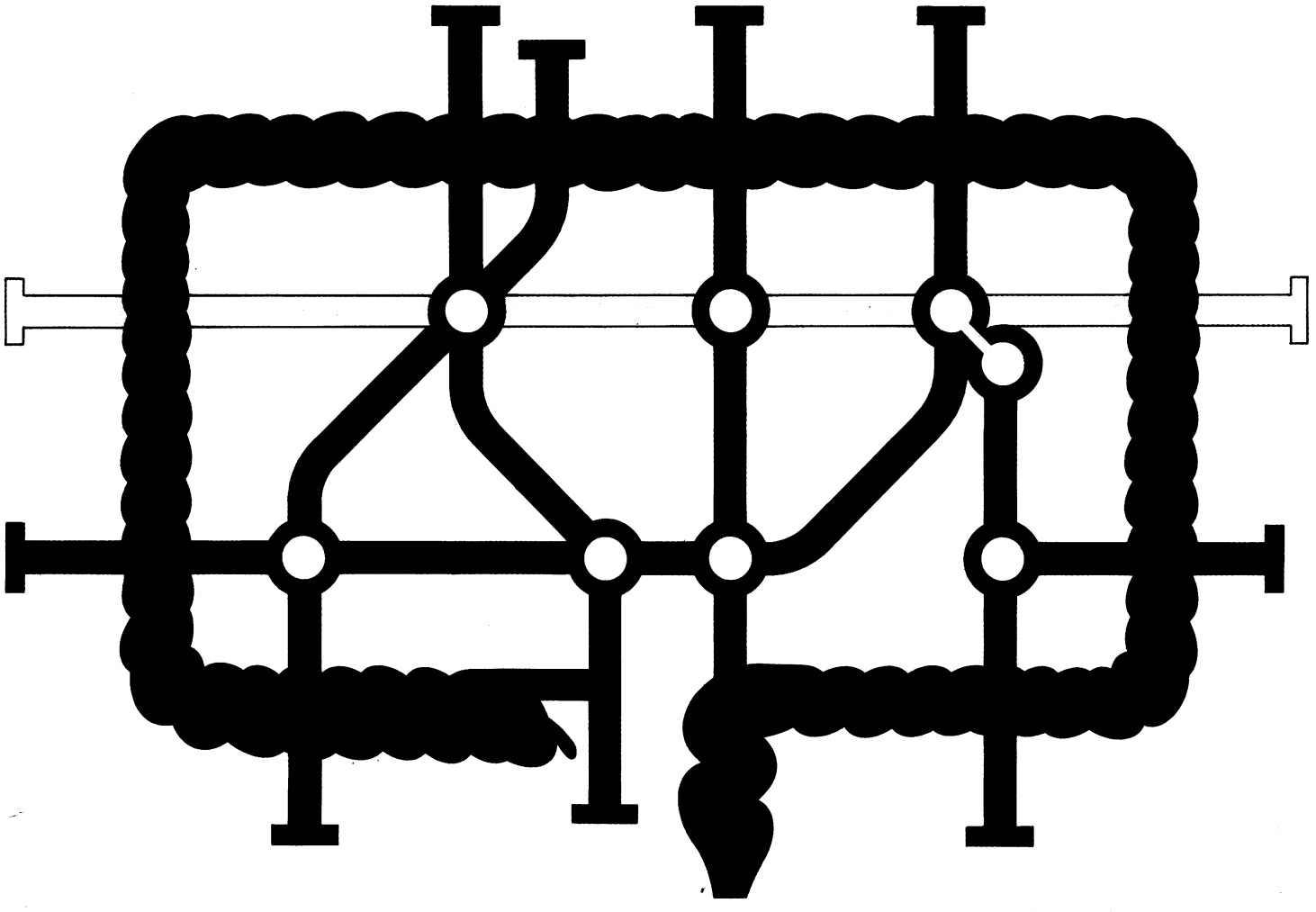


COLIFOAM

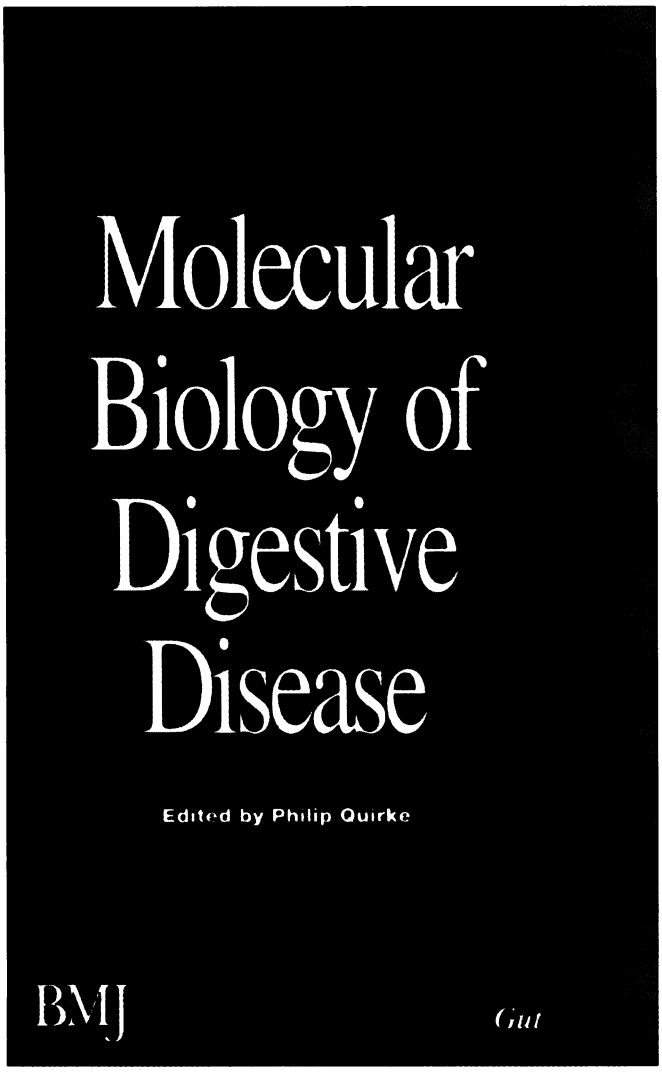
10% hydrocortisone acetate

FIRST CLASS TREATMENT WHICH TRAVELS TO WORK

- Colifoam is highly effective for distal ulcerative colitis.[1]
- The retrograde spread of Colifoam increases with the extent of disease.[2]
- Colifoam is easier to retain than liquid enemas and causes less interference with social, sexual and occupational activities.[1,3]

PRESCRIBED WITH CONFIDENCE FOR OVER 20 YEARS.

PRESCRIBING INFORMATION: Presentation: White odourless aerosol containing hydrocortisone acetate PhEur 10% w/w. **Uses:** Ulcerative colitis, proctosigmoiditis and granular proctitis. **Dosage and administration:** One applicatorful inserted into the rectum once or twice daily for two or three weeks and every second day thereafter. Shake can vigorously before use (illustrated instructions are enclosed with pack). **Contra-indications, warnings etc:** Local contra-indications to the use of intrarectal steroids include obstruction, abscess, perforation, peritonitis, fresh intestinal anastomoses and extensive fistulae. General precautions common to all corticosteroid therapy should be observed during treatment with Colifoam. Treatment should be administered with caution in patients with severe ulcerative disease because of their predisposition to perforation of the bowel wall. Safety during pregnancy has not been fully established. Although uncommon at this dosage, local irritation may occur. **Pharmaceutical precautions:** Pressurised container containing flammable propellant. Protect from sunlight and do not expose to temperatures above 50°C. Keep away from sources of ignition. Do not pierce or burn even after use. Do not refrigerate, store below 25°C. Keep out of reach of children. For external use only. **Legal category:** POM. **Package quantity & basic NHS cost:** 20.8g canister plus applicator, £7.07. Provides approximately 14 doses. **Product Licence No:** 0036/0021. Further information is available on request from Stafford-Miller Ltd, Broadwater Road, Welwyn Garden City, Herts. AL7 3SP. **Code:** DO2665.



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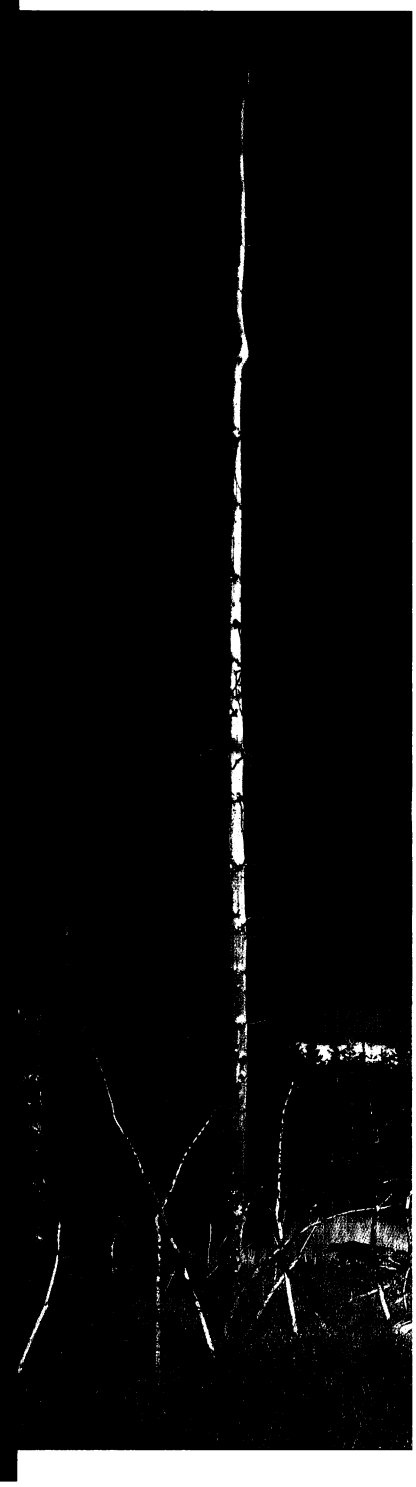
KEEP ACID WHERE IT WORKS NOT WHERE IT HURTS



Sadly, you're powerless over the scars which acid rain has left on the forests of Europe.

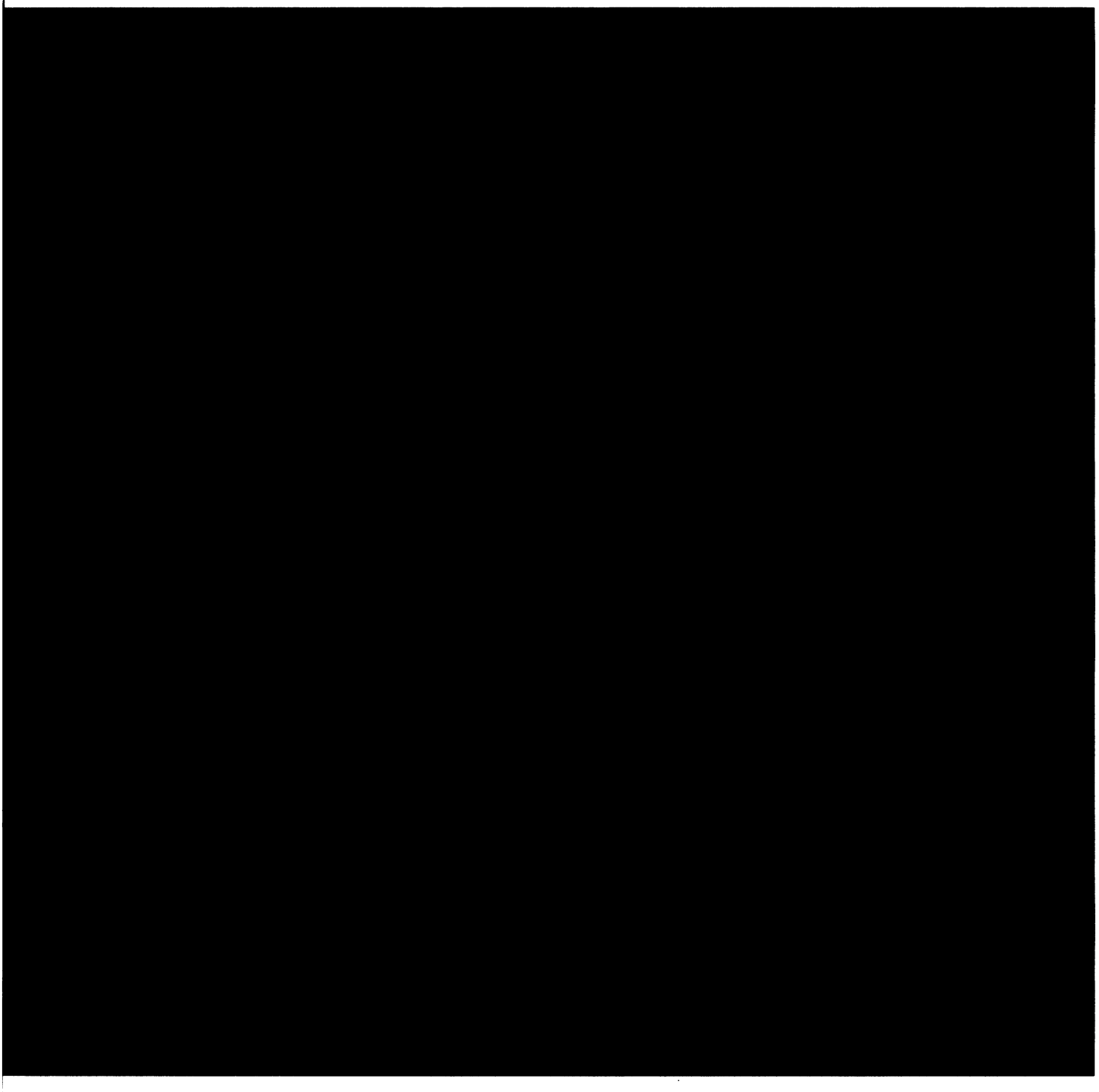
But if you know the true nature of the problem there's a lot you can do for the victims of acid reflux.

It's a little known fact that nearly 80% of reflux patients don't suffer from excess acid,[1,2] they suffer from acid in the wrong place.

So doesn't it make sense to use a reflux treatment which keeps acid where it works and not where it hurts?

Gaviscon works by forming a soothing alginate barrier

Prescribing Information. Liquid Gaviscon. Active Ingredients: Sodium alginate BP 500mg, sodium bicarbonate Ph.Eur. 267mg and calcium carbonate Ph.Eur. 160mg per 10ml dose. **Indications:** Heartburn, including heartburn of pregnancy, dyspepsia associated with gastric reflux, hiatus hernia and reflux oesophagitis. **Contra-Indications:** None known. **Dosage and Administration:** Adults and children over 12: 10-20ml liquid, after meals and at bedtime. Children 6-12: 5-10ml liquid after meals and at bedtime. **Note:** 10ml liquid contains 6.2mmol sodium. **Basic NHS Cost:** 500ml liquid £2.70. **PL:** 44/0058 Liquid Gaviscon, 44/0140 Liquid Gaviscon Peppermint Flavour. **Legal Category:** GSL. (PO). **Gaviscon Tablets. Active Ingredients:** Alginic acid BP 500mg, sodium bicarbonate Ph.Eur. 170mg, dried aluminium hydroxide gel BP 100mg, magnesium trisilicate Ph.Eur. 25mg per tablet. In a sugar free flavoured base containing calcium carbonate (40mg) and saccharin. **Indications:** Heartburn, including heartburn of pregnancy, dyspepsia associated with gastric reflux, hiatus hernia and reflux oesophagitis. **Contra-Indications:**



which prevents acid from rising into the oesophagus, bringing rapid relief to 4 out of 5 reflux patients.[3,4,5]

So to keep acid in its natural environment, make Gaviscon your first choice in reflux.

GAVISCON

liquid: **sodium alginate BP, sodium bicarbonate Ph.Eur., calcium carbonate Ph.Eur.**
tablets: **alginic acid BP, sodium bicarbonate Ph.Eur., aluminium hydroxide BP, magnesium trisilicate Ph. Eur.**

Keeps acid in its natural environment

None known. **Dosage and Administration:** Adults and children over 12: 1 or 2 tablets after meals and at bedtime. Children 6-12: 1 tablet after meals and at bedtime. **Note:** 1 tablet contains 2.1mmol sodium. Tablets should be thoroughly chewed. **Basic NHS Cost:** 60 tablets £2.25. **PL:** 44/0021 Gaviscon Tablets, 44/0141 Gaviscon Tablets Lemon Flavour. **Legal Category:** GSL. (PO). **Holder of product licences:** Reckitt & Colman Products Limited, Dansom Lane, Hull, HU8 7DS. Gaviscon and the sword and circle symbol are registered trademarks. **Date of preparation:** 20/9/94.

References 1. Ball C.S. *et al.* (1988) *GUT*, Vol. 29 (part 10) A 1449. 2. Cadiot G. *et al.* (1994) *Gastrointest. Res.* **22:** 209-222. 3. Chevrel B. (1980) *J. Int. Med. Res.* **8:** 300. 4. Ward A.E. (1989) *Br. J. Clin. Pract.* **43** (2) Suppl. 66: 52. 5. Williams D.L. *et al.* (1979) *J. Int. Med. Res.* **7:** 551.

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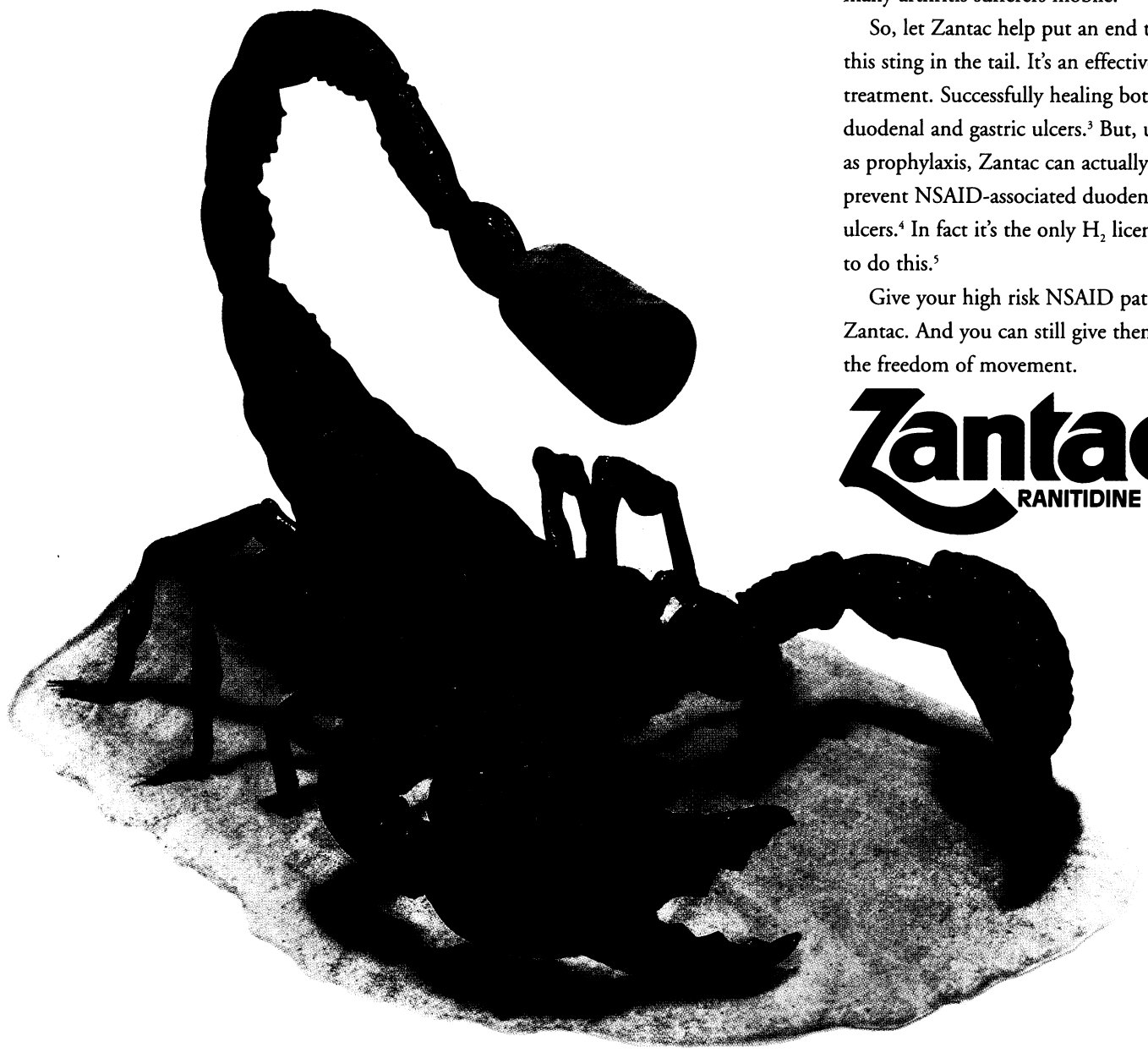
ZANTAC. TAKING THE STING OUT OF NSAIDs.



NSAIDs claim around 3,000 lives a year in the UK alone.[1] Patients with a history of ulcer disease being at greatest risk of life-threatening complications.[2]

However, NSAIDs also keep a great many arthritis sufferers mobile.

So, let Zantac help put an end to this sting in the tail. It's an effective treatment. Successfully healing both duodenal and gastric ulcers.[3] But, used as prophylaxis, Zantac can actually prevent NSAID-associated duodenal ulcers.[4] In fact it's the only H_2 licensed to do this.[5]

Give your high risk NSAID patients Zantac. And you can still give them the freedom of movement.

Zantac
RANITIDINE HCl

PRESCRIBING INFORMATION:
Indications Duodenal ulcer, benign gastric ulcer, ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), prevention of NSAID-associated duodenal ulcer, oesophageal reflux disease, severe oesophagitis, long-term management of healed oesophagitis, chronic episodic dyspepsia. **Dosage** *Adults:* Duodenal ulceration and gastric ulceration: A single 300mg dose at bedtime or 150mg twice daily in the morning and evening for four weeks. In duodenal ulcers, 300mg twice daily produces higher healing rates at four weeks. Continued maintenance treatment of 150mg at bedtime is recommended for patients with a history of recurrent ulceration. Ulcers following non-steroidal anti-inflammatory drug therapy or associated with continued non-steroidal anti-inflammatory drugs: 150mg twice daily for up to eight weeks. Prevention of NSAID-associated duodenal ulcer: 150mg twice daily concomitantly with NSAID therapy. Chronic episodic dyspepsia: 150mg twice daily for six weeks, investigate early relapsers and non-responders. Oesophageal reflux disease: 300mg at bedtime or 150mg twice daily for up to eight weeks. Moderate to severe oesophagitis: 150mg four times daily for up to twelve weeks (see data sheet for full dosage instructions). Long-term treatment of healed oesophagitis: 150mg twice daily. *Children:* Oral dose for peptic ulcer: 2mg/kg to 4mg/kg, twice daily to a maximum of 300mg per day. **Contra-indications** Patients with known hypersensitivity to ranitidine. **Precautions** In patients in whom sodium restriction is indicated, care should be taken when administering sodium-containing Effervescent Tablets. Exclude the possibility of malignancy in gastric ulcer before instituting therapy, especially in middle-aged patients with new or recently changed dyspeptic symptoms. Regular supervision of patients taking NSAIDs concomitantly with Zantac is recommended, especially if elderly. Protects against NSAID-associated ulceration in duodenum and not in stomach. Reduce dosage in the presence of severe renal failure (see data sheet). Avoid in patients with history of porphyria. Effervescent Tablets contain aspartame, use with caution in patients with phenylketonuria. Like other drugs, use during pregnancy and lactation only if strictly necessary. **Side effects** Headache, dizziness, skin rash, occasional hepatitis, rarely arthralgia, myalgia. Rarely, reversible mental confusion states, usually in very ill or elderly patients. Rare cases of leucopenia and thrombocytopenia, usually reversible, agranulocytosis and pancytopenia. Hypersensitivity reactions, anaphylactic shock. Rare cases of breast symptoms in men. As with other H_2-receptor antagonists rare cases of bradycardia, A-V block and asystole (see data sheet). **Presentations** Zantac 150 Tablets each containing 150mg ranitidine HCl, (Product licence number 10949/0042, 60 tablets £27·89); Zantac 300 Tablets each containing 300mg ranitidine HCl (Product licence number 10949/0043, 30 tablets £27·43); Zantac Effervescent Tablets each containing 150mg ranitidine HCl and 14·3mEq sodium, (Product licence number 0004/0392, 60 tablets £27·89); Zantac Effervescent Tablets each containing 300mg ranitidine HCl and 20·8mEq sodium (Product licence number 0004/0393, 30 tablets £27·43), Zantac Syrup each 10ml dose containing 150mg ranitidine HCl (Product licence number 10949/0108, 300ml bottle £22·32). **Product licence holders** Glaxo Operations UK Limited, Greenford, Middlesex UB6 0HE. Glaxo Pharmaceuticals UK Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. POM Zantac is a Glaxo trade mark. Further information is available on request from: Glaxo Laboratories Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Telephone 081-990 9444. June 1994.

References
1. Hayllar J, Macpherson A, Bjarnason I. Drug Safety 1992; 7(2): 86-105. 2. Rodriguez LAG, Jick H. The Lancet 1994. Vol 343: 769-772. 3. Lancaster-Smith ML, Jaderberg ME, Jackson DA. Gut 1991; **32**: 252-255. 4. Robinson MG, Griffin JW, Bowers J *et al.* Dig Dis Sci 1989; **34**(3): 424-428.
5. Zantac Data Sheet.

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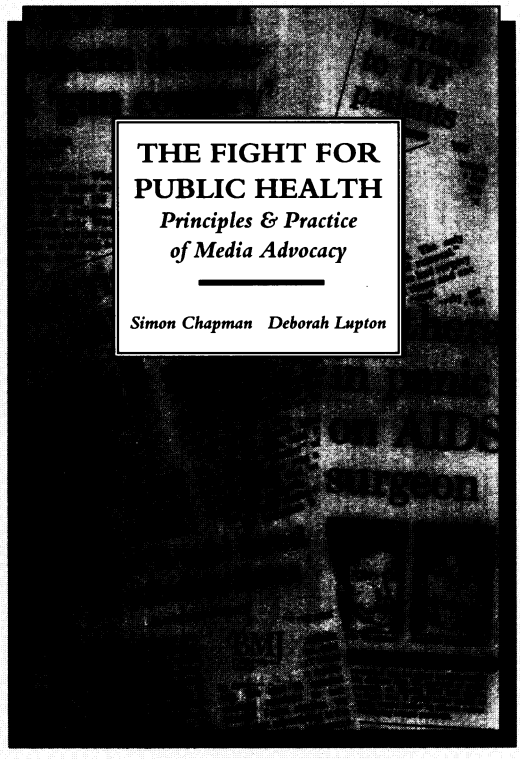

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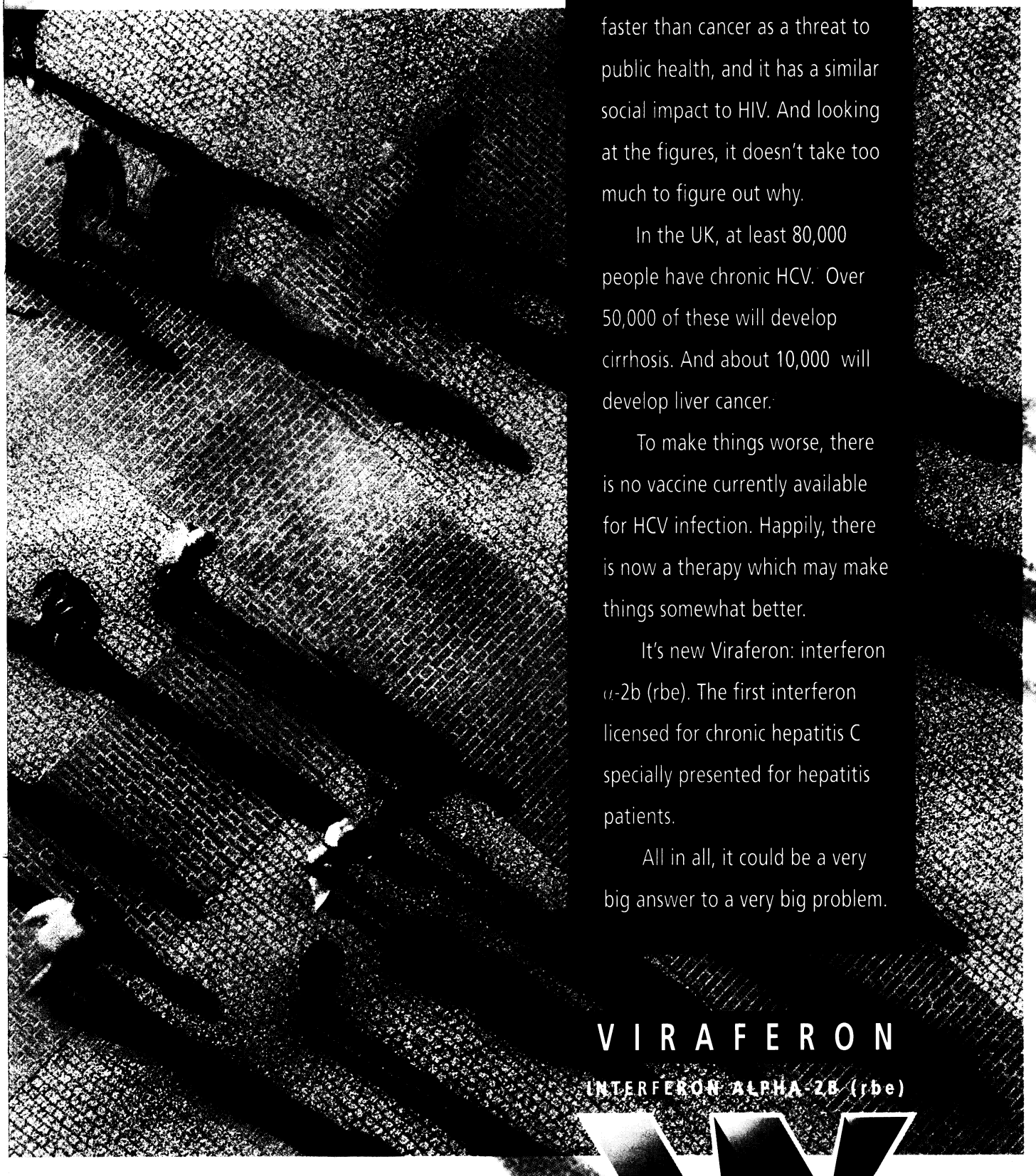
VIRAFERON ABBREVIATED PRESCRIBING INFORMATION

Before prescribing Viraferon please refer to full Data sheet. Presentation: 10 million or 25 million IU/vial of Interferon Alfa-2b(rbe) in solution. Uses: Treatment of Chronic Active Hepatitis B; reduction of disease activity in Chronic Hepatitis C/ Non-A, Non-B. Dosage and Administration: *Chronic Active Hepatitis B:* The recommended dosage is usually in the range of 2.5 million IU to 5.0 million IU/m^2 of body surface area administered subcutaneously three times per week for a period of four to six months. *Chronic Hepatitis C/Non-A, Non-B:* The recommended dose is 3 million IU administered three times a week. Most patients who respond demonstrate improvement in ALT levels within 12-16 weeks. In those patients, therapy should be continued with 3 million IU three times a week for up to 18 months. Contraindications, Warnings, Precautions, etc.: Contraindications: A history of hypersensitivity to recombinant Interferon Alfa-2b(rbe) or components of VIRAFERON Injection contraindicates its use; severe pre-existing cardiac disease, severe renal or hepatic dysfunction; epilepsy and/or compromised central nervous system function; chronic hepatitis with advanced decompensated cirrhosis of the liver; chronic hepatitis patients who are being or have been recently treated with immunosuppressive agents excluding short-term corticosteroid withdrawal. Autoimmune hepatitis or history of autoimmune disease, pre-existing thyroid disease not controlled by conventional therapy. Warnings and Precautions: Use with caution in patients with a history of pulmonary disease, diabetes mellitus, coagulation disorders or severe myelosuppression. Moderate to severe adverse experiences may require reduction of dosage or termination of VIRAFERON therapy. Patients with chronic Hepatitis B with evidence of decreasing hepatic synthetic function may be at increased risk of clinical decompensation if a flare up of aminotransferases occurs during treatment. Patients with a recent history of cardiovascular events should be closely monitored as adverse cardiovascular events including hypotension and cardiac arrhythmias have been observed. Adequate hydration of patients should be maintained during treatment. Pulmonary infiltrates, pneumonitis and pneumonia, including fatality, have been observed rarely. Reversible CNS effects commonly manifested by confusion have been seen, usually at high doses. Infrequently, patients treated for chronic Hepatitis C/Non-A, Non-B developed thyroid abnormalities, either hypothyroid or hyperthyroid. VIRAFERON may exacerbate pre-existing psoriatic disease. Ocular adverse events have been reported. Concomitant narcotics or sedatives should be administered with caution. Patients taking xanthine derivatives should be monitored and dosage adjusted as necessary. No information is available on the use of interferon in human pregnancy or its effect on human lactation. VIRAFERON should only be given if the benefits clearly

Schering-Plough



Hepatitis C (HCV) is growing faster than cancer as a threat to public health, and it has a similar social impact to HIV. And looking at the figures, it doesn't take too much to figure out why.

In the UK, at least 80,000 people have chronic HCV. Over 50,000 of these will develop cirrhosis. And about 10,000 will develop liver cancer.

To make things worse, there is no vaccine currently available for HCV infection. Happily, there is now a therapy which may make things somewhat better.

It's new Viraferon: interferon α-2b (rbe). The first interferon licensed for chronic hepatitis C specially presented for hepatitis patients.

All in all, it could be a very big answer to a very big problem.

VIRAFERON

INTERFERON ALPHA-2B (rbe)

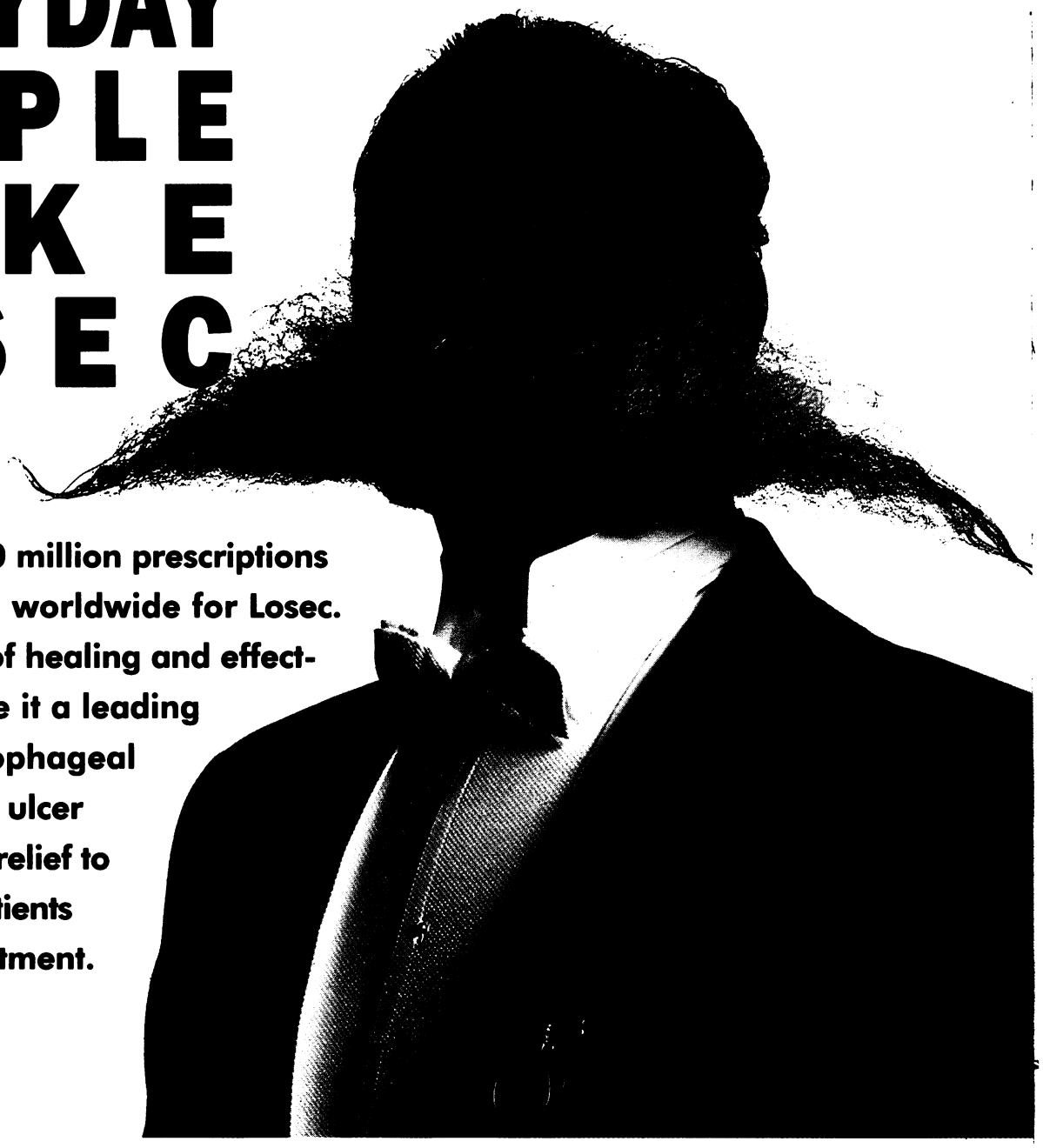
NEW HOPE FOR HEPATITIS

outweigh the potential hazard to the foetus or nursing infant. **Side Effects**: Elevated liver function tests, reduction in white blood cell, granulocyte and platelet counts have been observed especially at higher doses. Retinal haemorrhages, cotton wool spots and retinal artery or vein obstruction have been observed rarely. The most common adverse effects are 'flu-like' symptoms, leucopenia, thrombocytopenia and CNS effects, which are generally dose-related and reversible and can be ameliorated by dose adjustment. 'Flu-like' symptoms can be alleviated by the use of paracetamol. **Package Quantities**: 10 million IU (2ml) and 25 million IU (5ml) per vial. **Trade Price**: - 10 Million IU (2ml) pack containing 3x10M IU vials: £169.56. - 25 Million IU (5ml) pack containing 2x25M IU vials: £282.60 **Legal Category**: POM. **Product Licence Numbers**: PL 0201/0203-0204. Further information is available from the Product Licence Holder : Schering-Plough Ltd, Shire Park, Welwyn Garden City, Hertfordshire, AL7 1TW.

References 1. Lau JYN, Williams R. The GP-Specialist Forum, Medical Dialogue 1991; 334: 1- 4.
2. Hepatitis Information for General Practitioners; British Liver Trust.

Date of Preparation: December 1994

EVERYDAY PEOPLE TAKE LOSEC



Since 1989 over 100 million prescriptions have been written worldwide for Losec. Already its speed of healing and effectiveness have made it a leading treatment for oesophageal reflux disease*and ulcer disease – bringing relief to more and more patients earlier in their treatment.

LOSEC® 20mg Capsules

(omeprazole-Astra)

FOR HEALING

In oesophageal reflux disease*, duodenal and benign gastric ulcer.

LOSEC® CAPSULES (omeprazole) ABBREVIATED PRESCRIBING INFORMATION (refer to full data sheet before prescribing) **PRESENTATION:** LOSEC Capsules containing 10mg, 20mg or 40mg omeprazole as enteric coated granules with an aqueous based coating. **USES:** Oesophageal reflux disease. Duodenal and benign gastric ulcers (including NSAID-induced). Duodenal ulcer associated with *Helicobacter pylori*. Prophylaxis of acid aspiration. Zollinger-Ellison syndrome. **DOSAGE & ADMINISTRATION:** **Adults (including the elderly):** The usual dose in oesophageal reflux disease and peptic ulcer is 20mg once daily, increasing to 40mg once daily in severe or refractory cases, if required. **Oesophageal reflux disease:** Healing: 20mg daily for 4 weeks. Continue for further 4-8 weeks if required. **Maintenance in acid reflux disease:** LOSEC 10mg daily. Increase to 20mg daily if symptoms return. **Duodenal ulcer (DU):** Healing: 20mg daily for 4 weeks. **DU maintenance:** LOSEC 10mg daily increasing to 20mg daily if symptoms return. **DU associated with *Helicobacter pylori*:** Usual dose is LOSEC 40mg daily with amoxycillin 1.5g daily (750mg b.d.) for 2 weeks. Up to 2g/day of amoxycillin has been used in clinical studies. **Benign Gastric Ulcer:** 20mg daily for 8 weeks. **Prophylaxis of acid aspiration:** LOSEC 40mg on the evening before surgery followed by LOSEC 40mg on the morning of surgery. **Zollinger-Ellison Syndrome:** 60mg daily as long as clinically indicated. Individually adjust within range 20-120mg daily. If in excess of 80mg daily give in 2 equal divided doses. **Renal impairment:** No dose adjustment needed. **Hepatic impairment:** Adjust dose (maximum daily dose 20mg). **Children:** No experience of use. **CONTRA-INDICATIONS, WARNINGS, etc:** No known contra-indications. In gastric ulcer, exclude malignancy before starting therapy. Avoid in pregnancy unless no safer alternative. Discontinue breast feeding if LOSEC is considered essential. **Side effects:** LOSEC is well tolerated. Adverse reactions are generally mild and reversible (relationship to LOSEC not established in many cases). They include diarrhoea, headaches, skin disorders and in isolated cases, angioedema, musculoskeletal disorders, fatigue, insomnia, dizziness, blurred vision, vertigo, paraesthesia, liver enzyme and haematological changes. LOSEC can delay the elimination of diazepam, phenytoin and warfarin. Simultaneous treatment with omeprazole and digoxin may increase the bioavailability of digoxin. **PHARMACEUTICAL PRECAUTIONS:** Use within three months of opening. Store below 30°C. Replace cap firmly after use. Dispense in original container. **LEGAL CATEGORY:** POM. **FURTHER INFORMATION:** ***Helicobacter pylori*** (Hp) is associated with acid peptic and ulcer disease, contributing to gastritis and ulcer recurrence. In patients known to be allergic to amoxycillin, clarithromycin may be a useful alternative in dual therapy. Omeprazole 40mg daily, amoxycillin 1500mg daily and metronidazole 1200mg daily for 14 days achieved an overall Hp eradication rate of 89% (96% in metronidazole-sensitive isolates).

PACKAGE QUANTITIES: 10mg: bottles of 7*capsules £4.99, bottles of 28 capsules £19.95. 20mg: bottles of 7*capsules £8.86, bottles of 28 capsules £35.45. 40mg: bottles of 7* capsules £17.72, bottles of 14 capsules £35.45. (*Hospital pack only).

PRODUCT LICENCE NUMBERS:
PL 0017/0337 - LOSEC Capsules 10mg.
PL 0017/0238 - LOSEC Capsules 20mg.
PL 0017/0320 - LOSEC Capsules 40mg.

*Oesophageal reflux disease (GORD) = symptoms and/or tissue damage attributable to reflux. Symptoms vary considerably from one sufferer to another, but the most typical are heartburn and regurgitation.

For further information contact the **PRODUCT LICENCE HOLDER:** Astra Pharmaceuticals Limited, Home Park, Kings Langley, Hertfordshire. WD4 8DH. Telephone: (01923) 266191.

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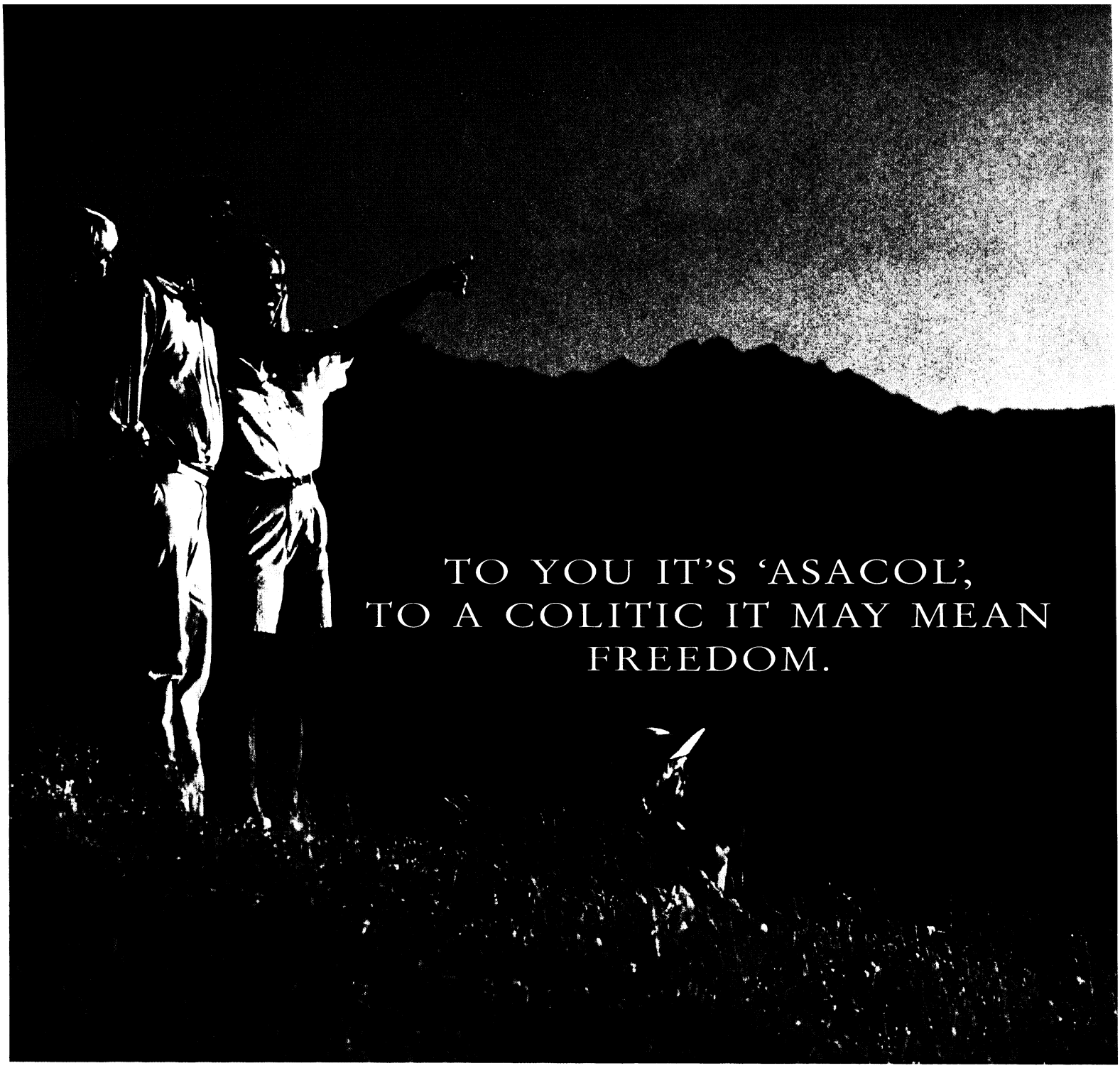
Date of preparation: February 1995 LOS/ADV 345b



Prescribing information: Presentation: 'Asacol' Tablets, PL 0002/0173, each containing 400 mg mesalazine (5-aminosalicylic acid) coated with a pH-dependent acrylic based resin (Eudragit S) formulated to release the active ingredient in the terminal ileum and colon. Blister packs of 120 (12 x 10), £39.62. 'Asacol' Suppositories 250 mg, PL 0002/0158, each containing 250 mg mesalazine. 20, £6.50. 'Asacol' Suppositories 500 mg, PL 0002/0195, each containing 500 mg mesalazine. 10, £6.50. 'Asacol' Foam Enema, PL 0002/0222, 1 g mesalazine per metered dose. Carton containing can of 14 metered doses, 14 disposable applicators and 14 disposable plastic bags. £39.60. **Uses:** For the treatment of mild to moderate acute exacerbations of ulcerative colitis. Tablets and Suppositories for the maintenance of remission of ulcerative colitis. The suppositories and foam enema are particularly appropriate in patients with distal disease. **Dosage and administration: Adults:** ***Tablets:*** *Acute disease:* Six tablets a day in divided doses, with concomitant corticosteroid therapy where clinically indicated. *Maintenance therapy:* Three to six tablets a day in divided doses. ***Suppositories:*** *250 mg suppositories:* Three to six suppositories a day, in divided doses, with the last dose at bedtime. *500 mg suppositories:* A maximum of three suppositories a day, in divided doses, with the last dose at bedtime. ***Foam Enema:*** For disease affecting the rectosigmoid region, one metered dose 1 g a day for 4-6 weeks; for disease involving the descending colon, two metered doses 2 g once a day for 4-6 weeks. **Children:** There is no dosage recommendation. **Contra-indications:** A history of sensitivity to salicylates or renal sensitivity to sulphasalazine. Severe renal impairment (GFR <20 ml/min). Children under 2 years of age. **Precautions:** Renal disorder: mesalazine is excreted rapidly by the kidney, mainly as its metabolite, N-acetyl-5-aminosalicylic acid. In rats, large doses of mesalazine injected intravenously produce tubular and glomerular toxicity. 'Asacol' is best avoided in patients with established renal impairment but, if necessary, it should be used with caution. 'Asacol' Tablets should not be given with lactulose or similar preparations which lower stool pH and may prevent release of mesalazine. **Use in pregnancy and lactation:** No information is available with regard to teratogenicity; however, negligible quantities of mesalazine are transferred across the placenta and are excreted in breast milk following sulphasalazine therapy. Use of 'Asacol' during pregnancy should be with caution, and only if, in the opinion of the physician, the potential benefits of treatment are greater than the possible hazards. 'Asacol' should, unless essential, be avoided by nursing mothers. **Elderly:** Use in the elderly should be cautious and subject to patients having a normal renal function (see **Precautions**). **Adverse reactions:** The side effects are predominantly gastrointestinal. Nausea, diarrhoea, abdominal pain and headache have been reported. 'Asacol' may be associated with the exacerbation of the symptoms of colitis in those patients who may have previously had such problems with sulphasalazine. There have been reports of leucopenia, neutropenia, thrombocytopenia aplastic anaemia, pancreatitis, hepatitis, and nephrotic syndrome with oral treatment, usually reversible on withdrawal. Renal failure has been reported. Mesalazine-induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment. Hypersensitivity reactions to mesalazine have been reported rarely, including interstitial nephritis, allergic myocarditis, lupus-like syndrome, pulmonary symptoms and rash (including urticaria). These reactions are usually reversible on cessation of mesalazine. Other side effects observed with sulphasalazine such as depression of sperm count and function have not been reported with 'Asacol'. **Treatment of overdosage:** Following tablet ingestion, gastric lavage and intravenous transfusion of electrolytes to promote diuresis. There is no specific antidote. **Legal category:** POM. **Further information:** Whilst mesalazine is known to be the active component of sulphasalazine in the treatment of ulcerative colitis, the other component of sulphasalazine, sulphapyridine, is thought to be responsible for the majority of side effects. 11.8.94

Smith Kline & French Laboratories, Welwyn Garden City, Hertfordshire AL7 1EY. Authorised user of the trade mark 'Asacol' in the UK. © 1995 Smith Kline & French Laboratories. *Mesalazine is the British approved name of 5-aminosalicylic acid.

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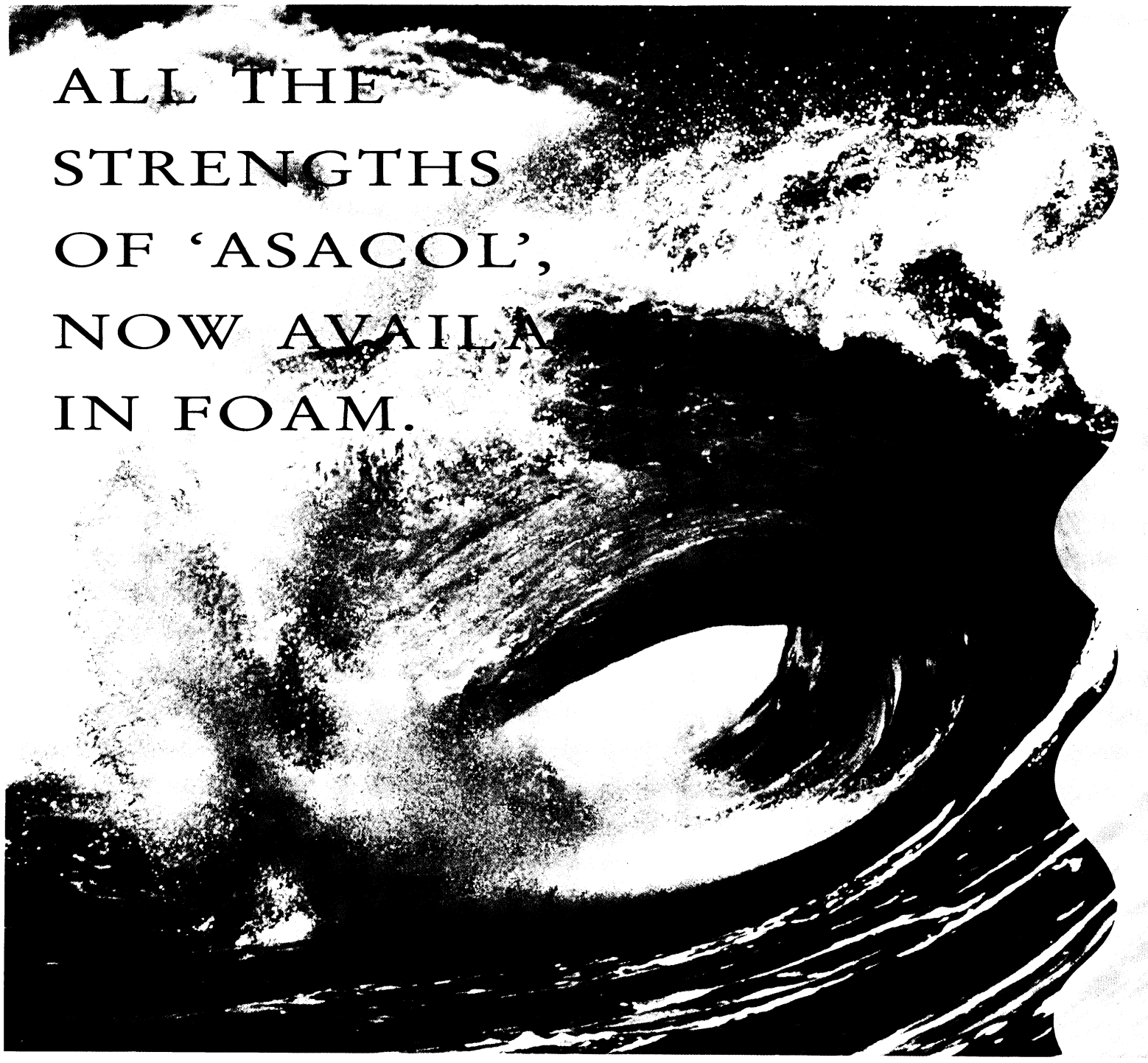
FIVE STAR, 5-ASA COLITIS CONTROL

0195 AS:AD/5/008



Prescribing information: Presentation: 'Asacol' Tablets, PL 0002/0173, each containing 400 mg mesalazine (5-aminosalicylic acid) coated with a pH-dependent acrylic based resin (Eudragit S) formulated to release the active ingredient in the terminal ileum and colon. Blister packs of 120 (12 x 10), £39.62. 'Asacol' Suppositories 250 mg, PL 0002/0158, each containing 250 mg mesalazine. 20, £6.50. 'Asacol' Suppositories 500 mg, PL 0002/0195, each containing 500 mg mesalazine. 10, £6.50. 'Asacol' Foam Enema, PL 0002/0222, 1 g mesalazine per metered dose. Carton containing can of 14 metered doses, 14 disposable applicators and 14 disposable plastic bags. £39.60. **Uses:** For the treatment of mild to moderate acute exacerbations of ulcerative colitis. Tablets and Suppositories for the maintenance of remission of ulcerative colitis. The suppositories and foam enema are particularly appropriate in patients with distal disease. **Dosage and administration: Adults:** *Tablets: Acute disease:* Six tablets a day in divided doses, with concomitant corticosteroid therapy where clinically indicated. *Maintenance therapy:* Three to six tablets a day in divided doses. ***Suppositories:*** *250 mg suppositories:* Three to six suppositories a day, in divided doses, with the last dose at bedtime. *500 mg suppositories:* A maximum of three suppositories a day, in divided doses, with the last dose at bedtime. ***Foam Enema:*** For disease affecting the rectosigmoid region, one metered dose 1 g a day for 4-6 weeks; for disease involving the descending colon, two metered doses 2 g once a day for 4-6 weeks. **Children:** There is no dosage recommendation. **Contra-indications:** A history of sensitivity to salicylates or renal sensitivity to sulphasalazine. Severe renal impairment (GFR <20 ml/min). Children under 2 years of age. **Precautions:** Renal disorder: mesalazine is excreted rapidly by the kidney, mainly as its metabolite, N-acetyl-5-aminosalicylic acid. In rats, large doses of mesalazine injected intravenously produce tubular and glomerular toxicity. 'Asacol' is best avoided in patients with established renal impairment but, if necessary, it should be used with caution. 'Asacol' Tablets should not be given with lactulose or similar preparations which lower stool pH and may prevent release of mesalazine. **Use in pregnancy and lactation:** No information is available with regard to teratogenicity; however, negligible quantities of mesalazine are transferred across the placenta and are excreted in breast milk following sulphasalazine therapy. Use of 'Asacol' during pregnancy should be with caution, and only if, in the opinion of the physician, the potential benefits of treatment are greater than the possible hazards. 'Asacol' should, unless essential, be avoided by nursing mothers. **Elderly:** Use in the elderly should be cautious and subject to patients having a normal renal function (see **Precautions**). **Adverse reactions:** The side effects are predominantly gastrointestinal. Nausea, diarrhoea, abdominal pain and headache have been reported. 'Asacol' may be associated with the exacerbation of the symptoms of colitis in those patients who may have previously had such problems with sulphasalazine. There have been reports of leucopenia, neutropenia, thrombocytopenia aplastic anaemia, pancreatitis, hepatitis, and nephrotic syndrome with oral treatment, usually reversible on withdrawal. Renal failure has been reported. Mesalazine-induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment. Hypersensitivity reactions to mesalazine have been reported rarely, including interstitial nephritis, allergic myocarditis, lupus-like syndrome, pulmonary symptoms and rash (including urticaria). These reactions are usually reversible on cessation of mesalazine. Other side effects observed with sulphasalazine such as depression of sperm count and function have not been reported with 'Asacol'. **Treatment of overdosage:** Following tablet ingestion, gastric lavage and intravenous transfusion of electrolytes to promote diuresis. There is no specific antidote. **Legal category:** POM. **Further information:** Whilst mesalazine is known to be the active component of sulphasalazine in the treatment of ulcerative colitis, the other component of sulphasalazine, sulphapyridine, is thought to be responsible for the majority of side effects. 11.8.94

Smith Kline & French Laboratories, Welwyn Garden City, Hertfordshire AL7 1EY. Authorised user of the trade mark 'Asacol' in the UK. © 1995 Smith Kline & French Laboratories. *Mesalazine is the British approved name of 5-aminosalicylic acid.

SB SmithKline Beecham Pharmaceuticals
Healthy Alliance
partnership beyond prescription

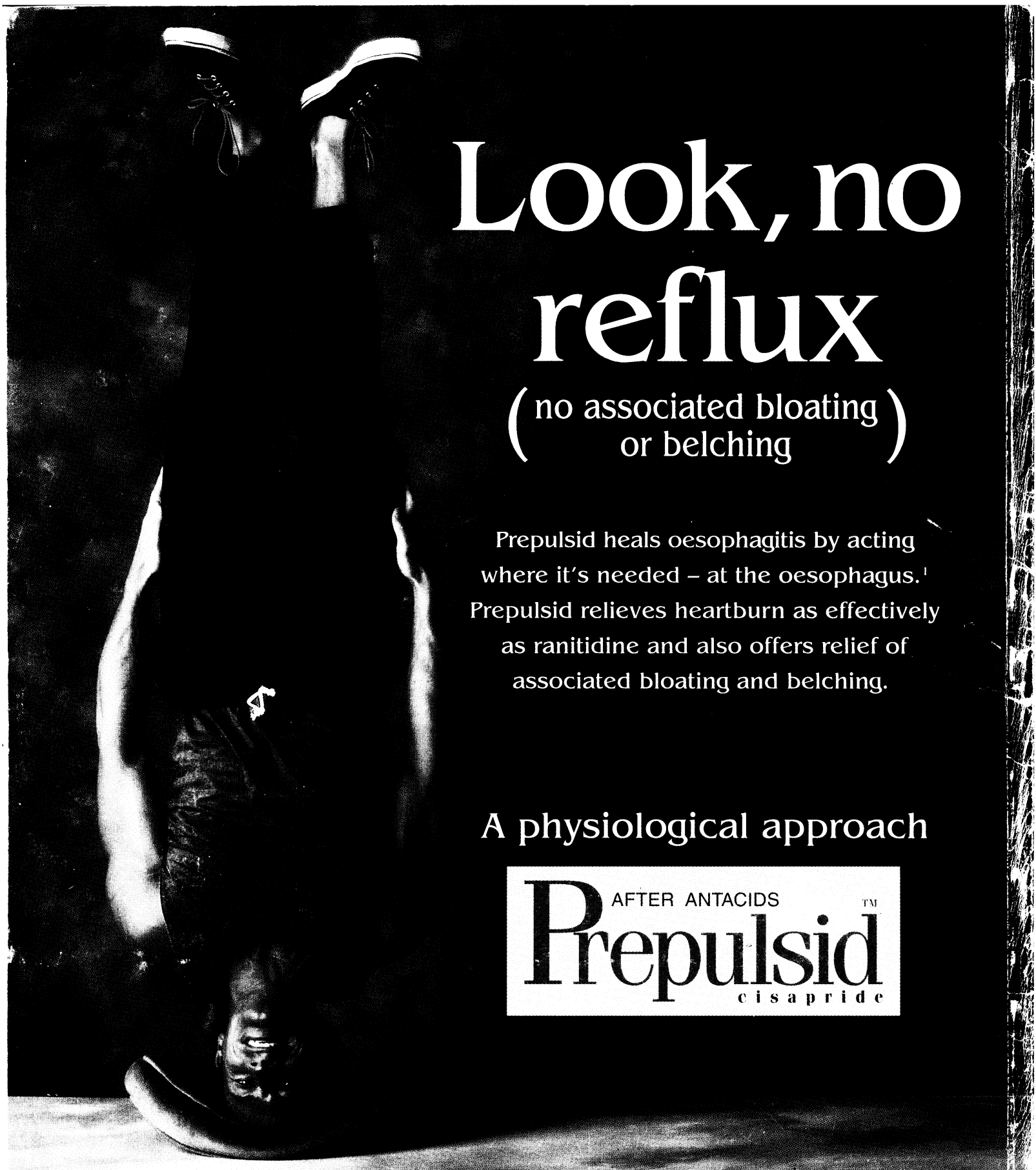
ASACOL

MESALAZINE* (5-AMINOSALICYLIC ACID)

FOAM

FIVE STAR, 5-ASA
COLITIS CONTROL

0195 AS:AD/5/009



Look, no reflux

(no associated bloating or belching)

Prepulsid heals oesophagitis by acting where it's needed – at the oesophagus.[1] Prepulsid relieves heartburn as effectively as ranitidine and also offers relief of associated bloating and belching.

A physiological approach

AFTER ANTACIDS

Prepulsid™

cisapride

PRESCRIBING INFORMATION Indications: GASTRO-OESOPHAGEAL REFLUX DISEASE: Treatment of symptoms and healing of mucosal lesions; maintenance treatment of reflux oesophagitis. DYSPEPSIA: Treatment of symptoms such as epigastric pain, early satiety, bloating and belching where organic disease has been excluded. IMPAIRED GASTRIC EMPTYING: Relief of the symptoms such as epigastric pain, early satiety, anorexia, bloating and nausea associated with delayed gastric emptying secondary to systemic sclerosis and autonomic neuropathy of diabetes. **Dosage and Administration:** Adults and children twelve years and over: Take 15 minutes before food. REFLUX: 20mg Prepulsid bd (before breakfast and at bedtime) or 10mg Prepulsid td (if necessary, night time symptoms can be treated with a fourth 10mg dose at bedtime) for 12 weeks to heal oesophagitis. For long term maintenance therapy, 20mg once daily (at bedtime) or 10mg twice daily (before breakfast and at bedtime) increasing to 20mg twice daily in patients whose lesions were initially very severe. DYSPEPSIA: 10mg Prepulsid td. Usual course of treatment is 4 weeks. IMPAIRED GASTRIC EMPTYING: 10mg Prepulsid td or qd. An initial course of 6 weeks is recommended but longer treatment may be required. CHILDREN: Not recommended in children under 12. ELDERLY: As for adults, but monitor response. ABNORMAL RENAL/LIVER FUNCTION: Initially dose should be halved. **Contra-indications:** Pregnancy; patients in whom gastrointestinal stimulation might be dangerous; hypersensitivity to Prepulsid. **Warnings:** Not recommended whilst breast feeding. **Drug Interactions:** Absorption from the stomach of concomitantly administered drugs may be diminished, whereas absorption of drugs from the small intestine may be accelerated. For drugs that require careful individual titration e.g. anticonvulsants, it may be useful to measure plasma concentrations. In patients receiving anticoagulants, check prothrombin time as it may be increased. The sedative effects of benzodiazepines and alcohol may be accelerated when given with Prepulsid. The effects of Prepulsid are antagonised by anticholinergic drugs. **Side Effects:** Abdominal cramps, borborygmi and loose stools are mainly transient. Should severe abdominal cramps occur with single administrations of 20mg Prepulsid, halve the dose per administration and double the frequency of dosing. Less frequent side-effects include headaches and lightheadedness. Reports of hypersensitivity, convulsions, extrapyramidal effects and increased urinary frequency have been received. Exceptionally, reversible liver function abnormalities have been reported - causal relationship not established. **Overdosage:** Treatment includes activated charcoal, close observation and general supportive measures. **Presentation:** Prepulsid Tablets: packs of 120 tablets each containing 10mg cisapride. Prepulsid Suspension: 500ml bottles containing cisapride 5mg/5ml. **Pharmaceutical Precautions:** Prepulsid Tablets: store at room temperature in a dry place and protect from light. Prepulsid Suspension: store at room temperature (below 25°C). **PL Nos:** Prepulsid Tablets PL0242/0136. Prepulsid Suspension PL 0242/0157. **PL Holder:** Janssen-Cilag Ltd., Saunderton, High Wycombe, Bucks, HP14 4HJ. **Basic NHS Cost:** 120 tablets - £37.60; 500ml bottle suspension £15.60. **Legal Category:** POM. **References** 1. Janssens J. Effect of cisapride on oesophageal motility. In Johnson A.G. Lux G. Eds. Progress in the treatment of gastrointestinal motility disorders. The role of cisapride. Amsterdam, Excerpta Medica 1988,11-18. 2. Geinst H et al. Two different dose regimens of cisapride in the treatment of reflux oesophagitis, a double-blind comparison with ranitidine. Ailment Pharmacol Ther 1993; 7: 409-415. TM = Trademark. Copyright ©1994. DATE OF PREPARATION: December 1994.