UK Prescribing Information Amlodipine Bristol 2.5mg Tablets

Consult the Summary of Product Characteristics before prescribing

Indications: Hypertension, Chronic stable angina pectoris, Vasospastic (Prinzmetal's) angina**.**
Presentation: **2.5mg only:** Each tablet contains 2.5mg Amlodipine as Amlodipine Besilate
Dosage and administration: Tablet for oral administration

Adults: For hypertension and angina, usual initial dose 5mg Amlodipine tablets od which may be increased to a maximum dose of 10mg od depending on individual patient's response. In hypertensive patients, Amlodipine has been used in combination with a thiazide diuretic, alpha-blocker, beta blocker, or angiotensin converting enzyme (ACE) inhibitor. For angina, Amlodipine may be used as monotherapy or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and /or adequate doses of beta blockers. No dose adjustment is required upon concomitant administration of thiazide diuretics, beta blockers, and ACE inhibitors.

Special populations: *Paediatric population:* Children and adolescents with hypertension aged 6-17 years, recommended antihypertensive starting dose 2.5mg od, up-titrated to 5mg od if blood pressure goal not achieved after 4 weeks. Doses in excess of 5mg daily have not been studied in paediatric patients. No data available in children under 6 years of age. *Elderly*: Normal dosage regimens are recommended in the elderly, but dosage increases undertake with care. *Hepatic impairment:* Dosage recommendations have not established in mild to moderate hepatic impairment; dose selection should be cautious and start at the lower end of the dosing range. Initiate Amlodipine at the lowest dose and titrate slowly in severe hepatic impairment. *Renal impairment:* Normal dosage recommended.

Contraindications: Hypersensitivity to dihydropyridines derivatives, amlodipine or any of the excipients, severe hypotension, shock (including cardiogenic shock), obstruction of the outflow tract of the left ventricle, (e.g. high grade aortic stenosis), haemodynamically unstable heart failure after acute myocardial infarction.

Warnings and Precautions: Safety and efficacy of amlodipine in hypertensive crisis has not been established. *Cardiac failure*: Treat with caution. Caution in patients with congestive heart failure, as may increase the risk of future cardiovascular events and mortality. *Hepatic impairment:* Dosage recommendations have not been established. Amlodipine should be initiated at lower end of the dosing range. Caution both on initial treatment and on dose increase. Slow dose titration and careful monitoring may be required in patients with severe hepatic impairment. *Elderly patients*: Care in increasing dosage. *Renal impairment*: Normal dosage recommended. Amlodipine is not dialysable.

Drug interactions: Concomitant use of strong or moderate CYP3A4 inhibitors (protease inhibitors, azole antifungals, macrolides e.g. erythromycin or clarithromycin, verapamil or diltiazem) may cause a significant increase in amlodipine exposure resulting in an increased risk of hypotension may require clinical monitoring and dose adjustment, Increased risk of hypotension in patients receiving clarithromycin. Close observation is recommended. Caution with concomitant use of CYP3A4 inducers. The concomitant use of CYP3A4 inducers (e.g., rifampicin, hypericum perforatum) may give a lower plasma concentration of amlodipine. Administration with grapefruit or grapefruit juice not recommended. Due to risk of hyperkalemia, recommended that co-administration of calcium channel blockers such as amlodipine be avoided in patients susceptible to malignant hyperthermia and when managing malignant hyperthermia. Blood pressure lowering effects of amlodipine adds to those of other medicinal products with antihypertensive properties. Administration of amlodipine

with tacrolimus requires monitoring of tacrolimus blood levels and dose adjustment of tacrolimus when appropriate. Consider monitoring cyclosporine levels in renal transplant patients. Cyclosporine dose reductions should be made as necessary. Limit the dose of simvastatin to 20 mg od in patients on amlodipine. In clinical interaction studies, amlodipine did not affect the pharmacokinetics of atorvastatin, digoxin or warfarin.

Fertility, pregnancy and lactation: Safety in pregnancy not established. Use in pregnancy only recommended when no safer alternative available and the disease itself carries greater risk for the mother and foetus. A decision to continue/discontinue should consider the benefit of breast-feeding and amlodipine therapy to the mother. Clinical data are insufficient regarding the potential effect of amlodipine on fertility.

Undesirable effects: *Very Common:* Oedema. *Common:* Somnolence, dizziness, headache (especially at the beginning of the treatment), visual disturbances (including diplopia), palpitations, flushing, dyspnoea, abdominal pain, nausea, dyspepsia, altered bowel habits (including diarrhoea and constipation), ankle swelling, muscle cramps, fatigue, asthenia. *Uncommon*: Insomnia, mood changes (including anxiety), depression, tremor, taste perversion, syncope, hypoaesthesia, paraesthesia, tinnitus, arrhythmia, (including bradycardia, ventricular tachycardia and atrial fibrillation), hypotension, cough, rhinitis, vomiting, dry mouth, alopecia, purpura, skin discolouration, hyperhidrosis, pruritus, rash, exanthema, urticaria, arthralgia, myalgia, back pain, micturition disorder, nocturia, increased urinary frequency, impotence, gynaecomastia, chest pain, pain, malaise, weight increase and decrease, dysgeusia. *Rare*: Confusion. *Very rare*: Thrombocytopenia, leukocytopenia, allergic reactions, hyperglycaemia, hypertonia, peripheral neuropathy, myocardial infarction, vasculitis, pancreatitis, gastritis, gingival hyperplasia, hepatitis, jaundice and hepatic enzyme increase (mostly consistent with cholestasis), angioedema, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, quincke oedema, photosensitivity. *Not known:* Extrapyramidal disorder, toxic epidermal necrolysis.

Prescribers should consult the Summary of Product Characteristics in relation to adverse reactions.

Presentation and basic NHS price (excl.VAT): Amlodipine Bristol 2.5mg 1 pack x 28 tablets £4.50
Marketing authorisation number: PL 17907/0435 **(2.5mg)**
Legal category: POM

Date of last revision of prescribing information: May 2020

Further information is available from the Marketing Authorisation Holder: Bristol Laboratories Ltd, Unit 3, Canalside, Northbridge Road Berkhamsted, Hertfordshire HP4 1EG, UK

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Bristol Laboratories Medical Information on Telephone: 0044 (0) 1442 200 922