped, biconvex, film coated tablet, break line on one sides and plain on other side, tablets filled in Alu-PVC Blister Pack.2x14 Tablets are in Alu-PVC Blister Pack. Such 2 Alu-Alu blisters are packed in a printed carton along with packing insert.

Manufactured by:

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Phone: +91-079-41078096
Telefax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

For any information about this medicinal product, please contact the local representative of the supplier:

Lincoln Pharmaceuticals Limited Trimul Estate, Khatraj, Taluka: Kalol, District: Gandhinagar Gujarat, India. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: hiren@lincolnpharma.com Website: www.lincolnpharma.com	**Abacus Pharma (A) Ltd** Kigali city market, B1-R85, PO Box 4344, Kigali, Rwanda. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: abacuspharmacist@gmail.com

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