The evidence is stacked in its favour

Established efficacy in both hypertension and angina

A reliable choice for good tolerability in both young and elderly patients[1]

More consistent compliance than nifedipine retard[2]

TM

AMLODIPINE

ABBREVIATED PRESCRIBING INFORMATION FOR ISTIN™ (AMLODIPINE): UK. PRESENTATION: TABLETS CONTAINING 5MG OR 10MG AMLODIPINE. **INDICATIONS:** FIRST-LINE TREATMENT OF HYPERTENSION AND MYOCARDIAL ISCHAEMIA ASSOCIATED WITH STABLE ANGINA PECTORIS OR VASOSPASTIC (PRINZMETAL'S OR VARIANT) ANGINA. **DOSAGE:** FOR HYPERTENSION AND ANGINA, INITIAL DOSAGE 5MG ORALLY ONCE DAILY WHICH MAY BE INCREASED TO A MAXIMUM DAILY DOSAGE OF 10MG. **USE IN CHILDREN:** NOT RECOMMENDED. **USE IN THE ELDERLY:** NORMAL DOSAGE. **USE IN RENAL IMPAIRMENT:** NORMAL DOSAGE. **USE IN HEPATIC IMPAIRMENT:** DOSAGE RECOMMENDATIONS HAVE NOT BEEN ESTABLISHED; USE WITH CAUTION. **CONTRA-INDICATIONS:** KNOWN SENSITIVITY TO DIHYDROPYRIDINES. **WARNINGS AND PRECAUTIONS:** PREGNANCY AND LACTATION: ISTIN SHOULD NOT BE ADMINISTERED DURING PREGNANCY OR LACTATION, OR TO WOMEN OF CHILD-BEARING POTENTIAL UNLESS EFFECTIVE CONTRACEPTION IS USED. **SIDE-EFFECTS:** OEDEMA, HEADACHE, FLUSHING, DIZZINESS, NAUSEA, PALPITATIONS, FATIGUE, ABDOMINAL PAIN AND SOMNOLENCE. LESS COMMONLY, PRURITUS, DYSPNOEA, ASTHENIA, MUSCLE CRAMPS, DYSPEPSIA AND GINGIVAL HYPERPLASIA. RASH, AND RARELY ERYTHEMA MULTIFORME HAVE BEEN OBSERVED. AS WITH OTHER CALCIUM CHANNEL BLOCKERS, THE FOLLOWING, WHICH CANNOT BE DISTINGUISHED FROM THE NATURAL HISTORY OF THE UNDERLYING DISEASE HAVE BEEN RARELY REPORTED: MYOCARDIAL INFARCTION AND CHEST PAIN. **FURTHER INFORMATION:** STUDIES HAVE SHOWN THAT ISTIN DID NOT LEAD TO CLINICAL DETERIORATION IN NYHA CLASS II-III HEART FAILURE. STUDIES HAVE NOT BEEN PERFORMED IN PATIENTS WITH CLASS IV HEART FAILURE. **LEGAL CATEGORY:** POM. **PACKAGE QUANTITIES AND BASIC NHS COST:** 5MG TABLETS CALENDAR PACK OF 28 £11.85 (PL 0057/0297); 10MG TABLETS CALENDAR PACK OF 28 £17.70 (PL 0057/0298). FURTHER INFORMATION ON REQUEST. **PFIZER LIMITED**, RAMSGATE ROAD, SANDWICH, KENT CT13 9NJ. **REFERENCES: 1.** CROSS BW ET AL. BR J CLIN PRACT, 1993, *47*(5): 237-240. **2.** DETRY JR. CLIN CARDIOL, 1994, *17* (SUPPL III): 12-16.

Pfizer

61436

Feb '96

Abbreviated Prescribing Information

Presentation: Ampoules containing dalteparin sodium 10,000 IU (anti-Factor Xa) in 1ml. No preservative present. **Indication**: Unstable coronary artery disease, defined as newly developed or increased angina or ongoing chest pain, with the electrocardiogram changes of non Q-wave myocardial infarction. **Dosage**: Adults and elderly. 120 IU/kg bodyweight subcutaneously twelve-hourly. The maximum dose is 10,000 IU/12 hours. The recommended treatment period is 5-8 days. Concomitant therapy with low-dose aspirin is recommended. **Contraindications**: Known hypersensitivity to Fragmin; acute gastroduodenal ulcer; cerebral haemorrhage; known haemorrhagic diathesis; subacute endocarditis; injuries to and operations on the central nervous system, eyes and ears; thrombocytopenia in patients with a positive result in the *in-vitro* aggregation test in the presence of dalteparin sodium. **Precautions**: Do not administer by the intramuscular route. Caution should be exercised in patients in whom there is an increased risk of bleeding complications, e.g. following surgery or trauma, haemorrhagic stroke, severe liver failure, thrombocytopenia or defective platelet function, uncontrolled hypertension, hypertensive or diabetic retinopathy, patients receiving concurrent anticoagulant / antiplatelet agents, and also patients with known hypersensitivity to heparin and/or to other low molecular weight heparins. Patients with severely disturbed hepatic function may need a reduction in dosage and should be monitored accordingly. Fragmin induces only a moderate prolongation of the APTT and thrombin time. Accordingly, dosage increments based upon prolongation of the APTT may cause overdosage and bleeding. Therefore, prolongation of the APTT should only be used as a test of overdosage. If a transmural myocardial infarction occurs in patients with unstable coronary artery disease, thrombolytic treatment might be appropriate. This does not necessitate discontinuation of treatment with Fragmin, but might increase the risk of bleeding. This medicinal product has been assessed in pregnant women and no harmful effects are known with respect to the course of pregnancy and the health of the unborn and neonate. No information is available as to whether Fragmin passes into breast milk. **Side-effects**: Bleeding may be provoked, especially at high dosages corresponding with anti-Factor Xa levels greater than 1.5 IU/ml. However, at recommended dosages bleeding rarely occurs. Transient, slight to moderate elevation of liver transaminases (ASAT, ALAT) has been observed, but no clinical significance has been demonstrated. Commonly reported side-effects include subcutaneous haematomas at the injection site. Thrombocytopenia and allergic reactions (urticaria, pruritus, hair loss and skin necrosis) occur rarely. Few cases of anaphylactoid reactions have been observed. Osteoporosis has been associated with long-term heparin treatment and therefore cannot be excluded with Fragmin. **Overdose**: 100 IU Fragmin is inhibited by 1mg protamine; see Summary of Product Characteristics for full prescribing information. **Legal category**: POM. **Packs**: Fragmin 10,000 IU/1ml ampoule, basic NHS price of £53.63 per pack of ten ampoules. **PL Number**: 10,000 IU/1ml 0022/0075. Further information is available on request: Pharmacia & Upjohn Limited, Davy Avenue, Milton Keynes, MK5 8PH. Tel: 01908 661101. Fax: 01908 690091. Date of preparation: March1997.

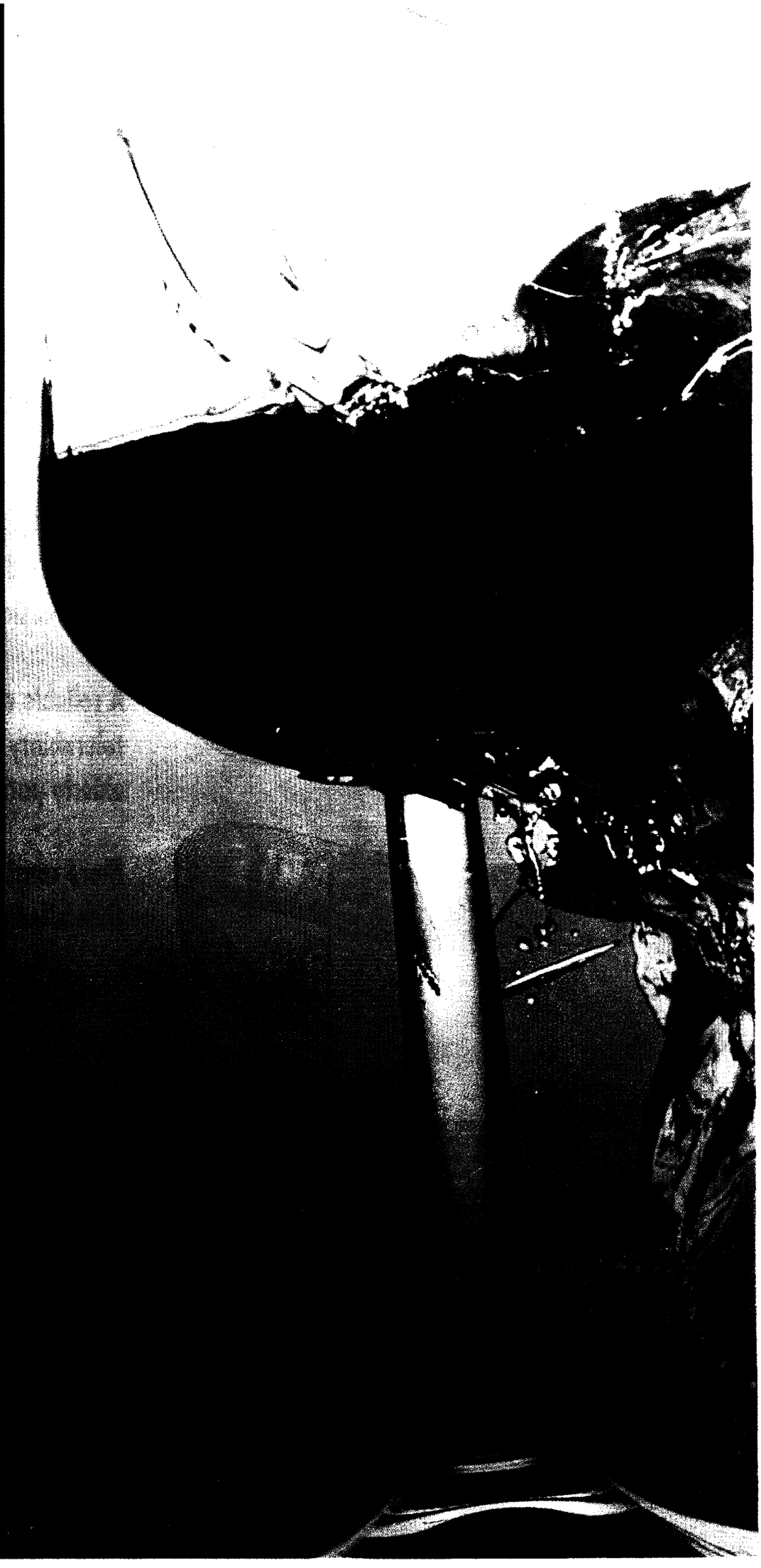
Reference:

1. FRISC Study Group. Lancet 1996; **347**: 561-568.

Pharmacia & Upjohn

Further information is available on request from: Pharmacia & Upjohn Limited, Davy Avenue, Milton Keynes MK5 8PH. Tel: 01908 661101. Fax: 01908 690091.

Date of preparation: March 1997. Ref: P2807



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nisoldipine

acts selectively on the coronary arteries

Syscor MR (nisoldipine) is a new, once-daily Ca^{2+} antagonist with different pharmacological properties to other Ca^{2+} antagonists[1,2].

Because nisoldipine acts selectively on the coronary arteries compared with the myocardium and peripheral vessels[2,3], there is no clinical negative inotropic effect[4], and "... no change in heart rate occurred with nisoldipine coat-core" (Syscor MR) in the DEFIANT I study[5]. Syscor MR also has a very low incidence of acute peripheral vasodilator side-effects[6].

Syscor MR, Bayer's 3rd generation Ca^{2+} antagonist, is an effective once-daily therapy in chronic stable angina and mild to moderate hypertension.

SYSCOR® MR 10, 20, 30 - ABRIDGED PRESCRIBING INFORMATION ▼ (Refer to full Summary of Product Characteristics before prescribing) **Qualitative and quantitative composition:** Film-coated tablets each containing 10 mg, 20 mg, or 30 mg nisoldipine. **Pharmaceutical form:** Modified (extended) release tablets for oral administration. **Therapeutic indications:** Mild to moderate arterial essential hypertension. Prophylaxis of chronic stable angina pectoris. **Posology and method of administration:** Syscor MR tablets must be swallowed whole; under no circumstances should they be bitten, chewed or broken up. Taken once-daily, swallowed whole with a little liquid at approximately 24-hour intervals, i.e. at the same time each day, preferably during the morning. A food interaction has been observed, and it is therefore preferable to administer Syscor MR in the fasting state i.e. before breakfast. The recommended initial dose in angina pectoris is 10 mg once-daily. The usual maintenance dose is 20-40 mg once-daily. The maximum recommended dose is 40 mg once-daily. In hypertension, the recommended initial dose is one 10 mg tablet once-daily. If necessary, the dosage can be increased according to individual requirements up to a maximum of 40 mg once-daily. Assess at least one week after starting on any dosage before titration to a higher dosage. *Renal impairment:* Dosage adjustment should not be necessary. *Elderly:* Therapy should commence with 10 mg once-daily, with titration to higher doses if clinically warranted and according to tolerability. Treatment may be continued indefinitely. **Contra-indications:** Known hypersensitivity to nisoldipine or other dihydropyridines; children aged less than 12 years; pregnant women or nursing mothers; cardiogenic shock, unstable angina or during or within one month of myocardial infarction; secondary prevention of myocardial infarction; acute angina attacks; malignant hypertension; fixed cardiac output obstruction, such as aortic stenosis; hepatic impairment. **Special warnings and special precautions for use:** Caution in patients with hypotension as there is a risk of further reduction in blood pressure. **Interactions with other medicaments and other forms of interaction:** If used in combination with beta-blocking drugs, a possible additive effect resulting in postural hypotension should be borne in mind. Syscor MR may not prevent possible rebound effects after cessation of other antihypertensive therapy. No significant interaction of Syscor MR and propranolol, but a possible additive effect of the two drugs must be borne in mind. Interactions have been observed with cimetidine, rifampicin, quinidine and grapefruit juice. Possibility of interaction with phenytoin or carbamazepine cannot be excluded. No interaction has been observed with ranitidine, warfarin or digoxin. **Effect on ability to drive and use machines:** None known. **Undesirable effects:** Gravitational oedema, headache, flushing, tachycardia, palpitation, dizziness and gastrointestinal disorders such as nausea and constipation. Less frequently, paraesthesia, hypotension, asthenia, dyspnoea and allergic skin reactions (rash, itching). Exacerbation of angina pectoris at the start of treatment. The occurrence of myocardial infarction was not distinguishable from the natural course of ischaemic heart disease. Disturbances of the enzymes AST (SGOT), ALT (SGPT) and CPK may occur which tend to return to normal with continuation of therapy. If abnormalities do not regress within a few weeks, discontinue treatment. Enzyme elevations usually regress on discontinuation of the drug. Syscor MR has a mild hypouricaemic effect. Increased diuresis has been observed in isolated cases. **Legal category:** POM. **Package quantities and basic NHS costs:** Calendar packs containing 28 tablets. Syscor MR 10 £9.80. Syscor MR 20 £13.72. Syscor MR 30 £17.64. **Marketing Authorisation numbers:** PL 0010 0198-0200. **Date of Preparation:** March 1997.

REFERENCES 1. Kazda S *et al. Arzneim-Forsch Drug Res* 1980; **30** (II): 2144-2162. **2.** Godfraind T *et al J Cardiovasc Pharmacol* 1992; **20** (Suppl 5): S34-S41. **3.** Schartl M *et al In: Hugenholtz PG, Meyer J, eds. Nisoldipine* 1987. Berlin, Heidelberg, Springer-Verlag; 1987: 109-114. **4.** Schartl M *et al J Cardiovasc Pharmacol* 1992; **20** (Suppl 5): S79-S81. **5.** DEFIANT I Research Group *Eur Heart J* 1992; **13**: 1496-1505. **6.** Lewis BS *Am J Cardiol* 1995; **75**: 46E-53E.

Further information available from:
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Prescribing information. Presentation [illegible] Indications [illegible] Dosage [illegible] Contra-indications [illegible] Precautions [illegible] Side-effects *Occasionally:* [illegible] *Rarely:* [illegible] Legal Category [illegible] Packs [illegible] Date of preparation October 1996.

NOVARTIS

ZOCOR® (simvastatin, MSD)

ABRIDGED PRODUCT INFORMATION

Refer to Summary of Product Characteristics before prescribing

PRESENTATION

Peach, oval-shaped, film-coated tablets, marked 'ZOCOR 10' on one side, containing 10 mg simvastatin, MSD.

Tan, oval-shaped, film-coated tablets, marked 'ZOCOR 20' on one side, containing 20 mg simvastatin, MSD.

Brick-red, oval-shaped, film-coated tablets, marked 'MSD 749' on one side, containing 40 mg simvastatin, MSD.

INDICATIONS

- Primary hypercholesterolaemia unresponsive to diet and other non-pharmacological measures.
- In patients with coronary heart disease and a plasma cholesterol level of 5.5 mmol l or greater, to
  - reduce risk of mortality
  - reduce risk of coronary death and non-fatal myocardial infarction
  - reduce risk for undergoing myocardial revascularising procedures (CABG and PTCA)
  - slow the progression of coronary athero-sclerosis, including reducing development of new lesions and new total occlusions.

DOSAGE AND ADMINISTRATION

Hypercholesterolaemia: Initially 10 mg *nocte*; dose range 10–40 mg once daily *nocte*. Maximum therapeutic response occurs within four to six weeks. Consider dose reduction if total serum cholesterol level falls below 3.6 mmol l or if LDL cholesterol falls below 1.94 mmol l. (See Data Sheet for full dosage instructions.) A standard cholesterol-lowering diet should be continued.

Coronary heart disease

Starting dose 20 mg day *nocte*. Adjustment of dose as above.

Concomitant therapy: 'Zocor' is effective alone or in combination with bile-acid sequestrants. In patients taking immunosuppressants concomitantly with 'Zocor', the maximum recommended dosage is 10 mg day (see below).

Impaired renal function: In patients with severe renal insufficiency (creatinine clearance < 30 ml/min), dosages above 10 mg day should be carefully considered and, if deemed necessary, implemented cautiously.

Elderly patients: Modification of dose should not be necessary.

Children: Studies to show safety and efficacy have not been done.

CONTRA-INDICATIONS

Hypersensitivity to this product; active liver disease or unexplained persistent elevations of serum transaminases; porphyria; pregnancy and breast-feeding; women of childbearing potential unless adequately protected by non-hormonal methods.

PRECAUTIONS

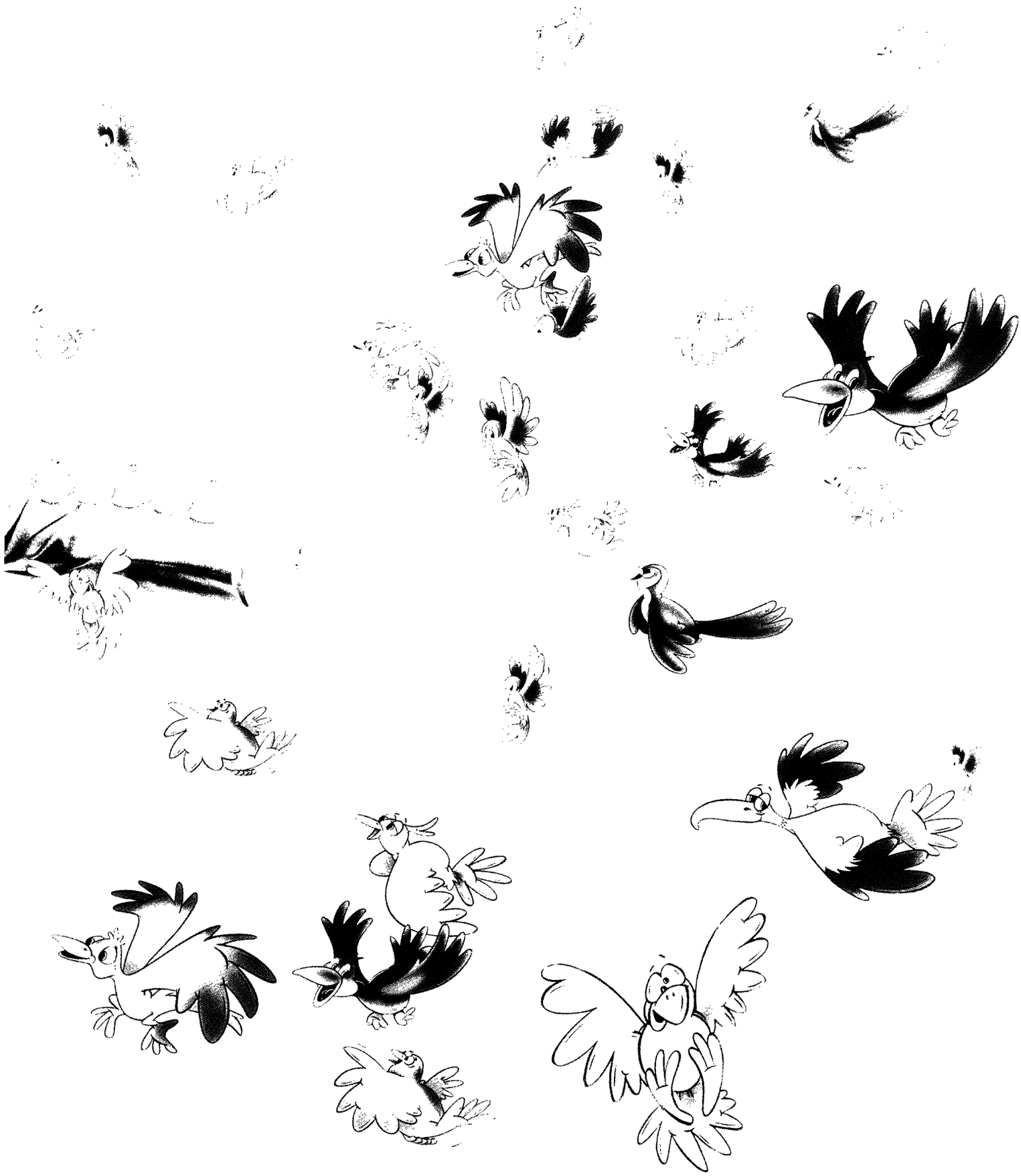
Homozygous familial hypercholesterolaemia: 'Zocor' is unlikely to be effective.

Hypertriglyceridaemia: 'Zocor' is not indicated where hypertriglyceridaemia is the abnormality of most concern.

Hepatic effects: Initial and periodic liver-function monitoring recommended. Discontinue if persistent enzyme elevations occur, particularly if they rise to three times the upper limit of normal. Caution in patients with a history of liver disease and or alcoholism.

Muscle effects: Clinically insignificant transient mild elevations of creatine phosphokinase have been seen. Therapy with HMG-CoA reductase inhibitors has rarely been associated with myopathy (< 0.1%). Myopathy should be considered in any patient with marked elevations of creatine phosphokinase (CPK) levels (≥10 times the upper limit of normal) or with diffuse myalgias, muscle tenderness and such marked elevations of CPK levels. The patient should be asked to report promptly unexplained muscle pain, tenderness or weakness.

The risk of myopathy with HMG-CoA reductase inhibitors is known to be increased by concomitant immunosuppressive therapy including cyclosporine, by concomitant therapy with a fibric acid derivative or lipid-lowering doses of nicotinic acid, and believed to be enhanced by itraconazole. There have been rare reports of severe rhabdomyolysis with secondary acute renal failure. Therefore, the benefits and risks of using simvastatin concomitantly with *immunosuppressive* or fibrate drugs, lipid-lowering doses of nicotinic acid, or itraconazole and other systemic azole antifungal derivatives should be carefully considered.



Pregnancy: Contra-indicated. One month should elapse between ending therapy with 'Zocor' and planned conception.
Paediatric use: Safety and effectiveness in children have not been established.
Drug interactions: Care should be taken in patients on concomitant lipid-lowering therapy, particularly fibrates or nicotinic acid derivatives or itraconazole or immunosuppressive therapies, as they are at increased risk of myopathy.
In two clinical studies, 'Zocor' modestly potentiated the anticoagulant effect of warfarin; patients taking coumarin derivatives should have their prothrombin time determined prior to therapy with 'Zocor' and monitored as usual.
Slight elevation in digoxin levels has been seen when co-administered with 'Zocor'.

SIDE EFFECTS

Side effects reported most frequently in controlled clinical trials: abdominal pain, constipation, flatulence, asthenia, and headache. Rarely, myopathy.
Side effects reported either in long-term extension studies or in marketed use: nausea, diarrhoea, rash, dyspepsia, pruritus, alopecia, dizziness, muscle cramps, myalgia, pancreatitis, paraesthesia, peripheral neuropathy, vomiting, and anaemia. Rarely, rhabdomyolysis and hepatitis jaundice occurred. An apparent hypersensitivity syndrome has been reported rarely which has included some of the following features: angioedema, lupus-like syndrome, polymyalgia rheumatica, vasculitis, thrombocytopenia, eosinophilia, ESR increased, arthritis, arthralgia, urticaria, photosensitivity, fever, flushing, dyspnoea, and malaise.
Marked and persistent increased serum transaminases have been reported infrequently. Elevated alkaline phosphatase and γ-glutamyl transpeptidase have been reported. Liver-function test abnormalities have generally been mild and transient. Increases in CPK (muscle derived) have been reported.
Side effects reported but where a causal relationship to 'Zocor' is not established; depression, erythema multiforme including Stevens-Johnson syndrome, leucopenia, and purpura.

PACKAGE QUANTITIES AND BASIC NHS COST

10 mg tablets, £18.29 for 28-tablet calendar pack
20 mg tablets, £31.09 for 28-tablet calendar pack
40 mg tablets, £47.04 for 28-tablet calendar pack

Product licence numbers:

10 mg tablets, 0025 0241
20 mg tablets, 0025 0242
40 mg tablets, 0025 0243

Product licence holder:

Merck Sharp & Dohme Limited
Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU

POM. Date of review: January 1997.

Reference

1. Scandinavian Simvastatin Survival Study Group. *Lancet*, 1994, *344*, 1383.

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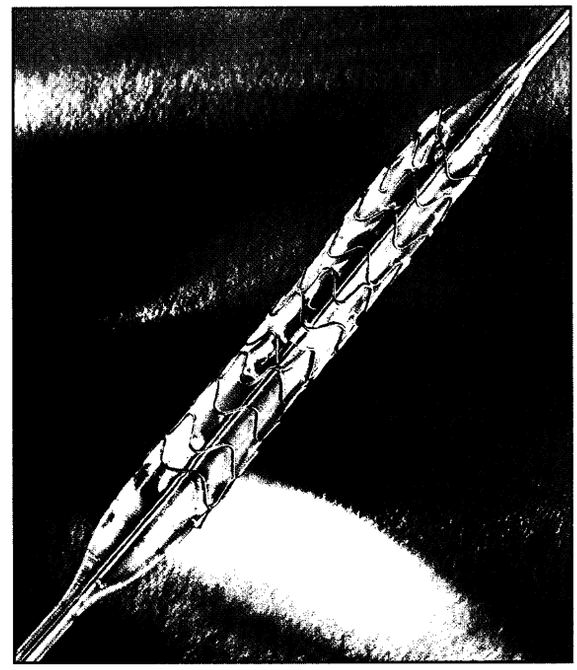

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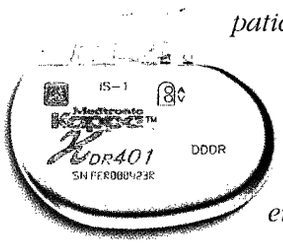

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Prescribing Information: Tildiem LA200 and LA300 capsules containing 200mg or 300mg diltiazem HCL in a mixture of immediate release and sustained release pellets. **Indications:** Angina pectoris and mild to moderate hypertension. **Dosage and Administration:** Elderly and patients with impaired hepatic or renal function: Angina and hypertension: The initial dose should be one Tildiem LA200 capsule daily. This dose may be increased to one capsule of Tildiem LA300 daily if clinically indicated. Heart rate should be monitored and if it falls below 50 beats per minute the dose should not be increased. Plasma levels of diltiazem can be increased in this group of patients. **Adults:** Angina and hypertension: The usual starting dose is Tildiem LA300 once daily. This dose may be increased to 2 capsules of Tildiem LA200 daily, and if clinically indicated a higher dose of one Tildiem LA200 plus one Tildiem LA300 capsule may be considered. **Children:** Tildiem LA should not prescribed. The capsules should not be chewed swallowed whole with water, ideally before or during a m When changing from one type of Tildiem formulatior another it may be necessary to adjust the dosage un satisfactory response is obtained. **Contraindicatic** Pregnancy, women of child-bearing potential, mar bradycardia, sick sinus syndrome, left ventricular failure \

diltiazem HCl 200 & 300

stasis, second or third degree AV block in the absence of a functioning pacemaker, concomitant use with dantrolene infusion. **Warnings and Precautions:** Caution in patients with reduced ventricular function, mild bradycardia, first degree AV block or prolonged PR interval. Concomitant use with drugs known to induce bradycardia or hypotension. **Side-effects:** Lower limb oedema, headache, hot flushes/flushing, asthenia/fatigue, palpitations, malaise, minor GI disorders and skin rash have been described. **Basic NHS Costs:** Tildiem LA200 28 capsules £11.61. Tildiem LA300 28 capsules £12.80. **Legal Category:** POM **Product Licence Numbers:** Tildiem LA200 4969/0016. Tildiem LA300 4969/0014. **Product Licence Holder:** Lorex Synthélabo Ltd, Lunar House, Globe Park, Marlow, Bucks, SL7 1LW. Date of preparation: April 1997. Code No: TIL301 AD97. Tildiem and Lorex Synthélabo are trade marks.

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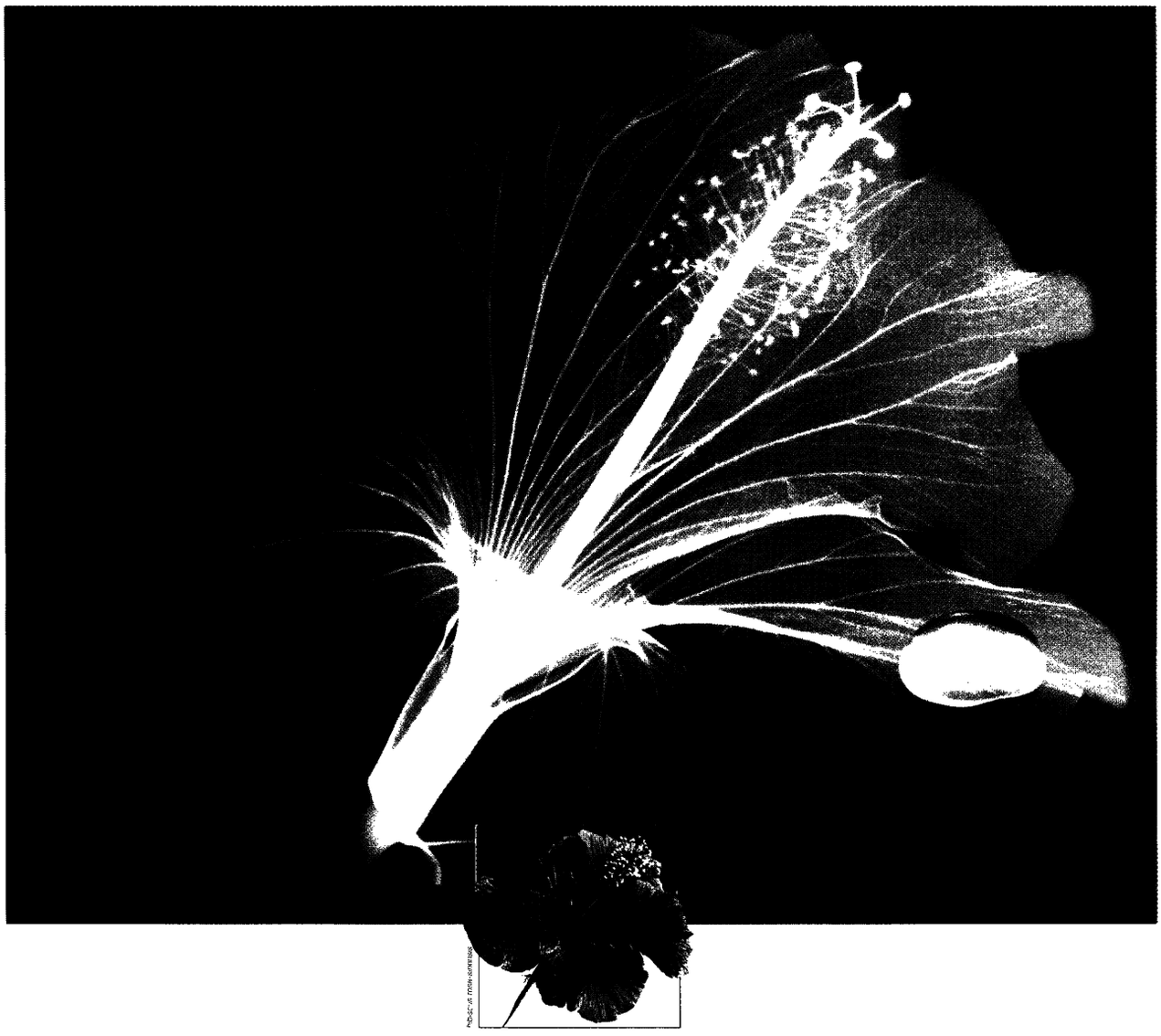

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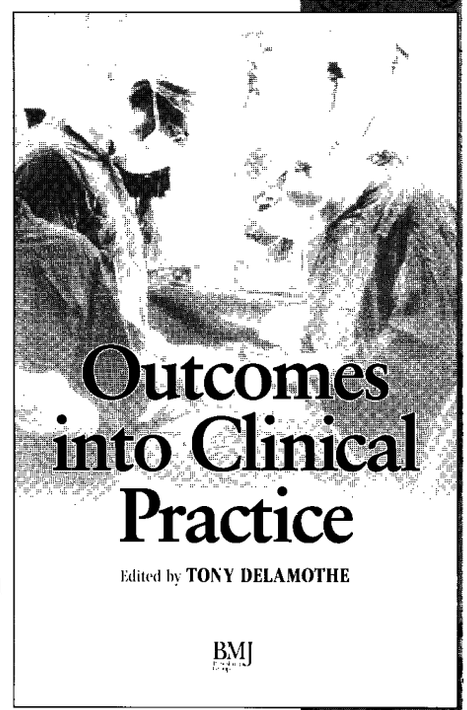

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Long term angina protection

(isosorbide mononitrate)

Presentation: Elantan LA25: Brown and white opaque gelatin capsules containing 25 mg isosorbide mononitrate in a slow release formulation. **Elantan LA50:** Brown and flesh coloured opaque gelatin capsules containing 50 mg isosorbide mononitrate in a slow release formulation. **Use:** Prophylaxis of angina pectoris. **Dosage and administration:** *Adults and Elderly:* Elantan LA25: One capsule in the morning. This may be increased to two capsules taken simultaneously if required. Elantan LA50: One capsule in the morning. This may be increased to two capsules if required. *Children:* Safety and efficacy has not been established in children. The capsules should be swallowed whole. **Contra-indications, warnings, etc.** *Contra-indications:* Acute myocardial infarction with low filling pressures, acute circulatory failure, (shock, vascular collapse), severe cerebrovascular insufficiency or very low blood pressure, known sensitivity to nitrates, marked anaemia, head trauma, cerebral haemorrhage, severe hypotension, hypovolaemia. *Interactions:* Some of the effects of alcohol and the action of hypotensive agents may be potentiated by this treatment. *Pregnancy and lactation:* Elantan LA25 and LA50 is not recommended for use during pregnancy or lactation. *Warnings:* Use with caution in patients predisposed to hypothyroidism, hypothermia, malnutrition, severe liver or renal disease. Circulatory collapse may arise after the first dose. A headache may occur at the start of treatment, usually this subsides after a few days. Symptoms of postural hypotension and syncope may result in some patients. *Overdosage:* May lead to vascular collapse, gastric lavage is indicated in severe cases. Further measures to support the circulation are recommended, e.g. elevate the foot of the bed and/or treat with hypertensive agents. **Pharmaceutical precautions:** None. **Legal category:** UK: P. ROI: POM. **Package quantity and price:** Elantan LA25 Original pack of 28 capsules UK £7.00, EIRE IR£7.07, Elantan LA50 Original pack of 28 capsules UK £11.30, EIRE IR £12.15. **Marketing authorisation numbers:** Elantan LA25: PL 4438/0028 PA 271/1/9, Elantan LA50: PL 4438/0015 PA 271/1/3. **Name and address of marketing authorisation holder:** Schwarz Pharma Limited, East Street, Chesham, Bucks. HP5 1DG. Telephone: 01494 772071. **Distributed in Republic of Ireland by:** Allphar Services Ltd., Burton Hall Park, Sandyford Industrial Estate, Foxrock, Dublin 18. Telephone Dublin 2952226. **Date of preparation:** August 1996 (167).

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