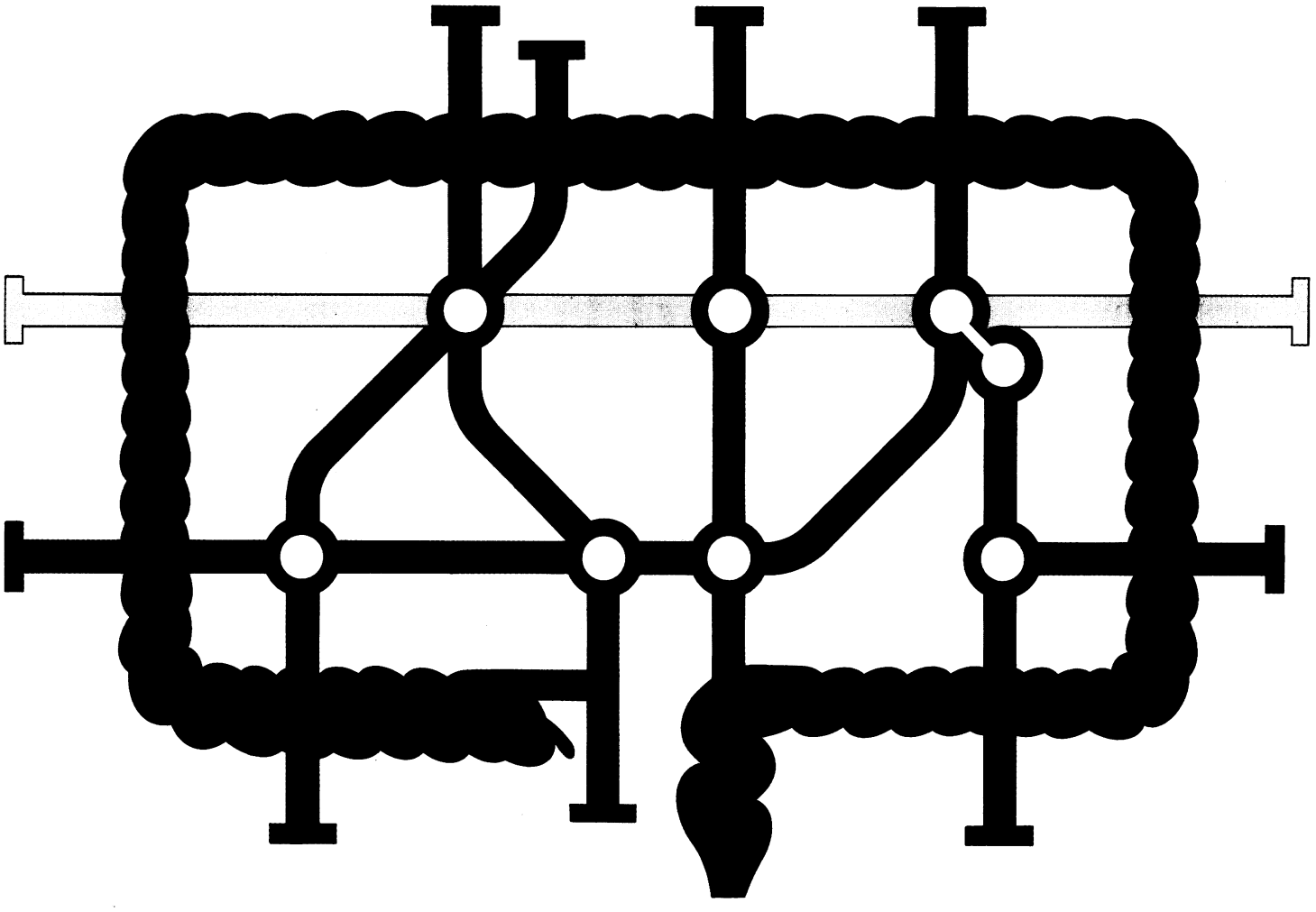

COLIFOAM

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. **References:** 1. Somerville KW *et al.* BMJ 1985;291:866. 2. Farthing MJG *et al.* BMJ 1979;2:822-824. 3. Ruddell WSJ *et al.* Gut 1980;21:885-889. Further information is available on request from Stafford-Miller Ltd., Broadwater Road, Welwyn Garden City, Herts. AL7 3SP. **Code:** DO2665.

Prescribing information
Klaricid 500
Presentation: Yellow ovaloid film coated tablets containing 500mg of clarithromycin. Each tablet is engraved with ◘ on one side. **Indications:** Klaricid in the presence of acid suppression effected by omeprazole is indicated for the eradication of H. pylori in patients with duodenal ulcers. **Dosage and Administration:** Adults: Clarithromycin 500mg t.d.s. for 14 days plus oral omeprazole 40mg o.d. The pivotal study was carried out with omeprazole 40mg o.d. for 28 days, whilst supportive studies were carried out with omeprazole 40mg o.d. for 14 days. See omeprazole data sheet for further information on omeprazole dosing. **Contraindications, Warnings etc:** *Contraindications:* Known hypersensitivity to macrolide drugs. Do not administer with ergot derivatives. *Precautions:* Caution in adults with impaired hepatic and renal function. Do not administer to paediatric patients with hepatic or renal failure. Prolonged or repeated use of clarithromycin may result in an overgrowth of non-susceptible bacteria or fungi. If superinfection occurs, clarithromycin should be discontinued and appropriate therapy instituted. Caution in patients taking drugs metabolised by the cytochrome P450 system as there may be elevations in their serum levels. H. pylori organisms may develop resistance to clarithromycin in a small number of patients. *Interactions:* Potentiation of terfenadine, astemizole, theophylline, digoxin, warfarin and carbamazepine. Interaction of Klaricid tablets with simultaneously administered zidovudine in adults. No interaction with oral contraceptives. *Side-effects:* Klaricid is generally well tolerated. Side-effects include nausea, vomiting, diarrhoea and rarely pseudomembranous colitis, abdominal pain, headache, taste perversion, reversible tongue discolouration, glossitis and stomatitis. Allergic reactions including anaphylaxis and Stevens-Johnson syndrome, and transient central nervous system side-effects have been reported. Hepatic dysfunction has also been reported. **Use in Pregnancy and Lactation:** The safety of Klaricid during pregnancy and breast feeding has not been established, and therefore if a patient becomes pregnant Klaricid should only be used if benefits outweigh risks. Clarithromycin has been found in the milk of lactating animals and humans. **Overdose:** Should be treated with gastric lavage and supportive measures. **Basic NHS Price:** £4.82 per day. **Legal Category:** POM. **Marketing Authorisation Number:** PL 0037/0254: 42 tablet calendar blister pack. Further information is available on request from Abbott Laboratories Ltd., Norden Road, Maidenhead, Berkshire SL6 4XE. Date of Preparation December 1995.

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Clarithromycin

CONSISTENTLY HIGH ERADICATION OF *H. PYLORI*.*

* Klaricid 500mg t.d.s. plus omeprazole 40mg o.d.

KEEP ACID WHERE IT WORKS NOT WHERE IT HURTS

Sometimes it's easy to see the damage that acid can cause. But rather than argue that acid should no longer be produced, why not just stop it getting into the environment?

Gaviscon does this by keeping acid where it works, not where it hurts. It forms a soothing alginate barrier which prevents acid from rising into the oesophagus, bringing rapid relief to 4 out of 5 reflux patients.[1,2,3]

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:** 0063/0031 Liquid Gaviscon, 0063/0032 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:**

In fact, it's just what you need to put stomach acid in its place.

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:** 0063/0033 Gaviscon Tablets, 0063/0029 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:** 27/7/95.

References:

1. Chevrel B. (1980) *J. Int. Med. Res.* **8:** 300.
2. Ward A.E. (1989) *Br. J. Clin. Pract.* **43 (2)** Suppl. 66: 52.
3. Williams D.L. *et al.* (1979) *J. Int. Med. Res.* **7:** 551.

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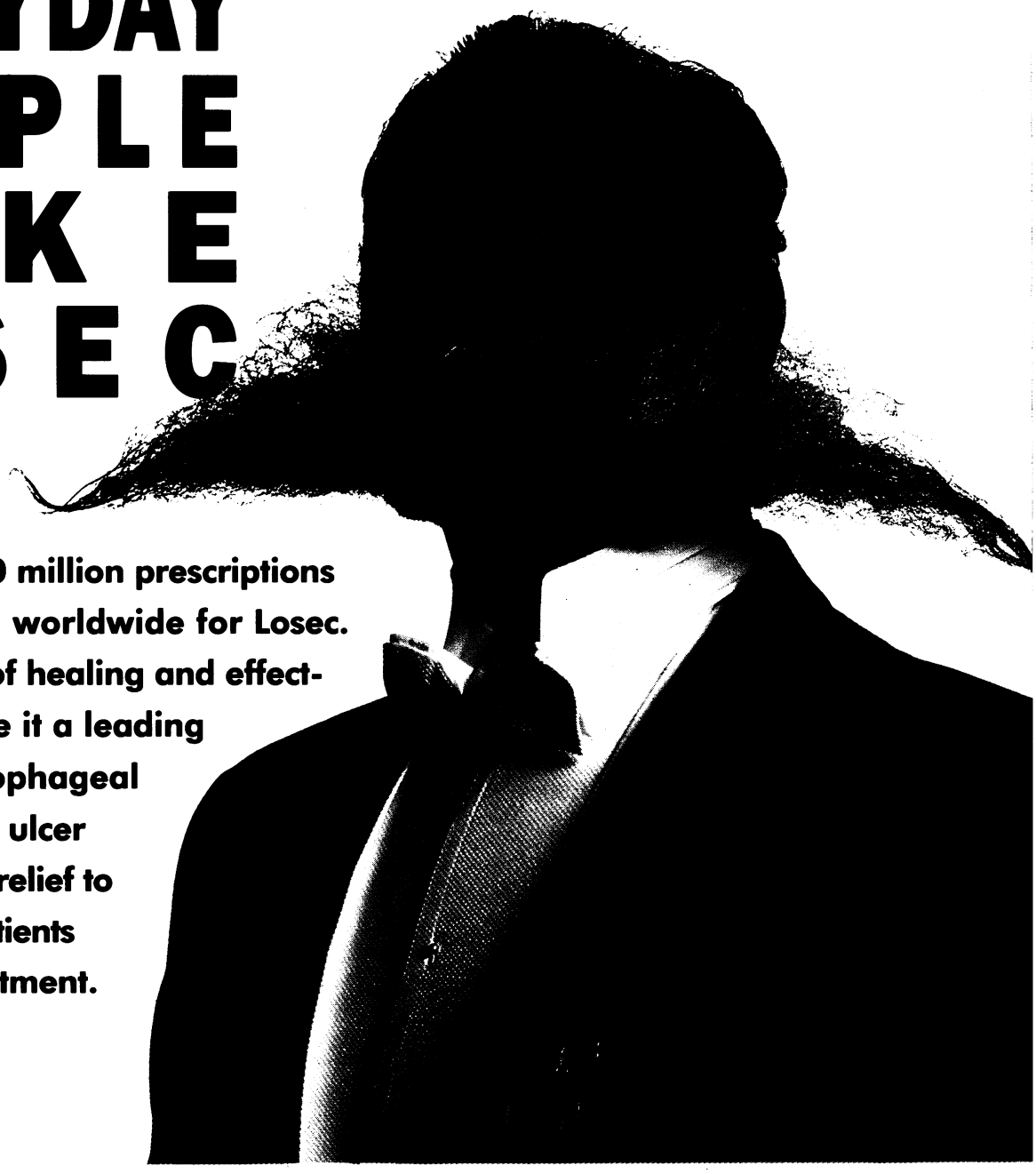

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LOSEC® 20mg Capsules

(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.

ASTRA
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LOSEC is a registered trademark.
Date of preparation: February 1995 LOS/ADV 345b

ZOTON*▼Lansoprazole: Abbreviated Prescribing Information. Presentation: Two tone lilac/purple hard gelatin capsule containing 30 mg Lansoprazole as enteric coated granules. **Indications:** Healing of duodenal ulcer, benign gastric ulcer, and reflux oesophagitis. Also benign peptic lesions including reflux oesophagitis unresponsive to H_2 receptor antagonists. **Dosage and Administration:** Lansoprazole should be administered once daily. *Duodenal ulcer:* 30 mg daily for 4 weeks. *Reflux oesophagitis:* 30 mg daily for 4-8 weeks. *Benign gastric ulcer:* 30 mg daily for 8 weeks Do not chew or crush capsules. Swallow whole. No dosage adjustment is necessary in the elderly, or patients with renal or hepatic impairment. There is no experience with Lansoprazole in children. Long term treatment cannot be recommended at this time. **Contra-indications:** No known contra-indications to Lansoprazole. **Warnings and Precautions:** As with other anti-ulcer therapies the possibility of malignancy should be excluded when gastric ulcer is suspected. There is no experience with the use of Lansoprazole in pregnancy, and its use should be avoided. Animal studies indicate Lansoprazole is excreted into breast milk, there is no information on secretion into breast milk in humans. Breast feeding should be discontinued if the use of Lansoprazole is considered essential. **Side effects:** Generally transient and self-limiting, including gastro-intestinal disturbances, headache, dizziness, dry mouth, fatigue, rashes, and increases in liver function tests. Arthralgia, peripheral oedema, and haematological changes have been reported rarely. **Legal Category:** POM. **Package Quantities:** *Original Packs:* Blister packs of 56, 28, 14 and 7 (hospital starter pack) capsules. **Product Licence No:** PL 0095/0264. **Cost:** 7's £9.09 (hospital starter pack), 14's £18.18, 28's £33.36, 56's £66.72. Full prescribing information is available on request * Trademark of Takeda Chemical Industries Ltd. **REFERENCES:** 1. Mee, A.S., *Gut*, 1995, **36** (Supp 1) Abs W8G (102648) 2. Hatlebakk, J.G., *Gastroenterology*, 1992, **102** (4, pt 2), (20224) 3. Castell, D.O., *Gastroenterol*, 1995, Vol 108, No 4, Abs 67 (102912) 4. Petite, J.P., Data on file, Lederle Laboratories (20502) 5. Corallo, J., *Gastroenterology*, 1993, **104** (4), A58 (20683) 6. Rampal, P., *Gastroenterology*, 1995, **108**, (4), A200 (102914) 7. Manufacturers recommended doses from Data Sheets Compendium 1994-5, and MIMS July 1995. 8. Bardhan, K.D., *Gastroenterology*, 1991, **100** (5), A30 (19804) and Data on file (19901) 9. Benhaim, M.C., *Gastroenterology*, 1990, **98** (5), A20 (20164) 10. Robinson, M., *Gastroenterology*, 1992, **102** (4), A153 (20225) 11. Dorsch, E., *Am J Gastroenterol*, 1991, **86** (9), A15 (20009). Date of preparation: July 1995

Takeda — Under Licence agreement with Takeda Chemical Industries Ltd. Japan.

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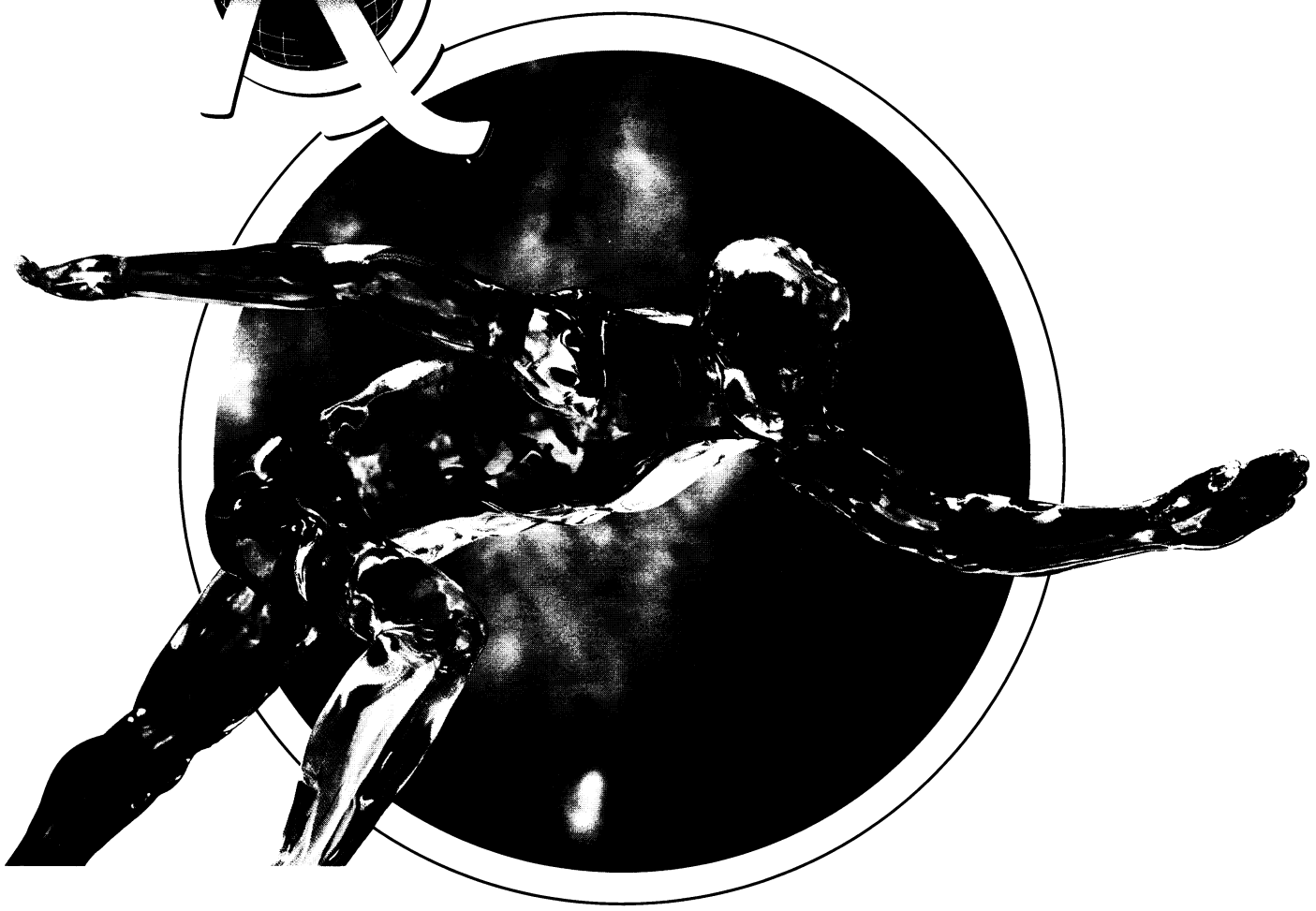

Faster symptom relief than omeprazole[1-3]

In six comparative trials,[1-6] three show significant superiority in favour of Zoton[1-3] one shows a trend in favour,[4] one shows no difference,[5] and one does not report symptom relief.[6] No studies show a benefit in favour of omeprazole.

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Up to 95% healing within eight weeks[1-5,8-11]

(Range 83-95%)

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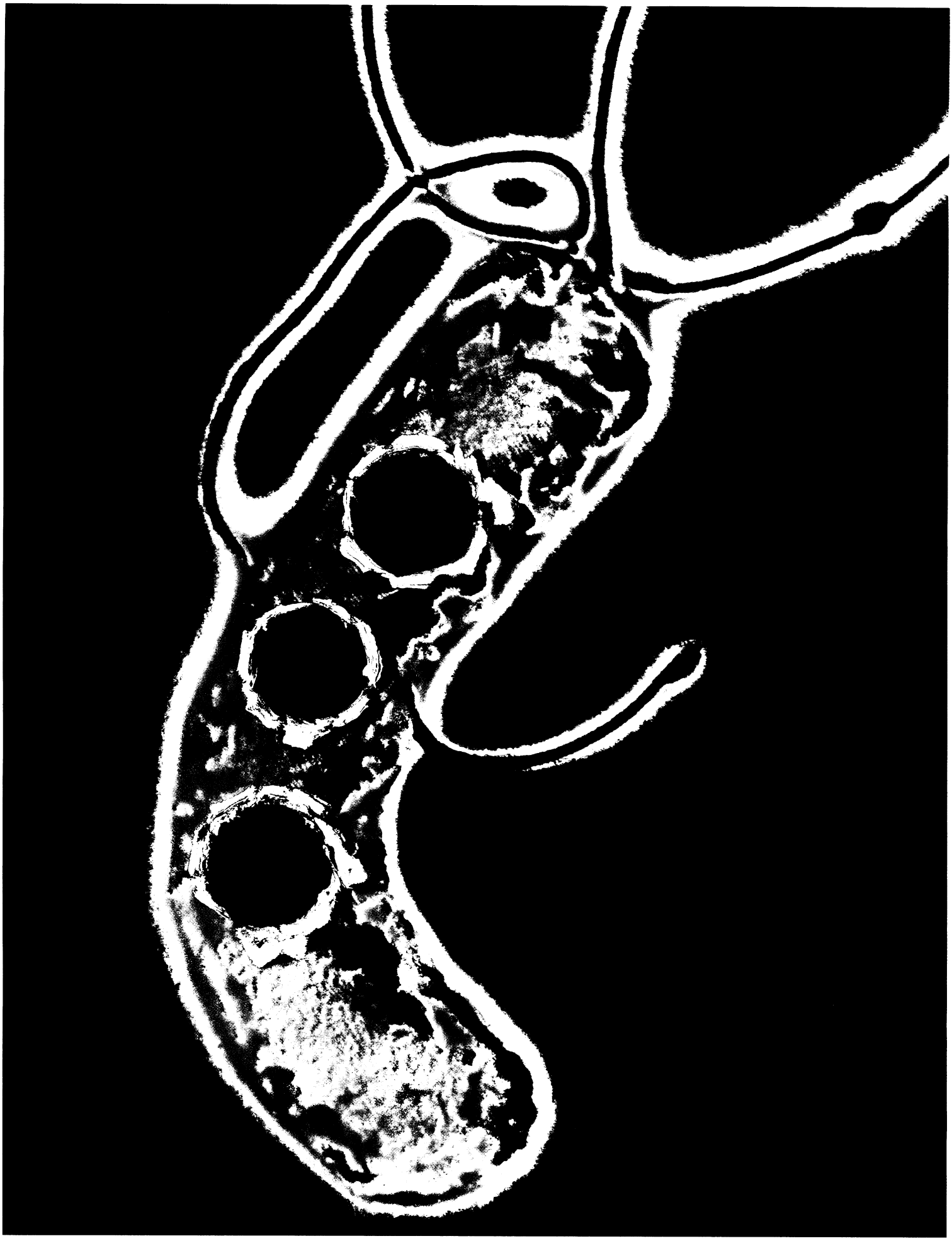

Pylorid Prescribing Information.
Indications Treatment of duodenal and benign gastric ulcer. *H. pylori* eradication and prevention of duodenal ulcer relapse when given with clarithromycin or amoxycillin. **Dosage** *Adults:* duodenal ulcer 400mg twice daily for four weeks. Treatment may be extended for further four weeks. Benign gastric ulcer 400mg twice daily for eight weeks. *H. pylori*-associated duodenal ulcer 400mg twice daily with amoxycillin 500mg four times daily (2g) or clarithromycin 250mg four times daily or 500mg three times daily (1g-1.5g) for first two weeks of treatment then Pylorid 400mg twice daily for further two weeks. *Children:* Not currently recommended. **Contra-indications** Known hypersensitivity to any of the ingredients. **Precautions** In gastric ulcer exclude malignancy before treatment. Plasma levels increased in renal impairment and elderly. Avoid use in extreme renal impairment (see data sheet). Avoid in patients with history of acute porphyria. As contains bismuth not recommended for maintenance use or more than 16 weeks in a year. *See* prescribing information for amoxycillin or clarithromycin before

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Combine new Pylorid with clarithromycin and you've a powerful weapon against H. pylori. And, when H. pylori is eradicated, duodenal ulcers are unlikely to return.

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co-prescribing. **Side Effects** Blackening of tongue and stools. Rarely hypersensitivity reactions including pruritus, skin rash, anaphylaxis. Gastrointestinal upsets including diarrhoea, abdominal discomfort, gastric pain. Headache. Transient changes in liver enzymes SGPT (ALT), SGOT (AST). Mild anaemia. Ranitidine-related side-effects (relevance to use of Pylorid unknown): Dizziness. Rarely, reversible mental confusion usually in ill or elderly patients. Occasional hepatitis. Rarely, acute pancreatitis, arthralgia, myalgia. Rare cases of leucopenia, thrombocytopenia, usually reversible. Agranulocytosis and pancytopenia. Rare cases of erythema multiforme. Rare reports of breast symptoms in men. As with other H_2-receptor antagonists rare cases of bradycardia, A-V block and asystole. **Presentations** Pylorid tablets each containing 400mg of ranitidine bismuth citrate. (Product licence number 14213/0001). 28 Tablets £26·00. 56 Tablets £52·00. **Product licence holders** Glaxo Group Ltd, Greenford Road, Greenford UB6 0HE. POM Pylorid is a Glaxo trade mark. Further information is available on request from: Glaxo Pharmaceuticals UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Telephone 0181-990 9444. Date of preparation: August 1995.

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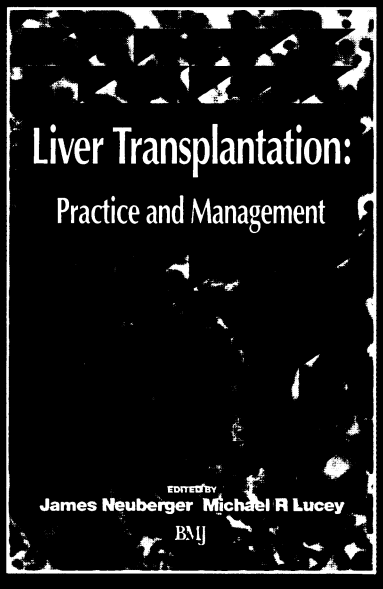

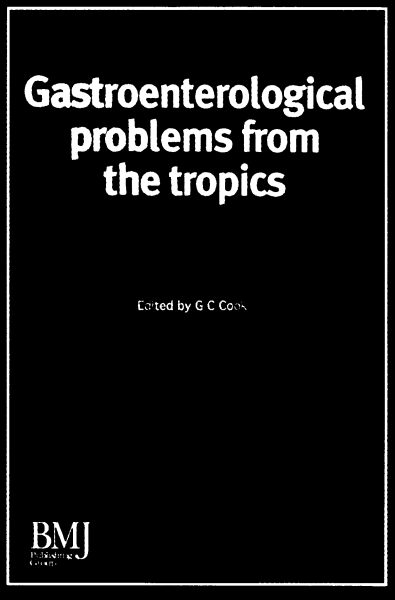

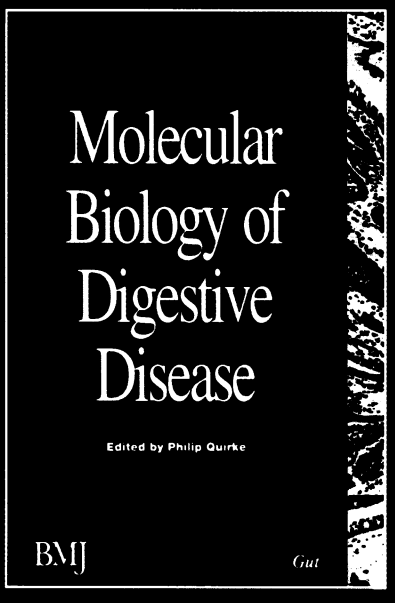

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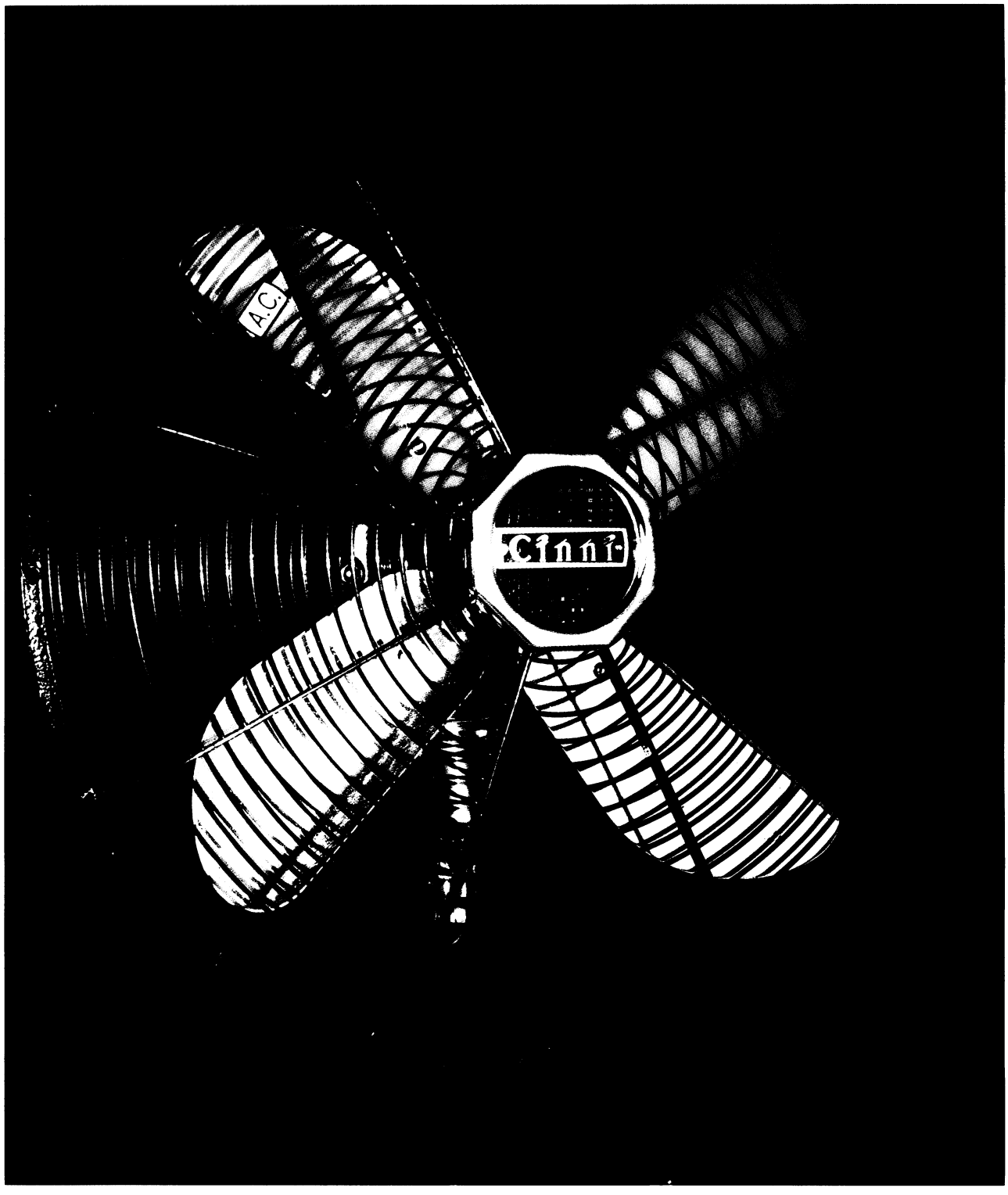

PRESCRIBING INFORMATION:

Indications Duodenal ulcer (including those associated with *H. pylori* infection), benign gastric ulcer, postoperative ulcer, oesophageal reflux disease, Zollinger Ellison Syndrome, prophylaxis of gastrointestinal haemorrhage from stress ulcer, recurrent haemorrhage from bleeding peptic ulcer, acid aspiration (Mendelson's Syndrome). Tablets, Syrup, Effervescent Tablets only, ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), prevention of NSAID-associated duodenal ulcer, chronic episodic dyspepsia, severe oesophagitis, long-term management of healed oesophagitis. **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 ulcer, 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. Duodenal ulcers associated with *H. pylori*, 300mg at bedtime or 150mg twice daily with oral amoxycillin 750mg three times daily and metronidazole 500mg three times daily for 2 weeks. Zantac therapy then continued for a further 2 weeks. Ulcers following 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. Long-term treatment of healed oesophagitis: 150mg twice daily. Obstetric patients at commencement of labour; oral dose of 150mg may be followed by 150mg at six-hourly intervals (see data sheet). Those at risk of acid aspiration syndrome; oral dose of 150mg two hours before induction of general anaesthesia with preferably 150mg the previous evening. Alternatively, Zantac Injection 50mg intramuscularly or by slow intravenous injection 45 to 60 minutes before general anaesthesia. Zantac Injection may be given every six to eight hours either as slow (over a period of at least two minutes) intravenous injection of 50mg, after dilution to a volume of 20ml per 50mg dose, or as intermittent intravenous infusion at a rate of 25mg per hour for two hours; alternatively, as intramuscular injection of 50mg (2ml) every six to eight hours. Prophylaxis of haemorrhage from stress ulceration or from bleeding peptic ulceration: parenteral administration may be continued until oral feeding commences. If still at risk, Zantac Tablets or Syrup 150mg may be given twice daily. Prophylaxis of haemorrhage from stress ulceration: priming dose of 50mg as a slow intravenous injection followed by continuous intravenous infusion of 0.125 to 0.250mg/kg/hr

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may be preferred. *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** Caution when using Effervescent Tablets in sodium-restricted patients. Exclude 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 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. Rapid administration of injection may rarely cause bradycardia; recommended rates of administration should not be exceeded. Like other drugs, use during pregnancy and lactation only if strictly necessary. **Side effects** Headache, dizziness, skin rash, occasional hepatitis, rarely arthralgia, myalgia, and with antibiotics, diarrhoea. 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 10949/0137, 60 tablets £27·89); Zantac Effervescent Tablets each containing 300mg ranitidine HCl and 20·8mEq sodium (Product licence number 10949/0138, 30 tablets £27·43); Zantac Syrup each 10ml dose containing 150mg ranitidine HCl (Product licence number 10949/0108, 300ml bottle £22·32); Zantac Injection each 2ml dose containing 50mg ranitidine HCl (product licence number 10949/0109, 5 x 2ml £3·21). **Product licence holders** 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 0181-990 9444. Date of preparation: September 1995.

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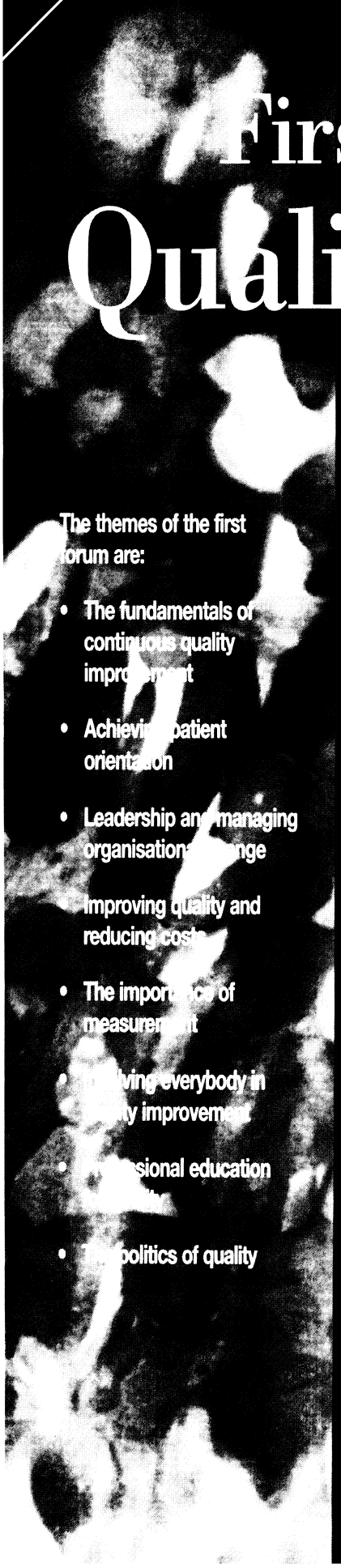

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- Leadership and managing organisational change
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- The importance of measurement
- Involving everybody in quality improvement
- Professional education
- The politics of quality

QEII Conference Centre, London, 7,8,9 March 1996

Chaired by: Mats Brommels, Helsinki, Finland; Christian Koeck, Vienna, Austria; Martin McNicol, London, UK

Bringing quality improvement to the heart of European health care.

This first European forum will allow the exchange of ideas on quality improvement in health care and provide education.

The forum will consist of plenary lectures, parallel seminars and workshops, panel discussions, and short educational courses. Open to all, the forum is aimed at: Doctors, nurses, other health professionals, health managers, quality managers and government officials responsible for health care. It will benefit both beginners and those experienced in quality improvement.

The European Forum has been developed from the United States National Forum on Quality Improvement in Health Care, which is now in its seventh year and attracts over 1500 health professionals annually.

The programme committee for the conference is:
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For more information, complete the form below:

First European Forum on Quality Improvement in Health Care

7, 8, 9 March 1996

Please send me more information on attending the conference

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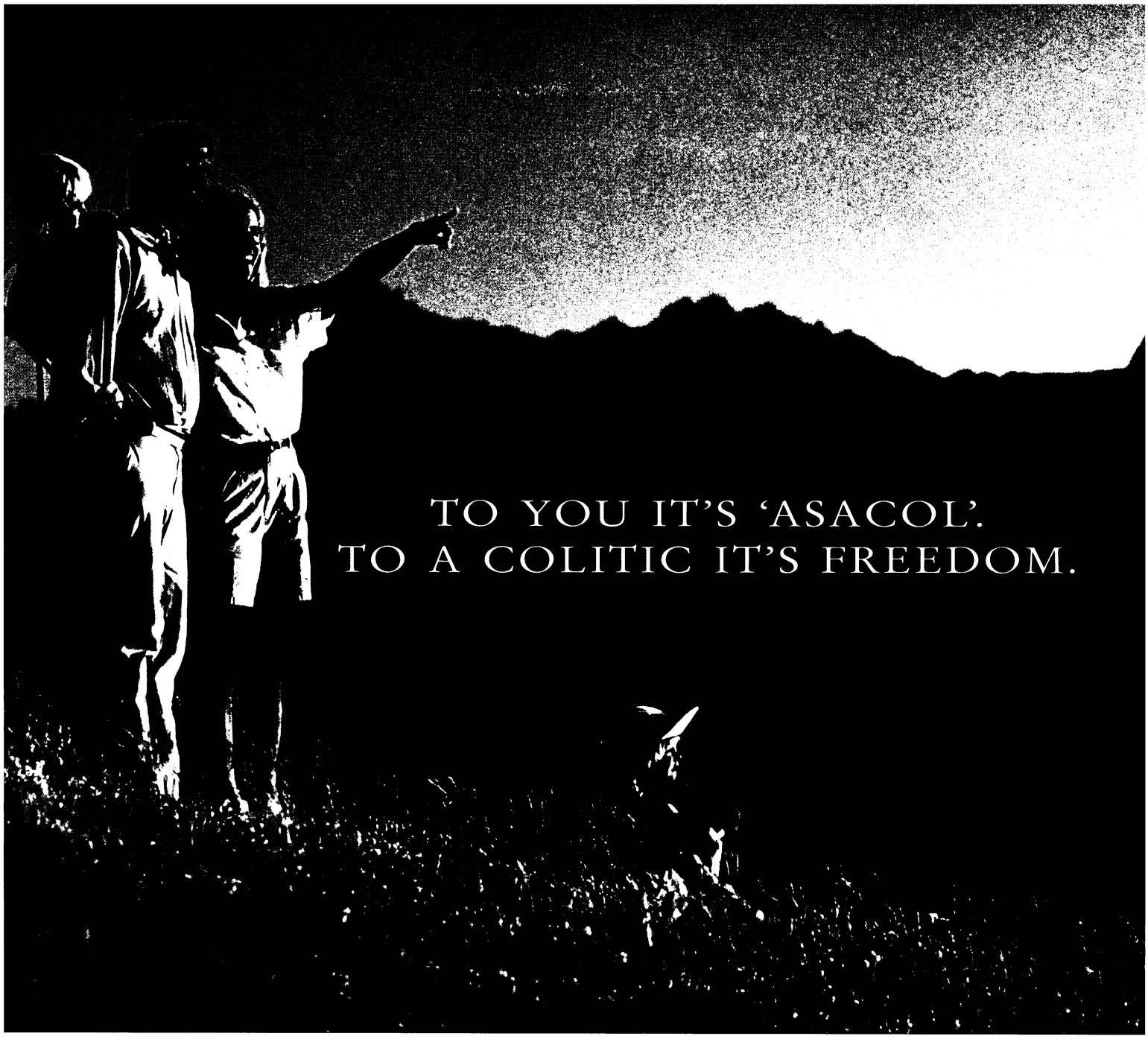

Prescribing Information: Presentation 'Asacol' Tablets, PL 0002/0173, each containing 400 mg mesalazine (5-aminosalicylic acid) coated with a pH-dependent acrylic based resin (Eudragit S) formulated to release the active ingredient in the terminal ileum and colon. Blister packs of 120 (12 × 10), £39.62 '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. Serious blood dyscrasias have been reported very rarely with mesalazine. Haematological investigations should be performed if the patient develops unexplained bleeding, bruising, purpura, anaemia, fever or sore throat. Treatment should be stopped if there is suspicion or evidence of blood dyscrasia. '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, including nausea, diarrhoea and abdominal pain. Headache has also been reported. Mesalazine may be associated with an exacerbation of the symptoms of colitis in those patients who have previously had such problems with sulphasalazine. There have been rare reports of leucopenia, neutropenia, agranulocytosis, aplastic anaemia and thrombocytopenia, pancreatitis, hepatitis, allergic lung reactions, lupus erythematosus-like reactions and rash (including urticaria), interstitial nephritis and nephrotic syndrome with oral mesalazine treatment, usually reversible on withdrawal. Renal failure has been reported. Mesalazine-induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment. 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. 24.6.95.

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
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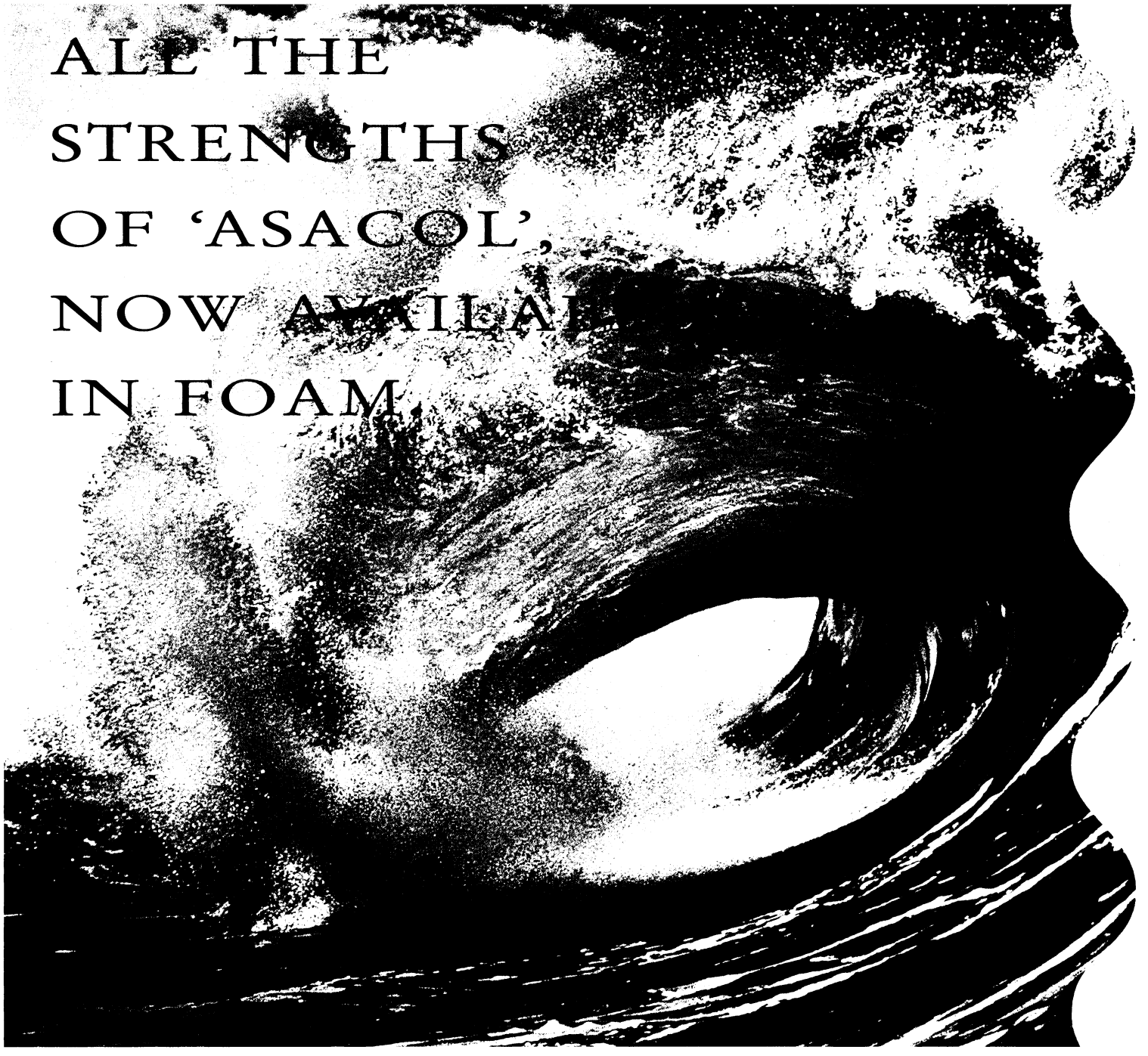
ASACOL

MESALAZINE* (5-AMINOSALICYLIC ACID)

FIVE STAR, 5-ASA COLITIS CONTROL

0195 AS:AD/5/089 GT



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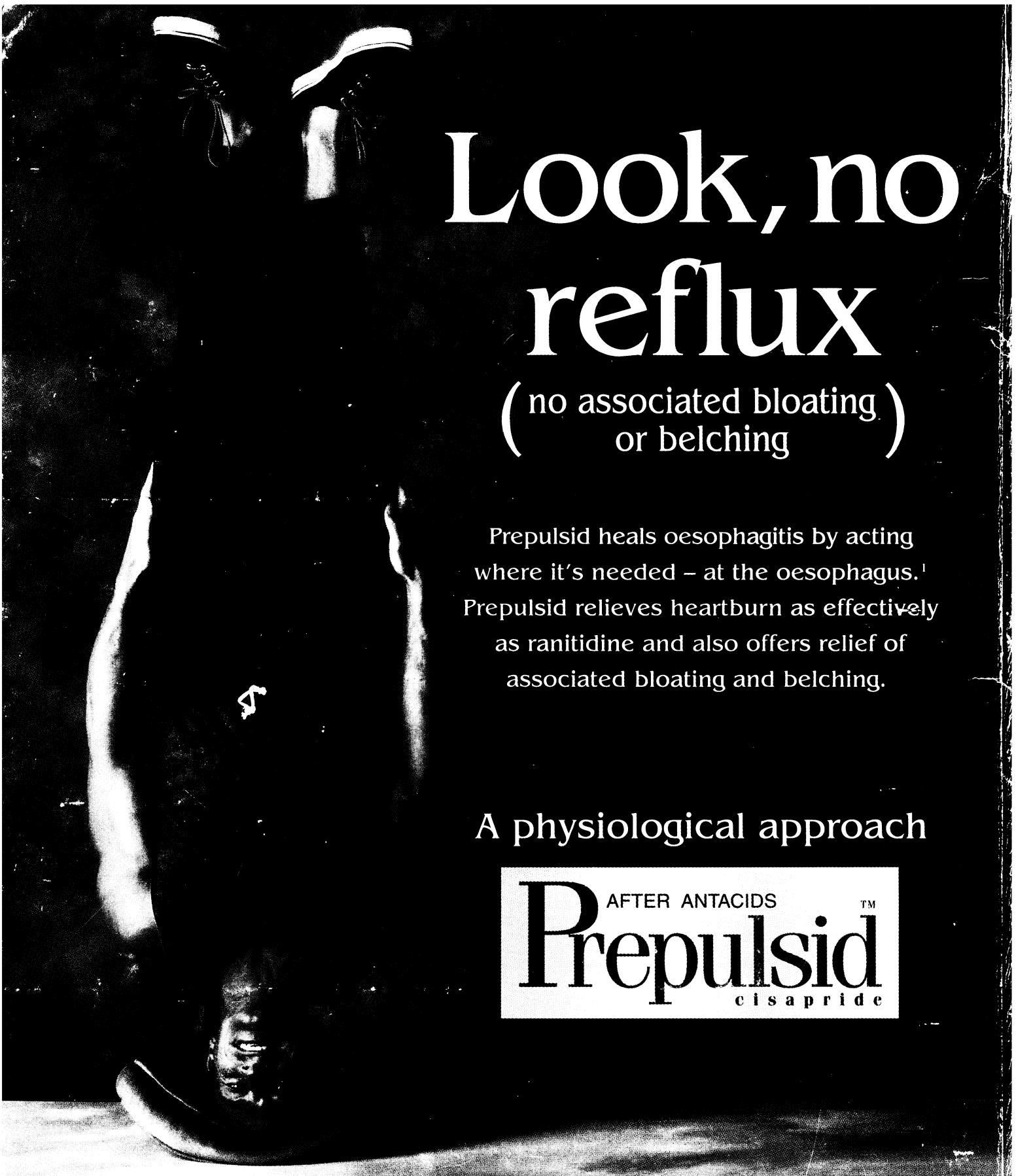

Look, no reflux

(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 qid (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 tid. Usual course of treatment is 4 weeks. IMPAIRED GASTRIC EMPTYING: 10mg Prepulsid tid or qid. An initial course of 4 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. Geldof H *et al.* Two different dose regimens of cisapride in the treatment of reflux oesophagitis: a double blind comparison with ranitidine. Aliment Pharmacol Ther 1993; 7: 409-415. TM = Trademark. Copyright 007478. DATE OF PREPARATION: December 1994