Slozem (Diltiazem Hydrochloride) 120mg, 180mg, 240mg, 300mg Capsules Prescribing Information. Prescribers should consult the SmPC before prescribing.

Presentation: Each Slozem prolonged release capsule contains 120mg, 180mg, 240mg, 300mg of diltiazem hydrochloride.

Indications: Treatment of mild to moderate hypertension and angina pectoris.

Dosage and administration: Adults: 240mg once daily. Titration: 60mg – 120mg every two weeks up to 360mg daily. Dosage should be reduced in the presence of adverse reactions or if the pulse rate falls below 50 per minute.

Method of Administration: Capsules should be swallowed whole with water, once daily.

Special Populations: Paediatric population: Not recommended. Elderly and patients with hepatic or renal impairment: Starting dose – 120mg once daily.

Fertility, pregnancy and lactation: Pregnancy: Not recommended during pregnancy as well as in women of child-bearing potential not using effective contraception. Diltiazem has been shown to have teratogenic effect in rats, mice and rabbits. Breastfeeding: Contra-indicated. Fertility: No human data available.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Sick sinus syndrome and second- or third-degree AV block except in the presence of a functioning ventricular pacemaker. Severe bradycardia (below 40bpm). Left ventricular failure with pulmonary congestion. Concomitant use of dantrolene infusion. Wolf-Parkinson-White syndrome or short PR syndrome and patients who develop atrial or flutter, should not be administered intravenous diltiazem. Concomitant use of ivabradine. Concurrent use with lomitapide & asunaprevir. Lactation.

Special warnings and precautions: Use with caution in patients with reduced left ventricular function, bradycardia (risk of exacerbation) or with first degree AV block or prolonged PR interval detected on the electrocardiogram. Cases of acute renal failure secondary to decreased renal perfusion have been reported in patients with existing cardiac disease especially reduced left ventricular function, severe bradycardia or severe hypotension. Careful monitoring of renal function is advised. Close observation is necessary prior general anesthesia (depression of cardiac contractility, conductivity and automaticity, as well as the vascular dilation may be potentiated by diltiazem). Careful observation and close monitoring, particularly of heart rate, should be carried out at the beginning of the treatment in the elderly and in patients with renal or hepatic insufficiency (increase of plasma concentration of diltiazem is observed). Calcium channel blocking agents, such as diltiazem may be associated with: mood changes (including depression), inhibitory effect on intestinal motility (should be used with caution in patients at risk of developing an intestinal obstruction). Residues from slow release formulations of the product may pass into the patient's stools; however, this has no clinical relevance. Careful monitoring in patients with latent or manifest diabetes mellitus. May induce bronchospasm, including asthma aggravation. Patients should be monitored for signs and symptoms of respiratory impairment. Slozem contains sucrose, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Drug Interactions: Concomitant use contraindicated: dantrolene (infusion), ivabradine, lomitapide, asunaprevir. Concomitant use requiring caution: lithium, nitrate derivatives, theophylline, alpha-antagonists such as prazosin, amiodarone, digoxin, beta-blockers, other antiarrhythmic agents, carbamazepine, rifampicin, anti-H2 agents such as cimetidine and ranitidine, ciclosporin, tricyclic antidepressants such as imipramine, phenytoin, X-ray contrast media, antiplatelet drugs. General information to be taken into account: caution and careful titration are necessary in patients receiving diltiazem concomitantly with other agents known to affect cardiac contractility and/or conduction. Diltiazem is metabolized by CYP3A4 (caution is necessary when diltiazem is co-administered with a stronger CYP3A4 inhibitors, other CYP3A4 substrates and with CYP3A4 inducers). Special care should be taken when prescribing short acting benzodiazepines metabolised by the CYP3A4 (midazolam, triazolam), corticosteroids (methylprednisolone), statins. Oral administration of diltiazem can raise blood levels of drugs exclusively metabolised by the iso-enzyme CYP3A4 – this can lead to increased plasma levels of carbamazepine, tacrolimus, sirolimus and erythromycin. Grapefruit juice may increase diltiazem exposure. Inhibition of cilostazol metabolism (CYP3A4).

Effects on ability to drive/use machines: Based on reported adverse drug reactions, i.e. dizziness (common), malaise (common), the ability to drive and use machines could be altered.

Undesirable effects: Thrombocytopenia, headache, dizziness, extrapyramidal syndrome, drug-induced Parkinsonism, atrioventricular block, palpitations, bradycardia, sinoatrial block, sinus arrest, congestive heart failure, cardiac arrest, flushing (the current literature suggests that the effects of vasodilation, particularly ankle oedema, are dose dependent and are more frequent in elderly), constipation, dyspepsia, gastric pain, nausea, hepatitis, erythema, photosensitivity, erythema multiform (including Steven-

Johnson's syndrome and toxic epidermal necrolysis), peripheral oedema, Lupus-like syndrome, malaise. See SmPC for full list of adverse events.

Pack size and UK list price:
Slozem 120mg Capsules (PL 17780/1007) pack size: 28, £5.49
Slozem 180mg Capsules (PL 17780/1008) pack size: 28, £5.58
Slozem 240mg Capsules (PL 17780/1009) pack size: 28, £5.67
Slozem 300mg Capsules (PL 17780/1010) pack size: 28, £6.03.

Legal category: POM

Marketing Authorisation Holder: Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK

Date of Preparation: 29 Aug 2023 **Ref:** 000603463

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 Zentiva via email to PV-United-Kingdom@zentiva.com or via phone on 0800 090 2408.