



# 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<sup>1</sup>**

**More consistent compliance  
than nifedipine retard<sup>2</sup>**

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 (PRINZMETALS 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.

#### 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: March 1997.

#### 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





# Adds convenience to your control of unstable coronary artery disease

- ◆ Fragmin is a new advance in cardiology: a convenient regimen for the control of unstable coronary artery disease — delivered by a simple s.c. injection.
- ◆ Fragmin avoids the cost and complexity of i.v. standard heparin, and does not require monitoring.
- ◆ Fragmin has reduced death and MI in UCAD by up to 63% ( $p=0.001$ ) when added to a standard regimen.<sup>1</sup>

Twice-daily injectable

**Fragmin**<sup>®</sup>  
dalteparin sodium



**The world's first LMWH in cardiology**

**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, quinine, 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.

ONCE-DAILY

# Adalat® LA

nifedipine 30mg & 60mg  
FOR HYPERTENSION AND ANGINA



**Bayer** 





# SYSCOR<sup>®</sup> MR

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<sup>1,2</sup>.

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

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 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. **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 in 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 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 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 MR10 £9.80. Syscor MR20 £13.72. Syscor MR30 £17.64. **Marketing Authorisation numbers:** PL 0010/0198-0200. **Date of preparation:** July 1996.

**REFERENCES** 1. Kazda S et al *Azmann-Forsch Drug Res* 1980; **30** (III): 2144-2162. 2. Goofrand T et al *J Cardiovasc Pharmacol* 1992; **20** (Suppl 5): S34-S41. 3. Scharli et al in: Hugenoltz PG, Meyer J, eds. *Nisoldipine* 1987. Berlin: Heidelberg: Springer-Verlag, 1987: 109-114. 4. Scharli et al *J Cardiovasc Pharmacol* 1992; **20** (Suppl 5): S79-S81. 5. DEFIANT Research Group *Eur Heart J* 1992; **13**: 1596-1505. 6. Lewis BS et al *Am J Cardiol* 1995; **75**: 46E-53E.

**Further information available from:** Bayer plc, Pharmaceutical Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA. Telephone: (01635) 563900. Registered trademark of Bayer AG, Germany. © Bayer plc, December 1996. Bayer and © are trademarks of Bayer AG, Germany.

**Bayer**

# Heaven Can Wait



## ZOCOR® (simvastatin, MSD)

### ABRIDGED PRODUCT INFORMATION

Refer to Summary of Product Characteristics before prescribing

#### PRESENTATION

Peacht, 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  $\geq 5.5$  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) and slow the progression of coronary atherosclerosis, 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 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) ( $\geq 10$  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 cyclosporin concomitant therapy with a fibrate acid derivative or lipid-lowering dose nicotinic acid, and believed to be enhanced by itraconazole. There have been reports of severe rhabdomyolysis with secondary acute renal failure. Therefore benefits and risks of using simvastatin concomitantly with immunosuppressive fibrates, lipid-lowering doses of nicotinic acid or itraconazole and systemic azole antifungal derivatives should be carefully considered.



**Pregnancy:** Contra-indicated. One month should elapse between ending therapy with 'Zocor' and planned conception.

**diatric use:** Safety and effectiveness in children have not been established.  
**eg 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 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'.

**ADVERSE 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, hralgia, urticaria, photosensitivity, fever, flushing, dyspnoea, and malaise.  
 Elevated and persistent increased serum transaminases have been reported frequently. Elevated alkaline phosphatase and  $\gamma$ -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.

**ZOCOR®**

(simvastatin, MSD)

The only statin proven to save the lives of post-MI and angina patients!



**MSD**

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

1-98 ZCR.96.GB.70826.J. D

To have one  
heart attack is  
unfortunate  
To have a second  
is CARE less



CARE IS THE MOST RECENT OF SIX LIPOSTAT STUDIES WHICH DEMONSTRATE ITS ABILITY TO REDUCE THE RISK OF A RANGE OF CARDIOVASCULAR EVENTS.<sup>1-6</sup> TO OBTAIN FURTHER DATA, PLEASE CALL THE FREEPHONE NUMBER BELOW.

THE  
  
CARE  
STUDY  
WITH

**LIPOSTAT**<sup>TM</sup>  
PRAVASTATIN SODIUM

**LIPOSTAT<sup>TM</sup> TABLETS ABBREVIATED  
PRESCRIBING INFORMATION**

**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**



Bristol-Myers Squibb Pharmaceuticals Limited

**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 rhabdomyolysis. 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. **BASIC 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,

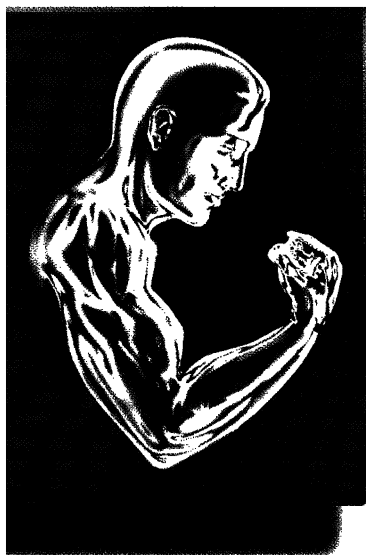
Hounslow, Middlesex, TW3 3JA. Date of Advertisement Preparation: November 1996.

**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 Cardiology* 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. Shephard J et al. *New Engl Med J* 1995; **333**: 1301-07.

**FULL CLINICAL  
RESULTS & INFORMATION  
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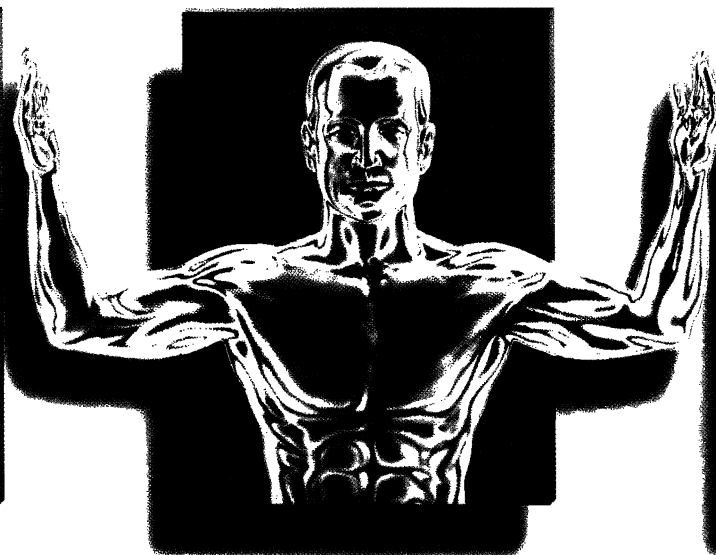
# NEW LIPITOR

## STRENGTH



to reduce cholesterol and triglyceride levels more than any other statin.<sup>1,2</sup>

## RANGE



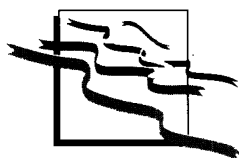
to treat more profiles and more patients than any other statin.<sup>3</sup>

## SIMPLICITY



to bring 70-90% of patients to their EAS treatment goals with the 10mg once daily starting dose.<sup>4</sup>

# ...never before seen in statin therapy.



*New*  
**Lipitor**<sup>®</sup>  
atorvastatin

## The most effective cholesterol lowering agent.

### Abbreviated prescribing information: Lipitor<sup>®</sup>

**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





Fybozest Orange UK

**Prescribing Information**

**Ingredients:** Each standard dose of Fybozest Orange contains 3.5g ispaghula Husk BP (high dose 5.25g) and also contains aspartame.

**Indications: Primary**

Hypercholesterolaemia. Reduction of mild to moderately elevated total serum cholesterol levels

(6.5-7.8mmol/l), and for the maintenance of lowered levels thereafter. To be used in conjunction with dietary modification.

**Dosage and administration:** (To be taken with water) Standard dose (1 measure): Adults: 3.5g ispaghula husk morning and evening.

Children: Not recommended. High dose (1.5 measures): Adults: 5.25g ispaghula husk morning and evening. Children: Not recommended.

Patients may be initiated on standard or high dose but high dose should only be used for two to three months.

**Contra-indications:** In cases of intestinal obstruction, faecal impaction and colonic atony. Should not be taken by patients with phenylketonuria or with hypersensitivity to any of the ingredients.

**Precautions for use:** Ispaghula husk should not be taken in the dry form. Patients with diabetes mellitus should only take Fybozest Orange under medical supervision. Flatulence and abdominal bloating may be experienced during the first few days of treatment but should diminish on continued use.

**Supply classification: P. PL no: 0063/0043. Reckitt & Coleman Products Ltd, Hull, HU8 7DS. Basic NHS price: £6.43 for a 265g pack (60 standard doses). Fybozest Orange and the Sword and Circle are trademarks of Reckitt & Coleman Products Ltd.**

Date of preparation: October 1996

**References:**

1. MacMahon MT, Carless J. Soluble fibre (ispaghula husk) in the treatment of hypercholesterolaemia: a double-blind controlled study. (Submitted for publication.)

2. Marmor M. Lowering population cholesterol concentrations probably isn't harmful. *BMJ* 1994; 308:351-352.

\* 60 standard doses.

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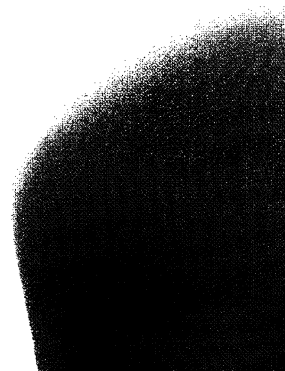
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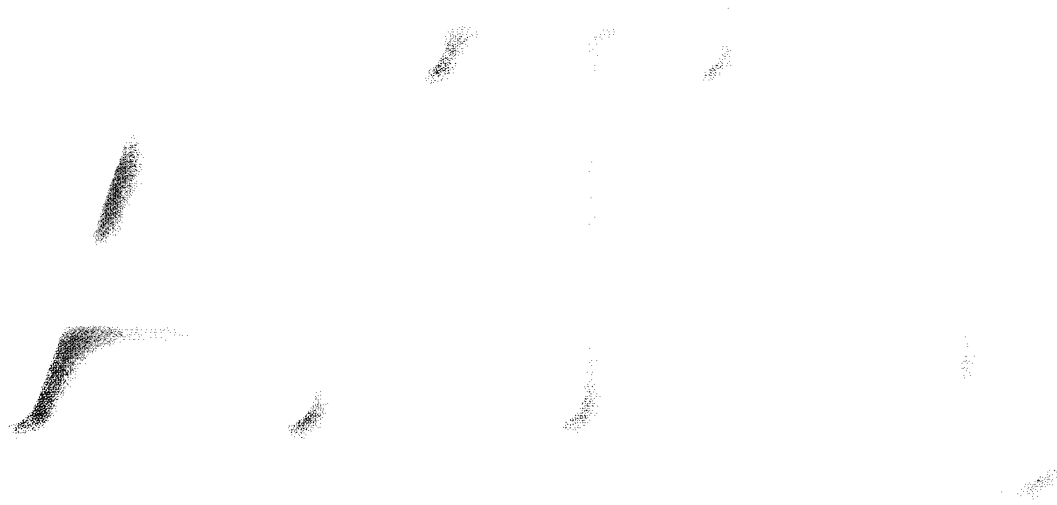
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**Prescribing information. Presentation** Capsules of 40mg, 80mg, and 160mg containing valsartan INN. **Indications** Hypertension. **Dosage** 80mg daily for most patients. The dosage can be increased to 160mg in patients whose blood pressure is not adequately controlled. For patients over 75, patients with moderate to severe renal impairment and patients on dialysis, a starting dose of 40mg once daily is recommended. For patients with mild to moderate hepatic impairment treatment should commence at 40mg once daily and a daily dose of 80mg should not be exceeded. For patients with intravascular volume depletion the diuretic dosage should be reduced several days before starting treatment with Diovan or a starting dose of

40mg is recommended. Not recommended for children. **Contra-indications** Hypersensitivity to any components of Diovan, pregnancy, severe hepatic impairment, cirrhosis and biliary obstruction. **Precautions** Use with caution in elderly patients and those with mild to moderate hepatic impairment. Those with severe hepatic impairment should not use Diovan. Sodium and/or volume depletion should be corrected before starting treatment with Diovan by reducing the diuretic dose or a lower starting dose should be used. Patients with renal artery stenosis should be carefully monitored. Exercise caution if driving or operating machinery. Use of potassium-sparing diuretics, potassium supplements or salt substitutes containing potassium may lead to

increases in serum potassium; concomitant use is not advisable. Use while breast-feeding is not advisable. **Side-effects** *Occasionally:* Fatigue, neutropenia, elevations of serum potassium, creatine and bilirubin. *Rarely:* Eosinophilia, decreases in haemoglobin and haematocrit. **Legal Category** POM. **Packs** Diovan 40mg (PL00001/0225), £3.35 per pack of 7 capsules, Diovan 80mg (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. Product licence holder: CIBA Laboratories, Horsham, West Sussex RH12 4AB. Telephone: (0) 4033 77757. **Date of preparation** October 1996.

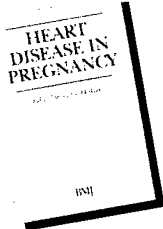
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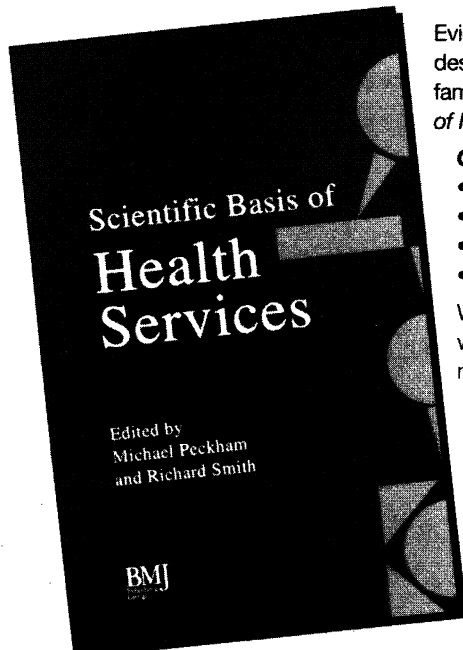
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# Applying science to health care



## Scientific Basis of Health Services

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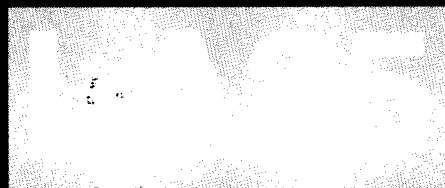
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**Presentation:** Elantan LA25: Brown and white opaque gelatin capsules containing 25 mg isosorbide mononitrate in a slow release formulation. **Elantan LA50:** Brown and flesh coloured opaque gelatin capsules containing 50 mg isosorbide mononitrate 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 col-

lapse 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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