PBS LISTED. STREAMLINED AUTHORITY CODE 3234

PBS Information: Authority Required (STREAMLINED). Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

NEBILET® Nebivolol Hydrochloride **Indication:** Essential hypertension. Stable chronic heart failure (CHF) as an adjunct to standard therapies in patients 70 years or older. **Dosage and administration:** Once daily dosing. Tablets can be given with or without meals, but a consistent approach is recommended. *Hypertension:* 5 mg daily. In renal insufficiency the recommended starting dose is 2.5 mg daily, which can be increased to 5 mg if needed. In patients > 65 years, the recommended starting dose is 2.5 mg daily, which can be increased to 5mg if needed. In patients > 75 years, caution must be exercised and these patients monitored closely. *Chronic Heart Failure:* The initial up titration should be done gradually at 1-2 weekly intervals based on patient tolerability starting at 1.25 mg once daily, increased to 2.5 mg , then to 5 mg and then to 10 mg once daily. Initiation of therapy and every dose increase should be done under close supervision for at least 2 hours. No dose adjustment is required in patients with mild to moderate renal insufficiency. Use in patients with severe renal insufficiency (serum creatinine ≥ 250µmol/L) is not recommended. **Contraindications:** Hypersensitivity to the active or any of the excipients; liver insufficiency or liver function impairment; acute heart failure; cardiogenic shock or episodes of heart failure decompensation requiring IV inotropic therapy; sick sinus syndrome, including sino-atrial block; second and third degree heart block (without a pacemaker); history of bronchospasm (e.g. including that in chronic obstructive pulmonary disease [COPD]) and/or asthma; untreated phaeochromocytoma; metabolic acidosis; bradycardia (heart rate < 60 bpm prior to starting therapy); hypotension (systolic blood pressure < 100 mmHg); severe peripheral circulatory disturbances. **Precautions:** Avoid abrupt cessation unless clearly indicated – reduce the dosage gradually over about 1-2 weeks during which time the patient's progress should be assessed. If nebivolol must be withdrawn abruptly, close observation is required. Anaesthesia; untreated congestive heart failure, unless stabilised; bradycardia; peripheral circulatory disorders (e.g. Raynaud's disease, intermittent claudication); first degree heart block; Prinzmetal's or variant angina; lipid and carbohydrate metabolism – does not affect glucose levels in diabetic patients, however nebivolol may mask certain symptoms of hypoglycaemia. Hyperthyroidism; use with caution in COPD; phaeochromocytoma; various skin rashes; conjunctival xerosis; oculomucocutaneous syndrome; psoriasis; increased sensitivity to allergens and severity of anaphylactic reactions; galactose intolerance, Lapp-lactase deficiency or glucose-galactose malabsorption; driving vehicles or operating machines. Pregnancy. Lactation. Children and adolescents. Elderly and renal insufficiency – see Dosage and Administration. **Side effects:** Headache, dizziness, tiredness, fatigue, paraesthesia, constipation, nausea, diarrhoea, cardiac failure aggravated, bradycardia, hypotension, dyspnoea, oedema, slowed AV conduction/AV-block, bronchospasm. Post-marketing reports of hypersensitivity, angioneurotic oedema, abnormal hepatic function, acute pulmonary oedema, acute renal failure, myocardial infarction.– see full PI.

See approved Product Information before prescribing. Approved Product Information available on request
Refer to **www.carbinemedia.com.au/pi/nebilet.pdf** for current Product Information.

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nebilet®
nebivolol hydrochloride