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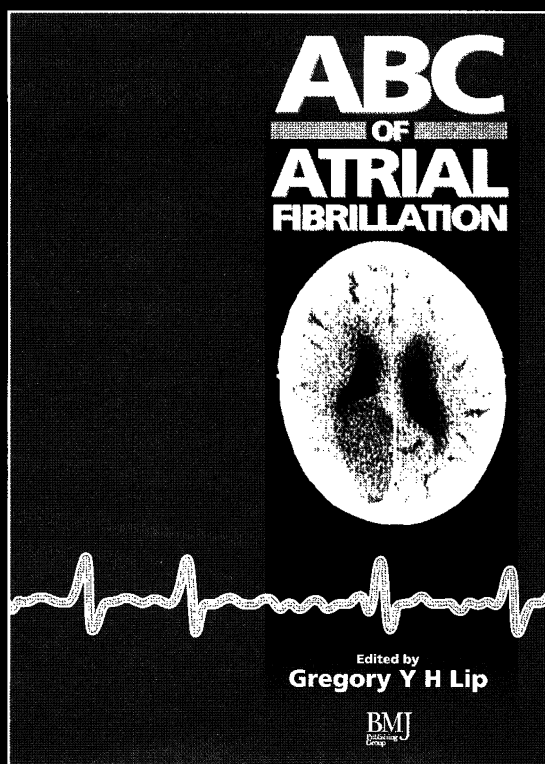
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ABBREVIATED PRESCRIBING INFORMATION FOR ISTIN™ (AMLODIPINE): UK.

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.



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Gregory Y H Lip

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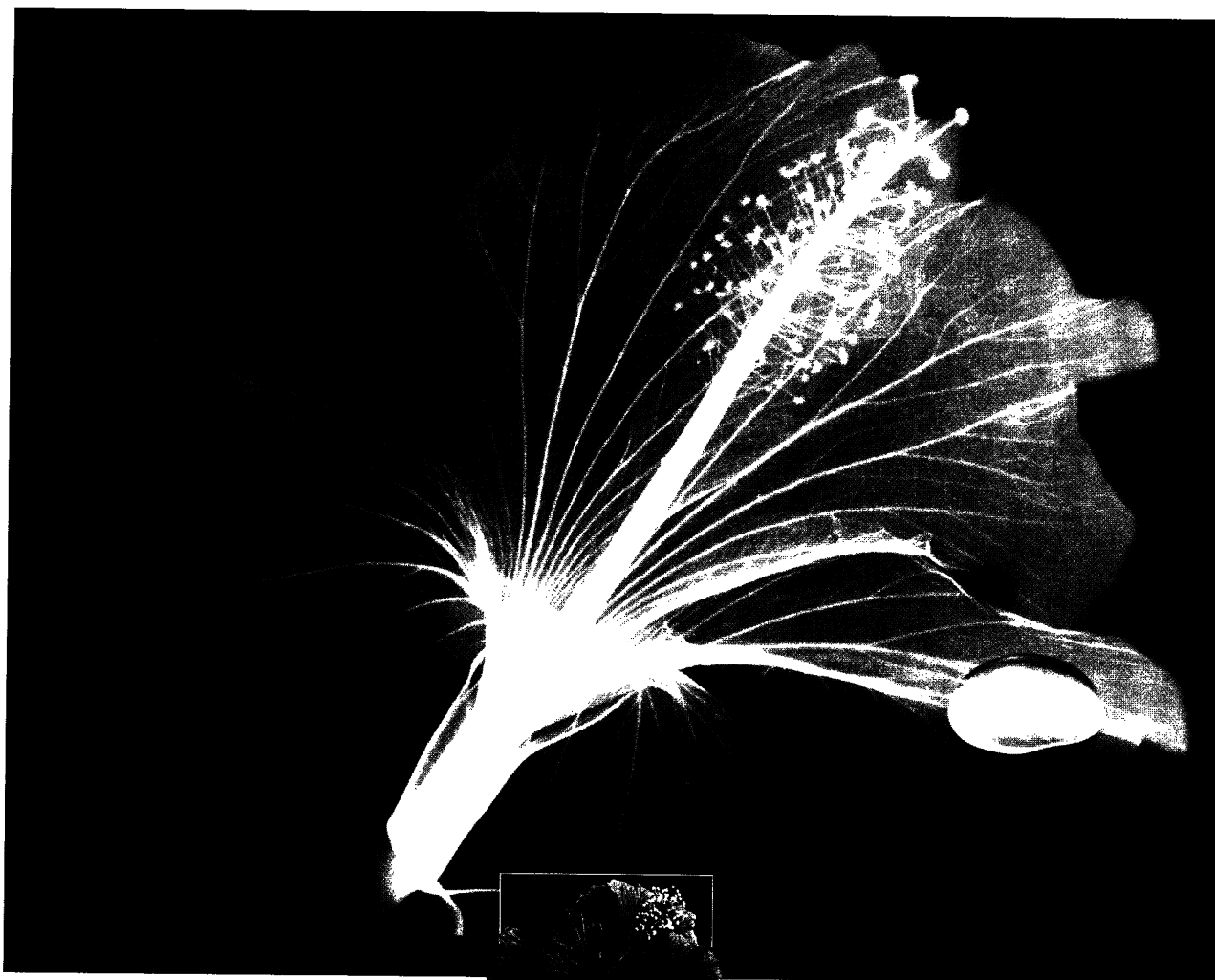
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IOMERON Prescribing Information Presentation: Sterile, aqueous solution of iomeprol. Iomeron 150 contains 30.62% w/v (150mg I/ml); Iomeron 200 contains 40.82% w/v (200mg I/ml); Iomeron 250 contains 51.03% w/v (250mg I/ml); Iomeron 300 contains 61.24% w/v (300mg I/ml); Iomeron 350 contains 71.44% w/v (350mg I/ml); Iomeron 400 contains 81.65% w/v (400mg I/ml). **Uses:** X-ray contrast medium **Dosage and Administration:** Angiography Iomeron 250, 300, 350, 400, dosage according to procedure* DSA intra-arterial: Iomeron 150, 200, 250, 300 DSA intravenous Iomeron 250, 300, 350, 400, dosage according to procedure; CT brain Iomeron 150, 200, 250, 300, 350 50-150ml* CT body Iomeron 150, 200, 250, 300, 350, 400 40-150ml*; Urography intravenous Iomeron 250, 300, 350, 400 50-150ml* Urography infusion Iomeron 150 250ml; Arthrography Iomeron 200, 300, 350 1-10ml ECRP Iomeron 300 12-30ml; Hysterosalpingography Iomeron 200 8-20ml Elderly - lowest effective dose *Children according to body size and age **Contra-indications:** Hypersensitivity to iodine; hysterosalpingography in pregnancy or acute inflammatory pelvic conditions **Precautions and Warnings:** May provoke anaphylaxis (appropriate resuscitative measures to be available). Care in patients with history of allergy, severe asthma, functional impairment of liver, kidneys or myocardium, myelomatosis, epilepsy, diabetes, pulmonary hypertension, hyperthyroidism, acute and chronic alcoholism. Increased risk of reaction in severe cardiac disease. In severe, chronic hypertension the risk of renal damage is increased. Abnormalities of fluid and electrolyte balance should be corrected. Ensure adequate hydration. Possibility of ventricular arrhythmias during cardiac procedures and interference with thyroid function tests. Increased risk of transient neurological complications in patients with cerebrovascular disease. In pheochromocytoma, premedication with an alpha blocker is advised. Anticonvulsant therapy should not be discontinued. Some neurological symptoms may be exacerbated. Non-ionic contrast media have less anticoagulant activity *in vitro* than ionic media, so particular attention must be paid to angiographic technique. Avoid in pregnancy. **Side Effects:** As for similar non-ionic products **Pharmaceutical Precautions:** Protect from light and secondary X-rays. Containers are not for multiple use. Not to be mixed with other drugs **Legal Category:** Prescription only medicine **MA Numbers:** Iomeron 150 PL 11648/0005 PA 54/80/3; Iomeron 200 PL 11648/0006 PA 54/81/2; Iomeron 250 PL 11648/0007 PA 54/82/2,5; Iomeron 300 PL 11648/0008 PA 54/83/4, 5, 6, 8; Iomeron 350 PL 11648/0009 PA 54/84/3, 4, 5, 7; Iomeron 400 PL 11648/0010 PA 54/85/2, 3, 4, 6, 7 **Prices:** Iomeron 300 10x50mls £255.26 Full prescribing information is available on request from E Merck Pharmaceuticals (A division of Merck Ltd), Harrier House, High Street, West Drayton, Middlesex UB7 7QG. **Date of preparation:** 31 October 1995 **References:** 1. Gallotti A *et al.* Eur J Radiol 18 (Suppl.1): S1-S12, 1994. 2. Morisetti A *et al.* Eur J Radiol 18 (Suppl.): S21-S31, 1994.

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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 the three times the upper limit of normal. Caution in patients with a history of disease and/or alcoholism.

Muscle effects: Clinically insignificant transient mild elevations of creatine phosphokinase have been seen. Therapy with HMG-CoA reductase inhibitors rarely been associated with myopathy (<0.1%). Myopathy should be considered in any patient with marked elevations of creatine phosphokinase (CPK) (≥10 times the upper limit of normal) or with diffuse myalgias, tenderness and such marked elevations of CPK levels. The patient is asked to report promptly unexplained muscle pain, tenderness or weakness. The risk of myopathy with HMG-CoA reductase inhibitors is known increased by concomitant immunosuppressive therapy including cyclosporin concomitant therapy with a fibric acid derivative or lipid-lowering nicotinic acid, and believed to be enhanced by itraconazole. There have been reports of severe rhabdomyolysis with secondary acute renal failure. Therapeutic benefits and risks of using simvastatin concomitantly with immunosuppressive drugs, lipid-lowering doses of nicotinic acid, or itraconazole or 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.
immunosuppressive therapies: as they are at increased risk of myopathy.

In two clinical studies, 'Zocor' modestly potentiated the anticoagulant effect of arfarin; patients taking coumarin derivatives should have their prothrombin time determined prior to therapy with 'Zocor' and monitored as usual.
No significant elevation in digoxin levels has been seen when co-administered with 'Zocor'.

IDE 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 jaundice. 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, 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.

* denotes registered trademark of Merck & Co., Inc., Whitehouse Station, NJ, USA.
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Reference

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

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PRESENTATION: Tablets containing 10 mg and 20 mg pravastatin. **INDICATIONS AND ADULT DOSAGE:** *Hypercholesterolaemia:* in patients unresponsive to dietary measures. *Coronary Atherosclerosis:* slows the progression of coronary atherosclerosis and reduces the incidence of clinical cardiac events in hypercholesterolaemic patients with documented disease. *Prevention of Coronary Heart Disease:* reduces cardiovascular deaths, the risk of myocardial infarction and the need for myocardial revascularisation procedures. Start with 10 mg at night. The usual dosage range is 10-40 mg at night. The maximum response from a given dose occurs within 4 weeks. A standard cholesterol lowering diet should be continued. **CONCOMITANT**

THERAPY: LIPOSTAT is effective alone or in combination with bile acid sequestrants. **IMPAIRED RENAL FUNCTION AND ELDERLY PATIENTS:** Modification of dose is not normally necessary. **CHILDREN:** LIPOSTAT has not been evaluated in children. **CONTRA-INDICATIONS AND WARNINGS:** Hypersensitivity to LIPOSTAT. Active liver disease or unexplained persistent elevations in liver function tests. Pregnancy and breast feeding. Women of child bearing potential unless protected by adequate contraception. **PRECAUTIONS:** Patients with homozygous familial hypercholesterolaemia or elevated HDL-C. **LIVER FUNCTION:** Liver function tests should be performed periodically; discontinue if elevated liver enzymes greater than 3 times the upper limit of normal persist. Caution should be exercised in patients with a history of liver disease or alcoholism. Increases in CPK have occasionally been observed. Discontinue if levels exceed 10 times upper level of normal

or if myopathy suspected. There have been rare reports of rhabdomyositis. Use with caution in patients taking cyclosporin, fibric acid derivatives and nicotinic acid. **DRUG INTERACTIONS:** No clinically significant effects were seen in a range of studies. **SIDE EFFECTS:** LIPOSTAT is generally well tolerated. Adverse events are usually mild and transient. Side effects include rash, myalgia, headache, diarrhoea, fatigue, nausea/vomiting, non-cardiac chest pain. **OVERDOSAGE:** Treat symptomatically. **PRODUCT LICENCE NUMBERS:** LIPOSTAT Tablets 10 mg 0034/0286; LIPOSTAT Tablets 20 mg 0034/0287. **BAS C NHS PRICE:** 10 mg tablets, £16.18 for 28 tablet calendar pack; 20 mg tablets, £31.09 for 28 tablet calendar pack. **LEGAL CATEGORY:** POM. LIPOSTAT is a Squibb Trade Mark. **PRODUCT LICENCE HOLDER:** ER Squibb & Sons Limited. Further information from: Medical Information, ER Squibb & Sons Limited, Bristol-Myers Squibb House, 141-149 Staines Road,

Hounslow, Middlesex, TW3 3JA. Date of Advertisement: Preparation: November 1996.


References: 1. Jukema JW *et al.* *Circulation* 1995; **9**(10): 2528-40. 2. Pitt B *et al.* *JACC* 1995; **26**(5): 1133-9. 3. Crouse III JR *et al.* *Am J Cardiol* 1995; **75**: 455-459. 4. The Pravastatin Multinational Study Group for Cardiac Risk Patients. *Am J Cardiol* 1993; **72**: 1031-37. 5. Sacks FM *et al.* *N Engl J Med* 1996; **335**: 1001-1009. 6. Shepherd J *et al.* *New Engl Med J* 1995; **333**: 1301-07.



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ADALAT® LA 30/ADALAT® LA 60 -
ABRIDGED PRESCRIBING INFORMATION
 (Refer to full data sheet before prescribing)
Presentation: Tablets each containing 30mg or 60mg nifedipine in a modified (extended) release formulation. **Indications:** Mild to moderate hypertension. Prophylaxis of chronic stable angina pectoris either as monotherapy or in combination with a beta-blocker. **Dosage and Administration:** Adalat LA tablets must be swallowed whole, under no circumstances should they be bitten, chewed or broken up. One 30mg tablet once-daily swallowed whole with a glass of water to be taken at approximately 24-hour intervals, preferably during the morning. Dosage can be increased according to individual requirements up to a maximum of 90mg once-daily. Patients in whom hypertension or anginal symptoms are controlled on Adalat capsules or Adalat retard may be switched safely to Adalat LA. Prophylactic anti-anginal efficacy is maintained when patients are switched from other calcium antagonists such as diltiazem or verapamil to Adalat LA at the recommended initial dose of 30mg Adalat LA once-daily, with subsequent titration to a higher dose as warranted clinically. **Renal impairment:** Dosage adjustment should not be necessary. Lower maintenance doses may be required in the elderly compared with younger patients. Treatment may be continued indefinitely. Nifedipine is not recommended for use in children. **Contra-indications, warnings, etc. Contra-indications:** Known hypersensitivity to nifedipine or other dihydropyridines because of the theoretical risk of cross-reactivity; women of child-bearing potential and nursing mothers; clinically significant aortic stenosis; cardiogenic shock; unstable angina, during or within one month of a myocardial infarction; do not use for treatment of acute angina attacks; safety in malignant hypertension not established; secondary prevention of myocardial infarction; hepatic impairment; history of gastro-intestinal obstruction, oesophageal obstruction, or any degree of decreased lumen diameter of the gastro-intestinal tract; inflammatory bowel disease or Crohn's disease. Concomitant administration with rifampicin. **Warnings and Precautions:** Outer membrane of tablet is not digested and may be seen in the toilet or associated with the patient's stools. If used in combination with beta-blocking drugs and other antihypertensives a possible additive effect resulting in postural hypotension should be borne in mind. Adalat LA will not prevent possible rebound effects after cessation of other antihypertensive therapy. Caution in patients with hypotension or whose cardiac reserve is poor. Deterioration of heart failure has occasionally been observed with nifedipine. If ischaemic pain is observed following the introduction of therapy, discontinue treatment. Diabetic patients may require adjustment of their control. Marked decrease in blood pressure can occur in dialysis patients with malignant hypertension and hypovolaemia. **Interactions:** Interactions have been observed with cimetidine, quinidine, digoxin, diltiazem and rifampicin. Nifedipine should not be taken with grapefruit juice. Spectrophotometric values of urinary vanillylmandelic acid may be increased falsely. **Side-effects:** Headache, flushing, tachycardia, palpitations, gravitational oedema, paraesthesia, dizziness, lethargy and gastro-intestinal symptoms such as nausea and altered bowel habit. Less commonly, skin reactions such as rash, pruritus and urticaria. Less frequently, myalgia, tremor, visual disturbances and increased frequency of micturition. Impotence and mood changes occur rarely. At the start of treatment, exacerbation of angina pectoris may occur rarely. The occurrence of myocardial infarction was not distinguishable from the natural course of ischaemic heart disease. Rare cases of gingival hyperplasia, gynaecomastia in older men on long-term therapy, hypersensitivity-type jaundice and disturbances of liver function such as intra-hepatic cholestasis, all of which regress on withdrawal of therapy. In isolated cases, photosensitivity, exfoliative dermatitis, systemic allergic reactions and purpura, which usually regress after discontinuation of the drug. **Legal Category:** POM. **Package Quantities and Basic NHS Costs:** Calendar packs containing 28 tablets: Adalat LA 30 £10.36, Adalat LA 60 £15.40. **Product Licence Numbers:** PL 0010/0174-0175. **Date of Preparation:** January 1997.

Further information available from: Bayer plc, Pharmaceutical Division, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA. Telephone: (01635) 563000. © Registered trademark of Bayer AG, Germany. © Bayer plc, January 1997. Bayer and  are trademarks of Bayer AG, Germany.



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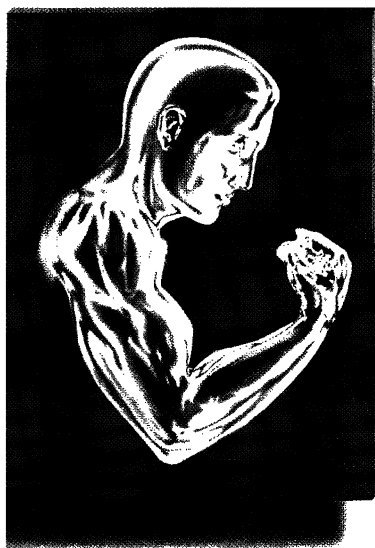
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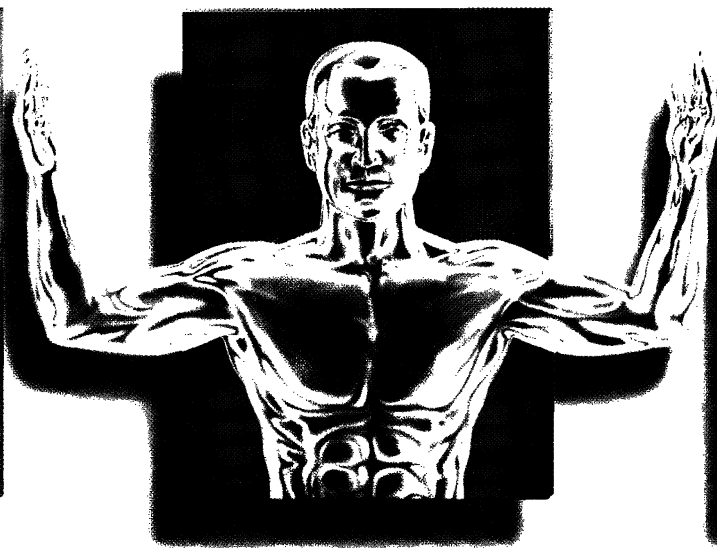
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Presentation: Lipitor is supplied as film coated tablets containing 10, 20 or 40mg of atorvastatin. **Indications:** In patients unresponsive to diet and other non-pharmacological measures, Lipitor is indicated for the reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides in patients with primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia or combined (mixed) hyperlipidaemia. Lipitor is also indicated for the reduction of elevated total cholesterol, LDL-cholesterol, and apolipoprotein B in patients with homozygous familial hypercholesterolaemia. **Dosage:** The usual starting dose is one Lipitor 10mg tablet daily. Doses may be given at any time of the day with or without food. The maximum daily dose is 80mg. **Contraindications:** Hypersensitivity to any of the ingredients, active liver disease, unexplained elevations in serum transaminases, pregnancy and breast feeding and in women of child-bearing potential not using contraception. **Warning and precautions:** Liver function tests should be performed before initiation and periodically thereafter and in patients who show signs and symptoms of liver injury (monitor raised transaminases until they return to normal). Drug dosage should be reduced or therapy discontinued if persistent elevations occur above 3-times the upper limit of normal. Lipitor should be used with caution in patients with a history of liver disease and/or alcoholism. Uncomplicated myalgias have been reported. Patients with signs and symptoms of myopathy should have their creatine phosphokinase (CPK) levels monitored. Lipitor should be discontinued if CPK levels are markedly or persistently raised or myopathy is diagnosed or suspected. Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with other drugs of this class. **Pregnancy and lactation:** Lipitor is contraindicated in pregnancy and

lactation. **Interactions:** There is an increased risk of myopathy if Lipitor is used concurrently with: cyclosporin, fibric acid derivatives, erythromycin, azole antifungals and niacin. Serum levels of enzyme inhibitors such as immunomodulators, many antiarrhythmic agents, some calcium channel blockers and some benzodiazepines may be raised or lowered (erythromycin may increase levels of Lipitor). The effect of enzyme inducers (eg rifampicin or phenytoin) on Lipitor is unknown. Digoxin levels can be increased by Lipitor. Patients on warfarin should be closely monitored as Lipitor caused a minimal decrease in clotting time. Colestipol was seen to lower levels of Lipitor and norethisterone and ethyl oestradiol levels were raised in patients taking the oral contraceptive. **Side effects:** Side effects most frequently reported in controlled clinical studies: constipation, flatulence, dyspepsia, abdominal pain, headache, nausea, myalgia, asthenia, diarrhoea, insomnia, elevations in ALT and CPK levels. Other side effects have been reported in clinical trials but were not necessarily associated with the product. See Summary of Product Characteristics. **Legal category:** POM. **Date of Revision:** December 1996. **Package quantities, marketing authorisation numbers and basic NHS price:** Lipitor 10mg (28 tablets), MA0018/0240 £18.88, Lipitor 20mg (28 tablets), MA0018/0241 £30.60, Lipitor 40mg (28 tablets) MA0018/0242 £47.04. **Marketing Authorisation Holder:** Parke-Davis & Company, Usk Road, Pontypool, NP4 0YH. Lipitor is a registered trade mark. Further information is available on request from: Parke-Davis, Lambert Court, Chestnut Avenue, Eastleigh, Hampshire SO53 3ZQ. **References:** 1. Bracs P, et al. Abstract, 66th Congress of the European Atherosclerosis Society, July 1996 + Data on file, Parke-Davis RR-720-03598. 2. Egros F, et al. Abstract, 66th Congress of the European Atherosclerosis Society, July 1996 + Data on file, Parke-Davis RR-720-03594. 3. Summary of Product Characteristics. 4. Data on file, Parke-Davis. **Date of preparation:** December 1996. Item code Z596/90036A
LIPITOR HOTLINE: 0645 68 69 70

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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 10mg, 20mg, or 30mg nisoldipine. **Pharmaceutical form:** Modified (extended) release tablets for oral administration. **Therapeutic indications:** Mild to moderate arterial essential hypertension. Prophylaxis of chronic stable angina pectoris. **Dosology 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 10mg once-daily. The usual maintenance dose is 20-40mg once-daily. The maximum recommended dose is 40mg once-daily. In hypertension, the recommended initial dose is one 10mg tablet once-daily. If necessary, the dosage can be increased according to individual requirements up to a maximum of 40mg 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 10mg 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, cardiogenic shock; children (aged less than 12 years); pregnant women or nursing mothers; 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, nifedipine, 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). 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 hypotensive effect. Increased duresis has been observed in isolated cases. **Legal category:** POM. **Package quantities and basic NHS costs:** Calendar packs containing 28 tablets: Syscor MR10 13, Syscor MR20 113.72, Syscor MR30 117.64. **Marketing Authorisation numbers:** PL 001 0200. **Date of preparation:** July 1996.

REFERENCES 1. Kazda S *et al* *Arzneim-Forsch Drug Res* 1980; **30** (II): 2144-2162. 2. Go T *et al* *J Cardiovasc Pharmacol* 1992; **20** (Suppl 5): S34-S41. 3. Schmitt *et al* *In: Hugenholz, Mayer J, eds. Nisoldipine* 1987, Berlin, Heidelberg, Springer-Verlag, 1987: 109-114. 4. Schmitt *et al* *J Cardiovasc Pharmacol* 1992; **20** (Suppl 5): S79-S81. 5. DEFIANT Research Group *Eur J Clin Invest* 1992; **22**: 1496-1505. 6. Lewis BS *et al* *Am J Cardiol* 1995; **75**: 46E-53E.

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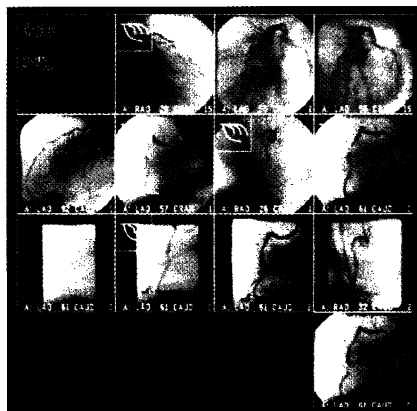
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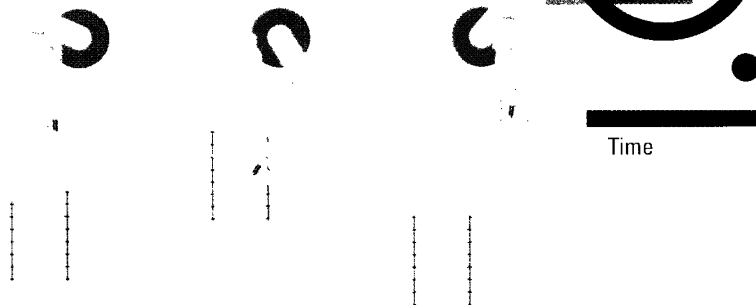
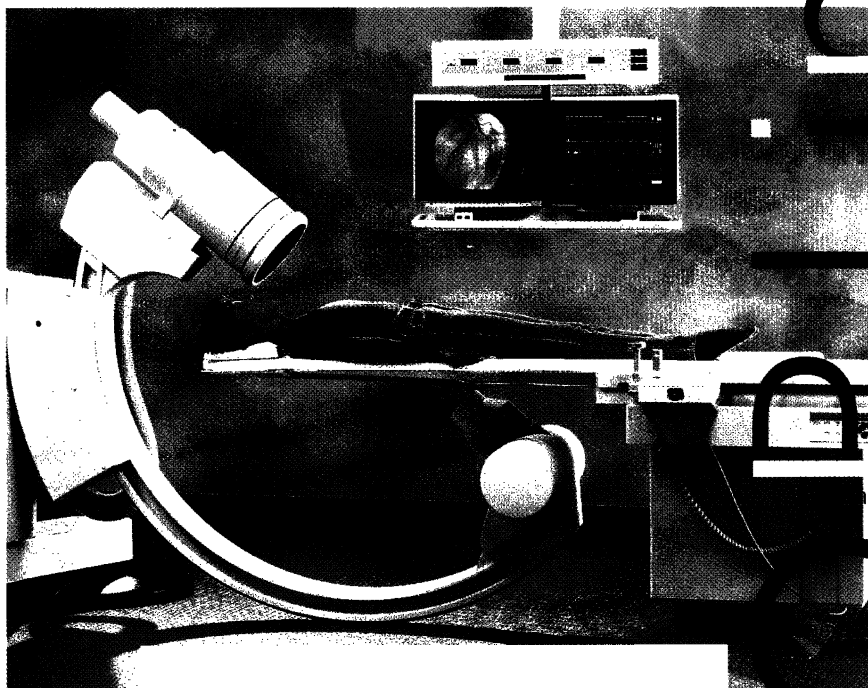
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(PL00001/0218), £3.94 per pack of 7 capsules and £15.75 per pack of 28. Diovan 160mg (PL00001/0219), £4.92 per pack of 7 capsules and £19.69 per pack of 28. ® denotes registered trademark. Full prescribing information is available on request from CIBA Laboratories, Horsham, West Sussex RH12 4AB. Telephone (01403) 272827. **Date of preparation** October 1996.

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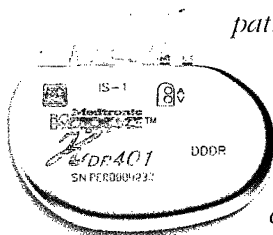
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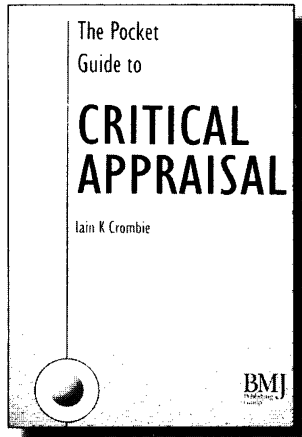


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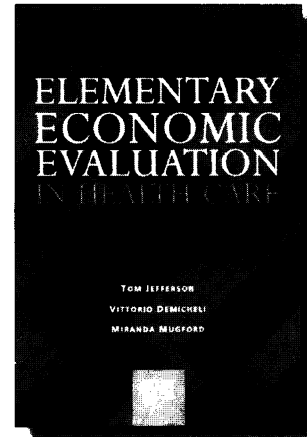
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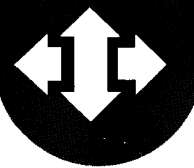
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