Prescribing Information: Nebilet (nebivolol) 5 mg tablets
Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.
Presentation: Tablet containing 5 mg of nebivolol hydrochloride. Also contains lactose.
Uses: Essential hypertension. Stable mild and moderate chronic heart failure in addition to standard therapies in patients aged 70 years or over.
Dosage and administration: Oral administration. Hypertension: Adults: One 5mg tablet daily. Over 65 years or renal insufficiency: Starting dose 2.5mg. Do not use in patients with hepatic insufficiency. Not recommended for children or adolescents.
Chronic heart failure: Adults: Starting dose 1.25 mg and titrated up to 10 mg daily, adjusted individually over 4-8 weeks. Do not use in patients with hepatic or severe renal insufficiency. Not recommended for children or adolescents.
Contra-indications: Hypersensitivity to nebivolol or any of the excipients, liver function disorder, acute heart failure, cardiogenic shock or episodes of heart failure decompensation requiring i.v. inotropic therapy. As with other beta-blockers: sick sinus syndrome, second and third degree heart block, history of bronchospasm and bronchial asthma, untreated phaeochromocytoma, metabolic acidosis, bradycardia, hypotension, severe peripheral circulatory disturbances.
Warnings and Precautions: As with other beta-blockers: Anaesthesia, ischaemic heart disease, untreated congestive heart failure, peripheral circulatory disorders, first degree heart block, Prinzmetal's angina, use with calcium channel antagonists, Class I antiarrhythmic drugs, centrally acting antihypertensive drugs, diabetes, hyperthyroidism, chronic obstructive pulmonary disorders, psoriasis, allergen sensitivity. Lactose: Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Not recommended in pregnancy or lactation.
Interactions: Not recommended: Class I antiarrhythmics, calcium channel antagonists of the verapamil/diltiazem type, centrally acting hypertensives. For other interactions where combinations should be used with caution or be taken into account, please consult the SmPC.
Pregnancy and Lactation: Do not use during pregnancy unless clearly necessary. Monitor uteroplacental blood flow and foetal growth if used. Breastfeeding not recommended. The effect on human fertility is unknown.
Side-effects:
Hypertension: Mostly mild to moderate intensity. Common (≥ 1/100 to < 1/10): headache, dizziness, paraesthesia, dyspnoea, constipation, nausea, diarrhoea, tiredness, oedema. Uncommon (≥ 1/1,000 to < 1/100): nightmares, depression, impaired vision, bradycardia, heart failure, slowed AV conduction/AV block, hypotension, (increase of) intermittent claudication, bronchospasm, dyspepsia, flatulence, vomiting, pruritus, rash erythematous, impotence. Very rare (≤1/10,000): syncope, psoriasis aggravated. Not known: angioneurotic oedema, hypersensitivity, urticaria.
Chronic heart failure: Data from clinical trials that were commonly reported – bradycardia, dizziness. Other incidences considered relevant – aggravation of heart failure, postural hypotension, drug intolerance, first degree atrio-ventricular block, oedema of the lower limb.
Package quantities and prices: Blister packs of 28 tablets: £9.23
Legal category: POM
Marketing authorisation number: PL 16239/0013
Marketing authorisation holder: Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg.
Marketed by: A. Menarini Farmaceutica Internazionale SRL.
Further information is available on request to A. Menarini Farmaceutica Internazionale SRL, Menarini House, Mercury Park, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH or may be found in the SmPC.
Last updated: June 2022.

Adverse events should be reported and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to A. Menarini Farmaceutica Internazionale SRL. Phone no: 0800 085 8678 or email: menarini@medinformation.co.uk