Yes, proton pump inhibitors really are amazing.

They already take up a jaw-dropping 6% of the total NHS drugs budget.[1] And as if that weren't enough, PPI prescriptions are increasing by 35% each year.[2] Shame your budget won't be doing the same.

But what's even more staggering is that an eye-opening 90% of them are used to treat common, recurrent, non-ulcer conditions such as reflux.[3] Which tends to explain the two figures above.

So is it really appropriate to use an expensive proton pump inhibitor when Gaviscon can prevent everyday reflux for a fraction of the price?

Inappropriate? It's enough to make your eyes pop out.

EVERYDAY PPIs ARE TAKING UP 6% OF THE NHS DRUGS BUDGET

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.**

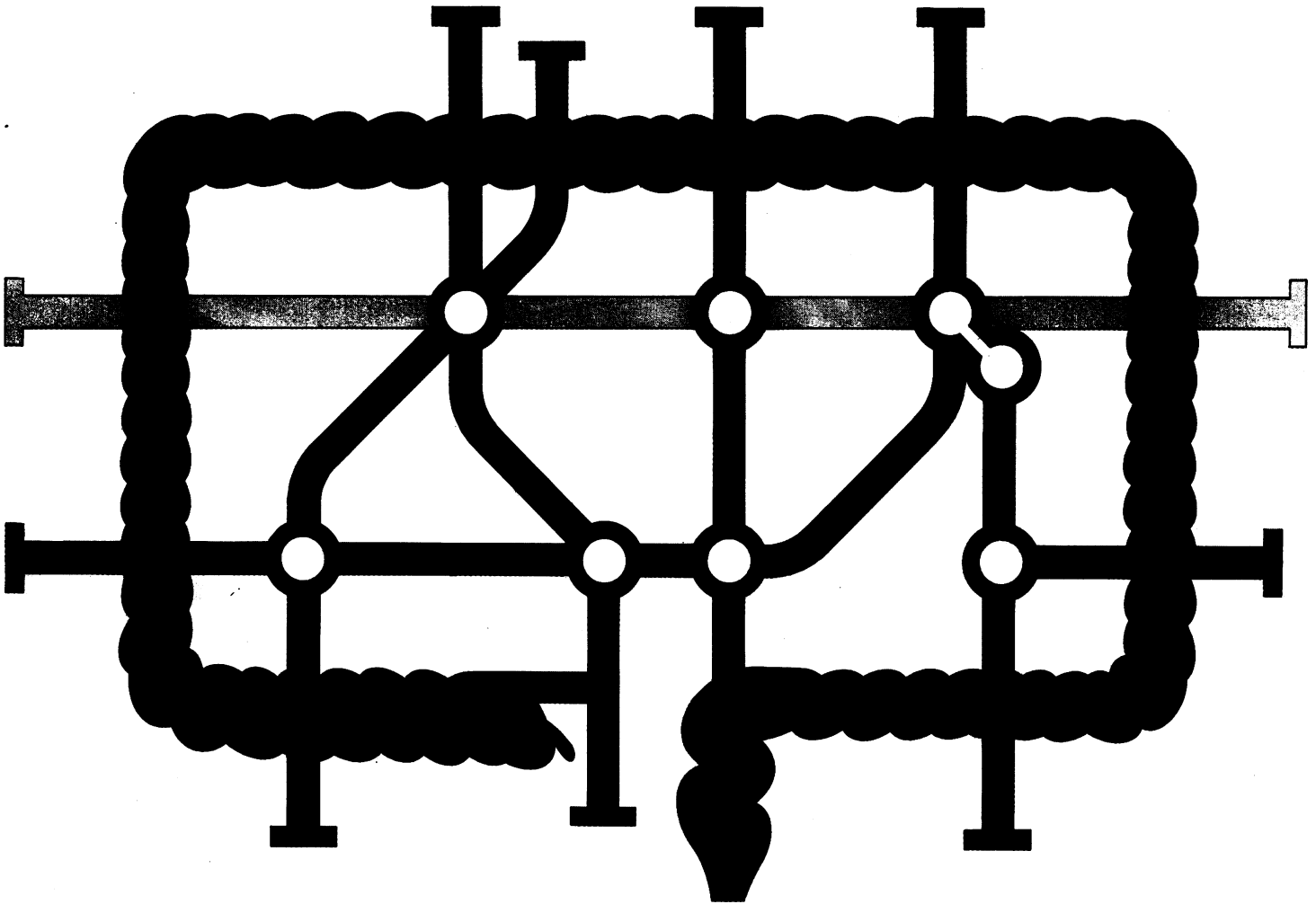
GAVISCON

TAKES THE FINANCIAL SHOCK OUT OF RECURRENT REFLUX

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:** Gastric reflux, reflux oesophagitis, heartburn, including heartburn of pregnancy, hiatus hernia, flatulence associated with gastric reflux. All cases of epigastric and retrosternal distress where the underlying cause is gastric reflux. **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. **Marketing Authorisations:** 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:** Gastric reflux, reflux oesophagitis, heartburn, including heartburn of pregnancy, hiatus hernia, flatulence associated with gastric reflux. All cases of epigastric and retrosternal distress where the underlying cause is gastric reflux. Treatment of regurgitation. **Contra-Indications:** 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. **Marketing Authorisations:** 0063/0033 Gaviscon Tablets, 0063/0029 Gaviscon Tablets Lemon Flavour. **Legal Category:** GSL. (PO). **Holder of Marketing Authorisations:** Reckitt & Colman Products Limited, Dansom Lane, Hull, HU8 7DS. Gaviscon and the sword and circle symbol are registered trademarks. **Date of preparation:** August 1996.

References:
1. BPI MAT, Dec. 1995. (The NHS bill in the community for 1995 was £4.25 billion, of which PPIs accounted for 6%.)
2. IMS MDI Data, Qtr. 1, 1995/6.
3. IMS MDI Data, Qtr. 1, 1996.

Reckitt & Colman Products Limited



COLIFOAM

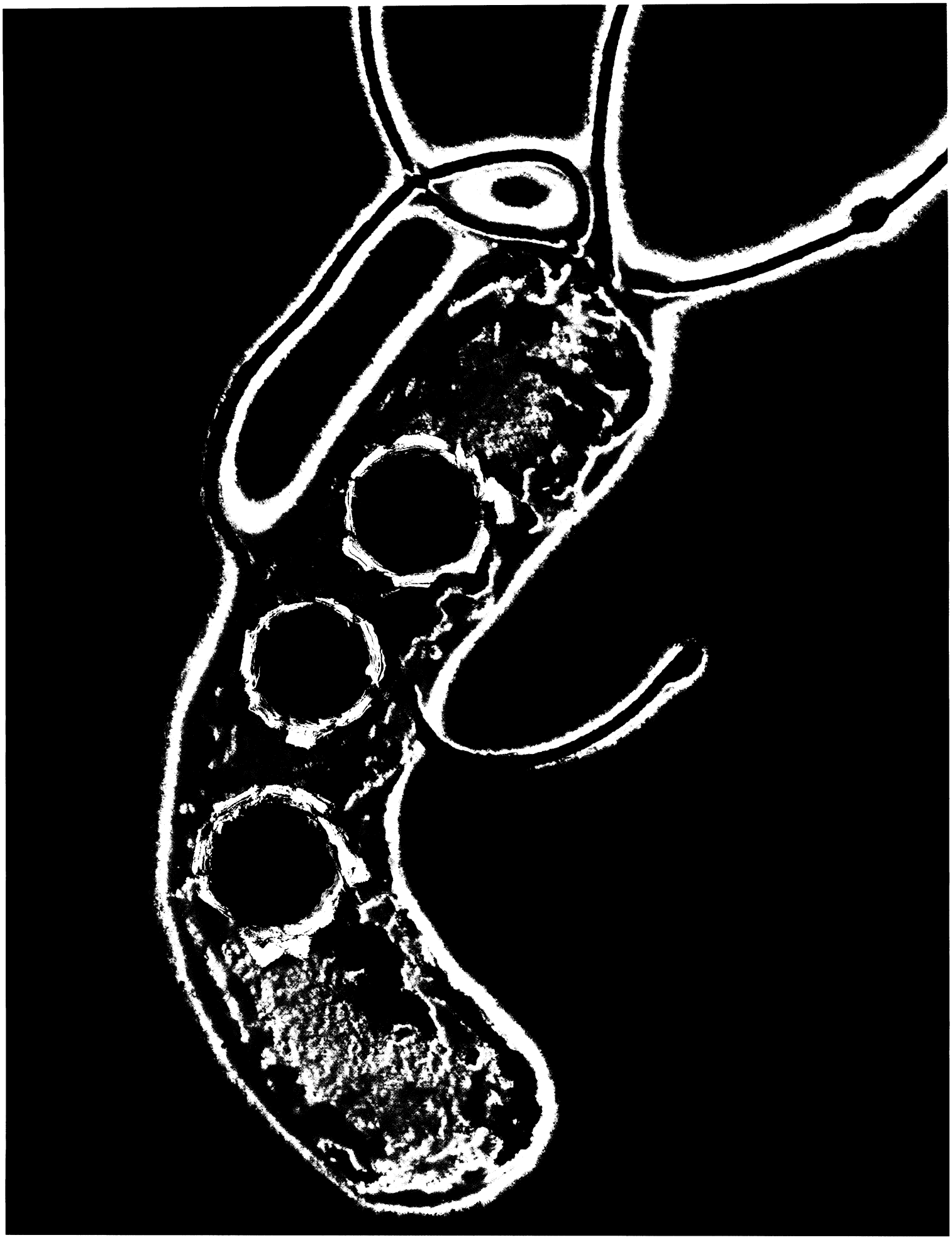
10% hydrocortisone acetate

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.



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 co-prescribing. **Side Effects**

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"GO AHEAD H. PYLORI, MAKE MY DAY"

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

WHEN ERADICATING H. PYLORI

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RANITIDINE BISMUTH CITRATE

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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 (relevence 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 holder** Glaxo Group Limited, Greenford Road, Greenford UB6 0HE. POM Pylorid is a trade mark of the Glaxo Wellcome Group of Companies. Further information is available on request from: Glaxo Wellcome UK Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Telephone 0181-990 9444. Date of preparation: June 1996.

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NOW APPROVED IN MAINTENANCE

15mg ZOTON*▼

Lansoprazole

† Up to 87% remission rate in reflux oesophagitis after 1 year. (Range 69-87%)[1-5]

ZOTON*▼ Abbreviated Prescribing Information
Presentation: Two tone lilac/purple capsules containing lansoprazole 30 mg. Opaque yellow capsules containing lansoprazole 15 mg. **Indications:** Healing and maintenance of gastro-oesophageal reflux disease (GORD) or duodenal ulcer. Healing of benign gastric ulcer. Effective for benign peptic lesions including reflux oesophagitis unresponsive to H_2 receptor antagonists. Eradication of *Helicobacter pylori* (*H. pylori*) in patients with duodenal ulcer or gastritis. **Dosage and Administration:** Duodenal ulcer: 30 mg for 4 weeks, then 15 mg for maintenance dose. GORD: 30 mg daily for 4-8 weeks, then 15 mg or 30 mg for maintenance dose. Benign gastric ulcer: 30 mg daily for 8 weeks. *H. pylori* eradication: 30 mg twice daily plus two of the following antibiotics for 7 days: clarithromycin 250 mg twice daily, amoxycillin 1 g twice daily or metronidazole 400 mg twice daily. Swallow capsules whole. No dosage adjustment is necessary in the elderly, or the renally or hepatically impaired. There is no experience with Zoton in children. **Contra-indications:** None known. **Precautions:** Exclude the possibility of malignancy when gastric ulcer is suspected. When using in combination with antibiotics, refer to the prescribing information of the respective antibiotics. **Pregnancy and Lactation:** Avoid in pregnancy. Avoid during breast feeding unless essential. **Interactions:** Interactions with drugs metabolised by the liver are possible. Apply caution when used concomitantly with oral contraceptives, phenytoin, theophylline or warfarin. Antacids should not be taken within an hour of Zoton. **Side Effects:** Generally mild and transient, including gastro-intestinal disturbances, headache, dizziness, malaise, dry or sore mouth or throat, fatigue, rashes, urticaria, pruritis and alterations in liver function test values. A few cases of arthralgia, myalgia, peripheral oedema, depression, haematological changes, bruising, purpura, petechiae, jaundice, hepatitis, paraesthesia or blurred vision have been reported. **Legal Category:** POM **Package Quantities:** 30 mg capsules: Blister packs of 56, 28, 14 and 7 (hospital starter pack) capsules. 15 mg capsules: Blister packs of 56 and 28 capsules. **Product Licence Number:** 30 mg capsules: PL 0095/0264 15 mg capsules: PL 0095/0302 **Cost:** 30 mg capsules: 7 £9.09 (hospital starter pack) 14 £16.68 28 £33.36 56 £66.72 15 mg capsules: 28 £18.95 56 £37.90 Full prescribing information is available on request. **Name and Address of Licence Holder:** Cyanamid of Great Britain Ltd, Fareham Road, Gosport, Hampshire, PO13 0AS.

REFERENCES: 1. Gough, A.L. et al, *Aliment Pharmacol Ther*, 1996, **10**, 529-539 2. Hatlebakk, J.G., and Berstad, A., *Gastroenterol*, 1995, **108** (4), A111 (102909) 3. Poynard, T. et al, *Gastroenterol*, 1995, **108** (4), A195 (102907) 4. Robinson, M., *Ann Intern Med*, 1996, **126**, 859-867 5. Baldi, F., *Gastroenterol*, 1996, **110** (4) Suppl A55 (107136), and Data on file, Lederle Laboratories (105806). * Trademark of Takeda Chemical Industries Ltd.
Date of preparation: August 1996

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Lederle Further information can be obtained from: Wyeth Laboratories, Huntercombe Lane South, Taplow, Maidenhead, Berks SL6 0PH

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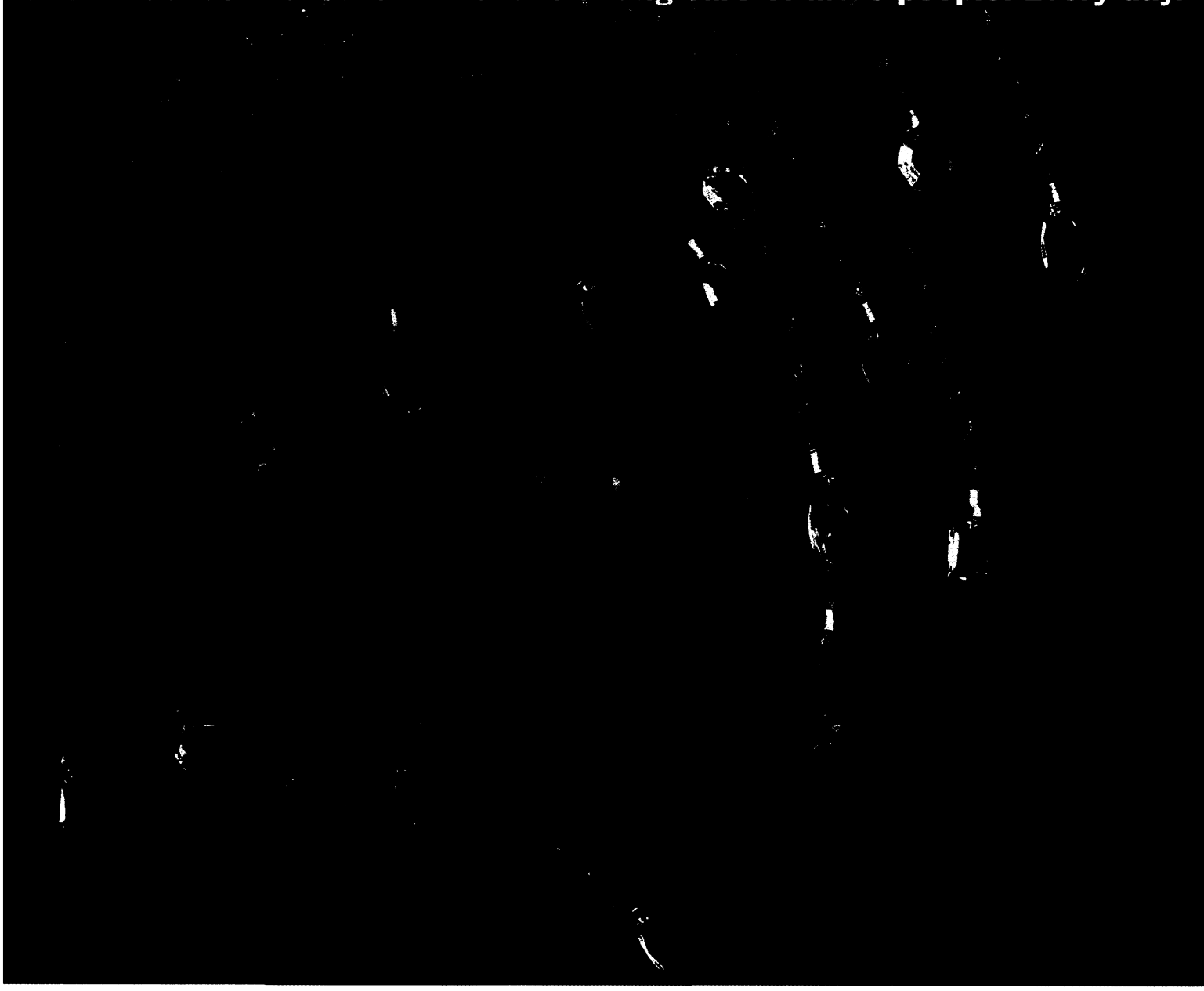

LOSEC® CAPSULES (omeprazole) PRESCRIBING INFORMATION (refer to full data sheet before prescribing)

PRESENTATION: Losec Capsules containing 10mg, 20mg or 40mg omeprazole **(O)** as enteric coated granules with an aqueous based coating. **USES:** Oesophageal reflux disease. Duodenal and benign gastric ulcers (including NSAID-induced). *Helicobacter pylori* eradication: Relief of associated dyspeptic symptoms in combination treatment with antibiotics. 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. **Benign Gastric Ulcer**: 20mg daily for 8 weeks. ***Helicobacter pylori* eradication: DU disease: Triple therapies:** Losec 40mg daily with amoxycillin **(A)** 500mg and metronidazole **(M)** 400mg, both three times a day for 1 week. Or clarithromycin **(C)** 250mg and metronidazole 400mg (or tinidazole 500mg) both bd for 1 week. Or amoxycillin 1g and clarithromycin 500mg both bd for 1 week. **Dual therapies:** Losec 40mg daily with amoxycillin 750mg to 1g bd or clarithromycin 500mg tid, both for 2 weeks. **GU disease**: Losec 40mg daily with amoxycillin 750mg to 1g bd for 2 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:** Known hypersensitivity to omeprazole. 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, dry mouth, vertigo, paraesthesia, anaphylaxis, liver enzyme and haematological changes. **Interactions**: The absorption of ketoconazole may be reduced. Losec can delay the elimination of diazepam, phenytoin and warfarin. Plasma concentrations of omeprazole and clarithromycin are increased when used concomitantly. 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. Eradication of *Hp* with omeprazole and antibiotics gives rapid symptom relief, high healing rates and long-term remission of ulcer disease.

Quality of life. In recent clinical data, in patients with acute peptic ulcer disease, omeprazole *Hp* eradication therapy improved patients' quality of life. **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). **MARKETING AUTHORIZATION NO:** PL 0017/0337 – Losec Capsules 10mg. PL 0017/0238 – Losec Capsules 20mg. PL 0017/0320 – Losec Capsules 40mg.

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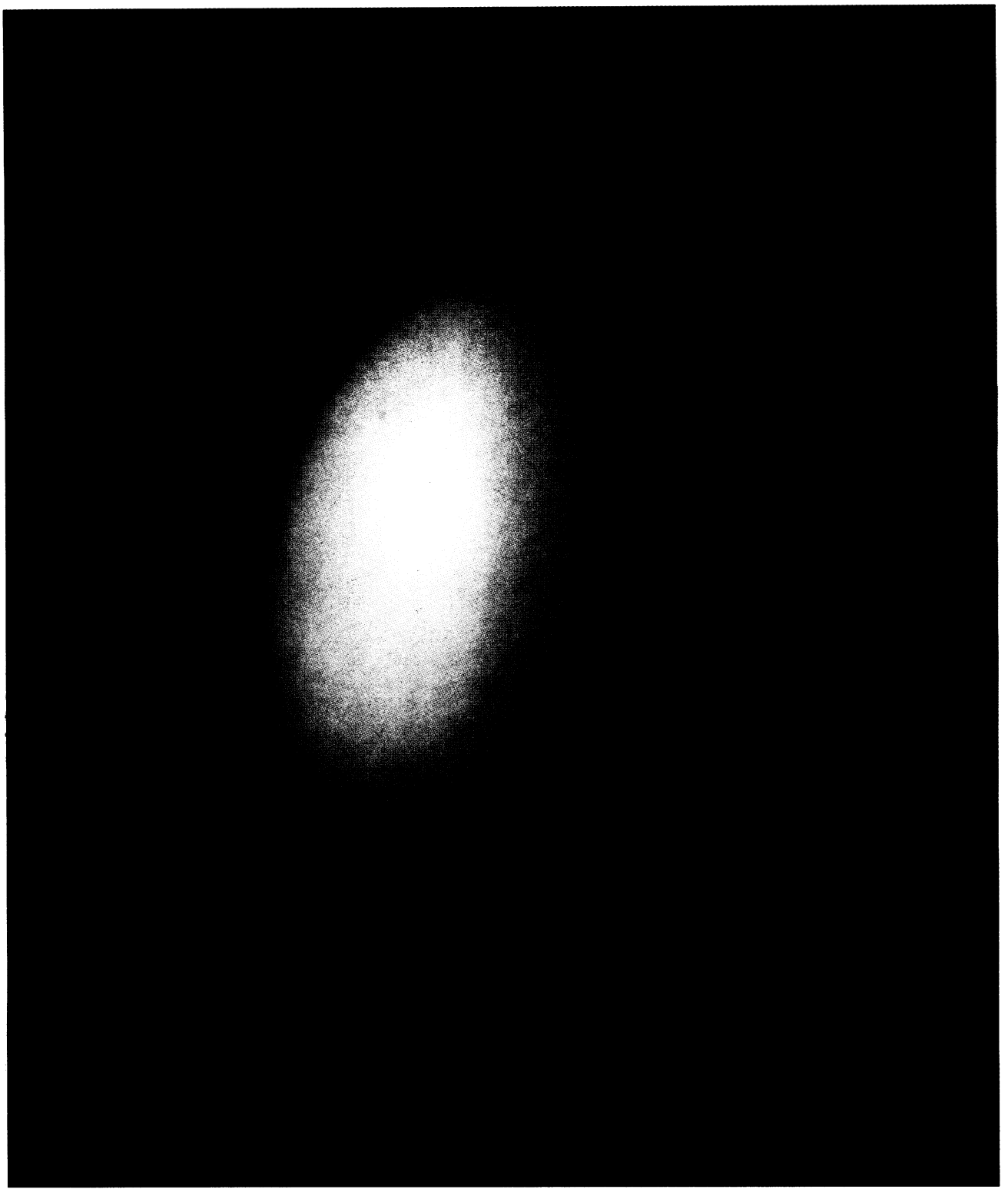


PRESCRIBING INFORMATION:

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

cellent

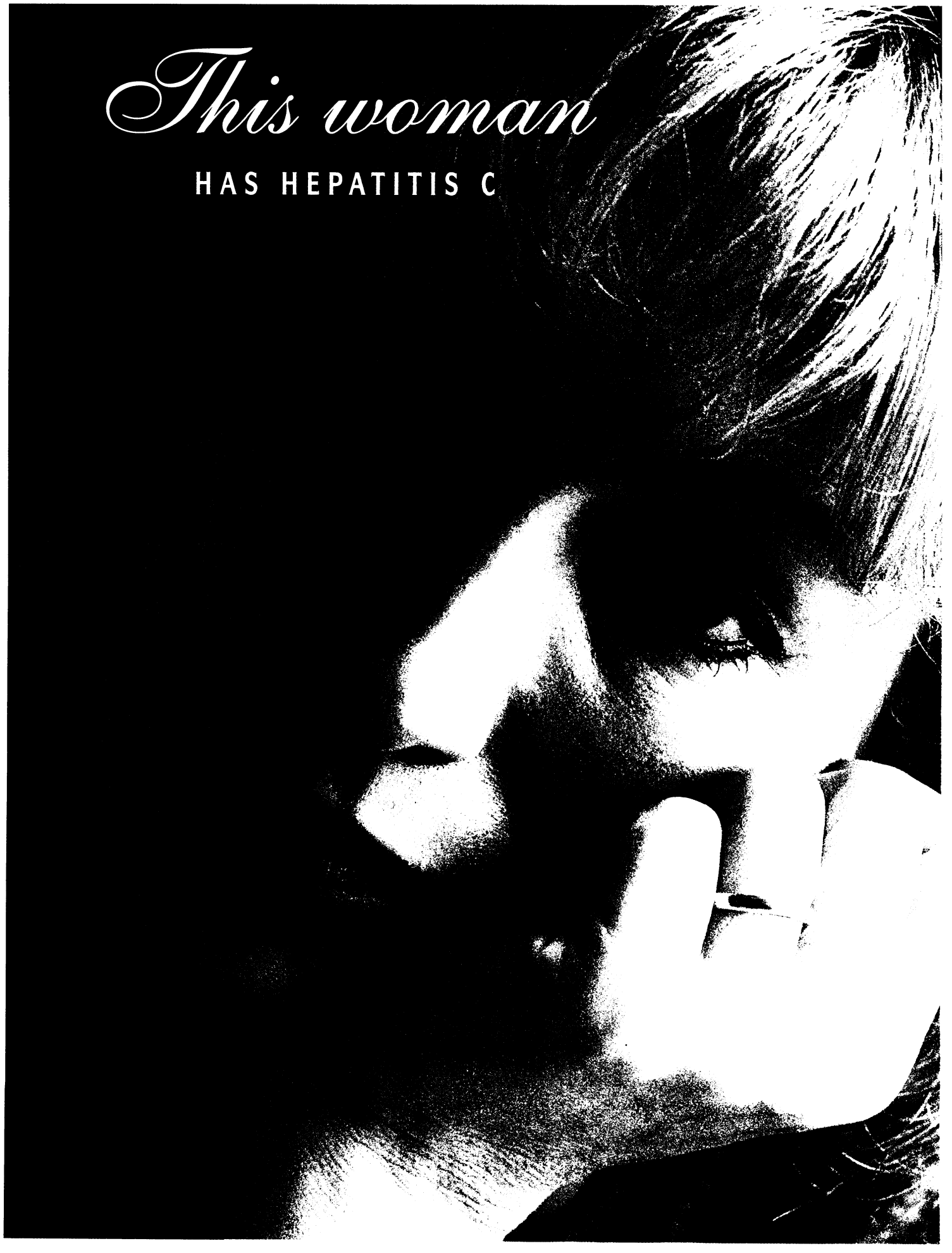
Zantac
RANITIDINE HCl

Zantac is now healing ulcers in over 100 countries[1]

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 Laboratories, Stockley Park West, Uxbridge, Middlesex UB11 1BT. POM Zantac is a trade mark of the Glaxo Wellcome Group of Companies. Further information is available on request from Glaxo Wellcome UK Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Telephone 0181-990 9444. Date of preparation: September 1995

Reference
1. Data on file. GlaxoWellcome UK Limited 1995.

GlaxoWellcome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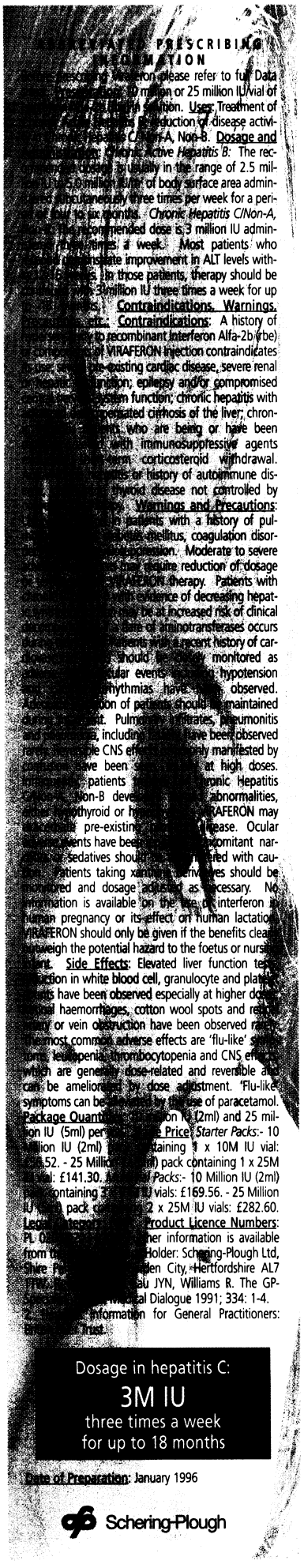

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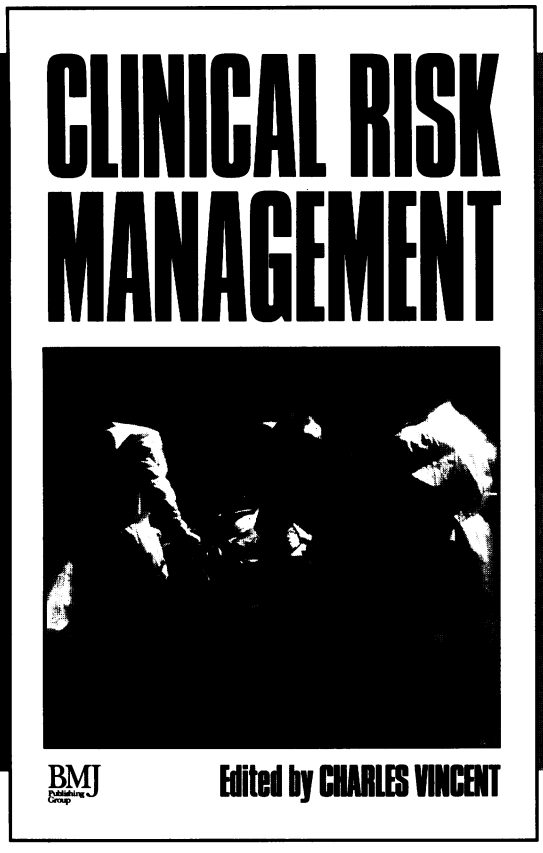

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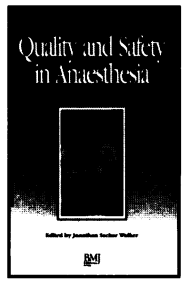

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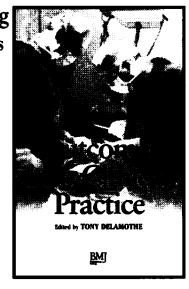

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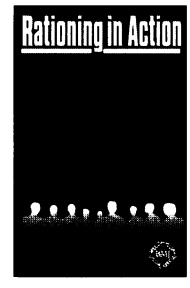

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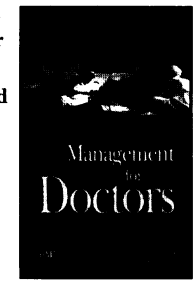

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Entocort® CR 3mg Capsules (budesonide)
PRESCRIBING INFORMATION (Refer to full Summary of Product Characteristics before prescribing). **Presentation:** Capsules containing 3mg budesonide **Use:** Induction of remission of mild to moderate Crohn's disease affecting the ileum and/or ascending colon. **Dosage and Administration: Adults:** 9mg once daily in the morning before breakfast for up to 8 weeks. When treatment is to be discontinued, the dose should normally be reduced for the last 2 to 4 weeks of therapy. **Children:** Not recommended. **Elderly:** No special dose adjustment, though limited experience in elderly. **Contra-Indications:** Bacterial, fungal or viral infections. Known hypersensitivity. **Precautions:** Treatment with Entocort CR Capsules results in lower systemic steroid levels than conventional oral steroid therapy. However, in common with all oral steroids use with caution in patients with tuberculosis, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts, chicken pox and measles or patients with a family history of diabetes or glaucoma. Corticosteroids may cause suppression of HPA axis and reduce the stress response. As with any glucocortico steroids, blood levels may increase in patients with compromised liver function. **Interactions:** Cholestyramine may reduce uptake. **Pregnancy and lactation:** Use during pregnancy should be avoided unless essential. It is not known whether budesonide passes into breast milk. **Adverse Events:** Those characteristic of systemic corticosteroid therapy. Others include (most classed as mild to moderate) – dyspepsia, muscle cramps, tremor, palpitations, nervousness, blurred vision, skin reactions and menstrual disorders. In clinical studies adverse event incidence was similar to placebo. **Legal Category:** POM. **Packs and prices:** Polyethylene bottles of 100 capsules. Price: £90.00. **Pharmacological Properties:** Budesonide has a high local anti-inflammatory effect and a significantly lower effect on HPA axis and adrenal function than prednisolone. **Marketing Authorization No:** PL0017/0359.

References: 1. Edsbäcker S, Wollmer P, Nilsson A, *et al.* Abstract. *Gastroenterol* 1993; **104** (4pt 2): A695. 2. Rutgeerts P, Löfberg R, Malchow H, *et al. N Engl J Med* 1994; **331:** 842-845. 3. Jewell DP, Campieri M, Järnerot G, *et al. Gastro Int* 1993; **6:** 1-4. 4. Campieri M, Ferguson A, Doe W, and The International Budesonide Study Group. Abstract. *Gastroenterol* 1995; **108** (4 suppl.): A790.

ASTRA Astra Pharmaceuticals

Further information available from the **Marketing Authorization Holder:** Astra Pharmaceuticals Limited, Kings Langley, Herts, WD4 8DH. Tel: (01923) 266191.

Date of preparation: May 1996 ENT/ADV 1047

We've re-shaped steroid delivery for Crohn's -

and taken the edge off side effects.

Astra have developed Entocort® CR from an established steroid, budesonide, in a formulation that's designed specifically for Crohn's disease.

Entocort CR acts where it's needed - a unique delivery system targets the ileum and ileocaecal area,[1] achieving rapid results equivalent to prednisolone.[2] But more importantly, the fact that 90% of the budesonide is metabolised on first pass through the liver,[3] means that Entocort CR sets a low level of systemic steroid side effects.[4]

With efficacy and low steroid side effects,[2-4] Entocort CR is tailor-made for Crohn's disease.

ENTOCORT® CR 3mg Capsules
budesonide

A tried and trusted steroid, adapted for Crohn's disease.

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ENTOCORT® CR 3mg Capsules
budesonide

A tried and trusted steroid, adapted for Crohn's disease.

NOW CROHN'S SUFFERERS CAN EXPERIENCE THE FREEDOM OF 'ASACOL'

Already the most widely prescribed 5-ASA in the treatment of inflammatory bowel disease, 'Asacol' is now indicated for the maintenance of remission of Crohn's ileo-colitis.

ow indicated for the maintenance of remission of Crohn's ileo-colitis.

SmithKline Beecham
Pharmaceuticals

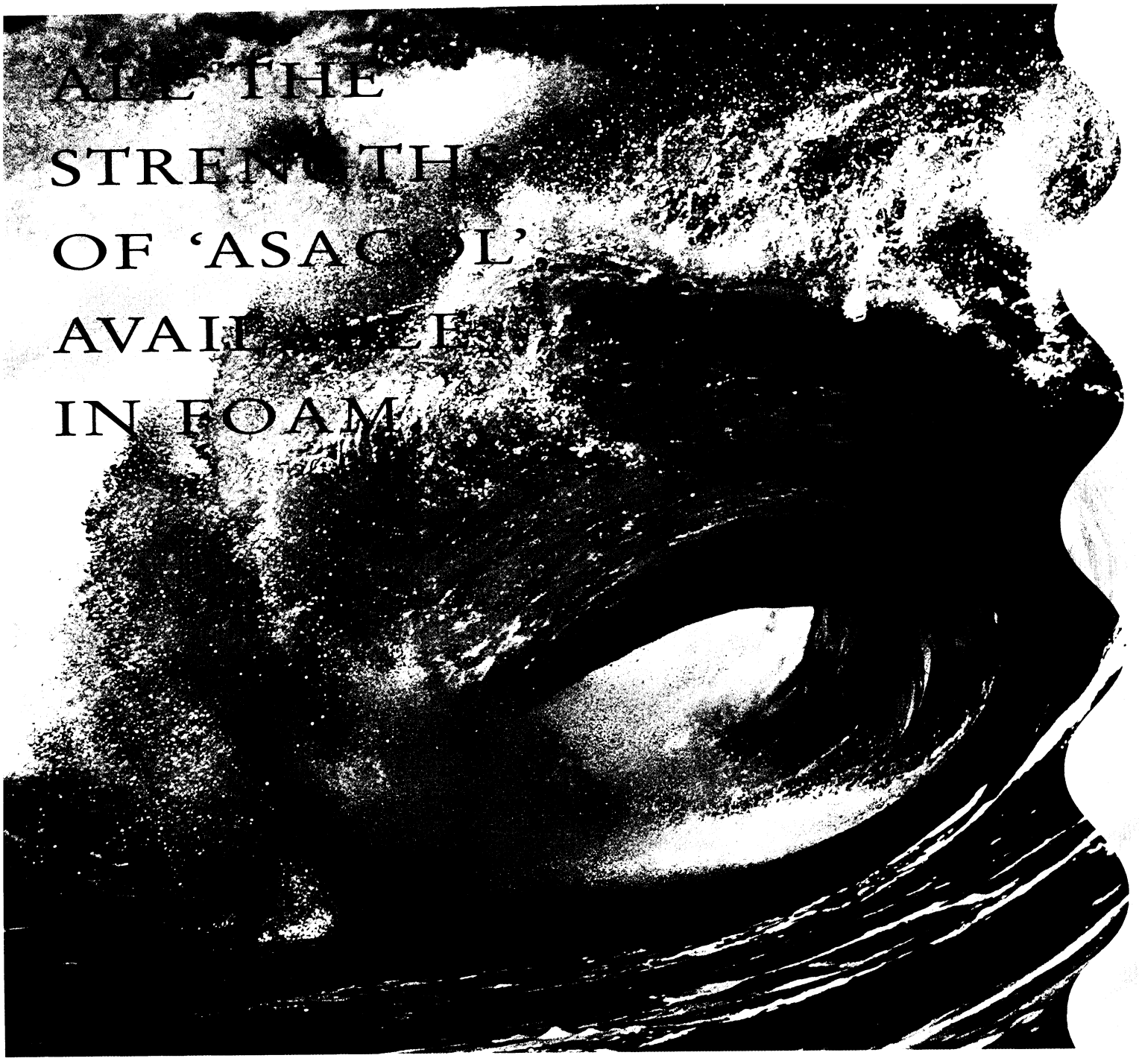
:h Kline & French Laboratories, Welwyn Garden City, Hertfordshire AL7 1EY.
ıorised user of the trade mark 'Asacol' in the UK. ©1996 Smith Kline & French Laboratories.
:cribing information is available on reverse

ASACOL

MESALAZINE* (5-AMINOSALICYLIC ACID)

FREEDOM IN IBD

0996AS:AD/6/517 GT



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), £43.58. 'Asacol' Suppositories 250 mg, PL 0002/0158, each containing 250 mg mesalazine. 20, £7.15. 'Asacol' Suppositories 500 mg, PL 0002/0195 each containing 500 mg mesalazine. 10, £7.15. '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** *Ulcerative colitis:* Treatment of mild to moderate acute exacerbations. Suppositories and Foam Enema particularly appropriate for distal disease. Maintenance of remission, Tablets and Suppositories. *Crohn's ileo-colitis:* Maintenance of remission, Tablets. **Dosage and administration: Adults:** ***Tablets:*** *Acute disease:* 6 tablets a day, in divided doses, with concomitant corticosteroid therapy where clinically indicated. *Maintenance therapy:* 3 to 6 tablets a day, in divided doses. ***Suppositories:*** *250 mg:* 3 to 6 a day, in divided doses, with the last dose at bedtime. *500 mg:* A maximum of 3 a day, in divided doses, with the last dose at bedtime. ***Foam Enema:*** 1 or 2 metered doses as single daily dose. **Children:** 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:** Best avoided in patients with established renal impairment but, if necessary, use with caution. Very rare reports with mesalazine of serious blood dyscrasias, perform haematological investigations if patient develops unexplained bleeding, bruising, purpura, anaemia, fever or sore throat. Stop treatment if suspicion or evidence of blood dyscrasia. Do not give tablets with lactulose or similar preparations which lower stool pH. Only use during pregnancy if benefits outweigh the risk. Avoid during lactation. Caution in elderly and only where renal function is normal. **Adverse reactions:** Nausea, diarrhoea, abdominal pain, headache. Exacerbation of symptoms of colitis. Rare reports of leucopenia, neutropenia, agranulocytosis, aplastic anaemia, thrombocytopenia, pancreatitis, hepatitis, allergic lung reactions, lupus erythematosus-like reactions, rash, interstitial nephritis and nephrotic syndrome, with oral mesalazine treatment, usually reversible on withdrawal. Renal failure has been reported. Suspect nephrotoxicity in patients developing renal dysfunction. **Legal category:** POM. 5.6.96.

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.

SmithKline Beecham Pharmaceuticals
Healthy Alliance
partnership beyond prescription

ASACOL

MESALAZINE* (5-AMINOSALICYLIC ACID)

FIVE STAR, 5-ASA
COLITIS CONTROL

0996AS:AD/6/539 C

NO

REFLUX

NO

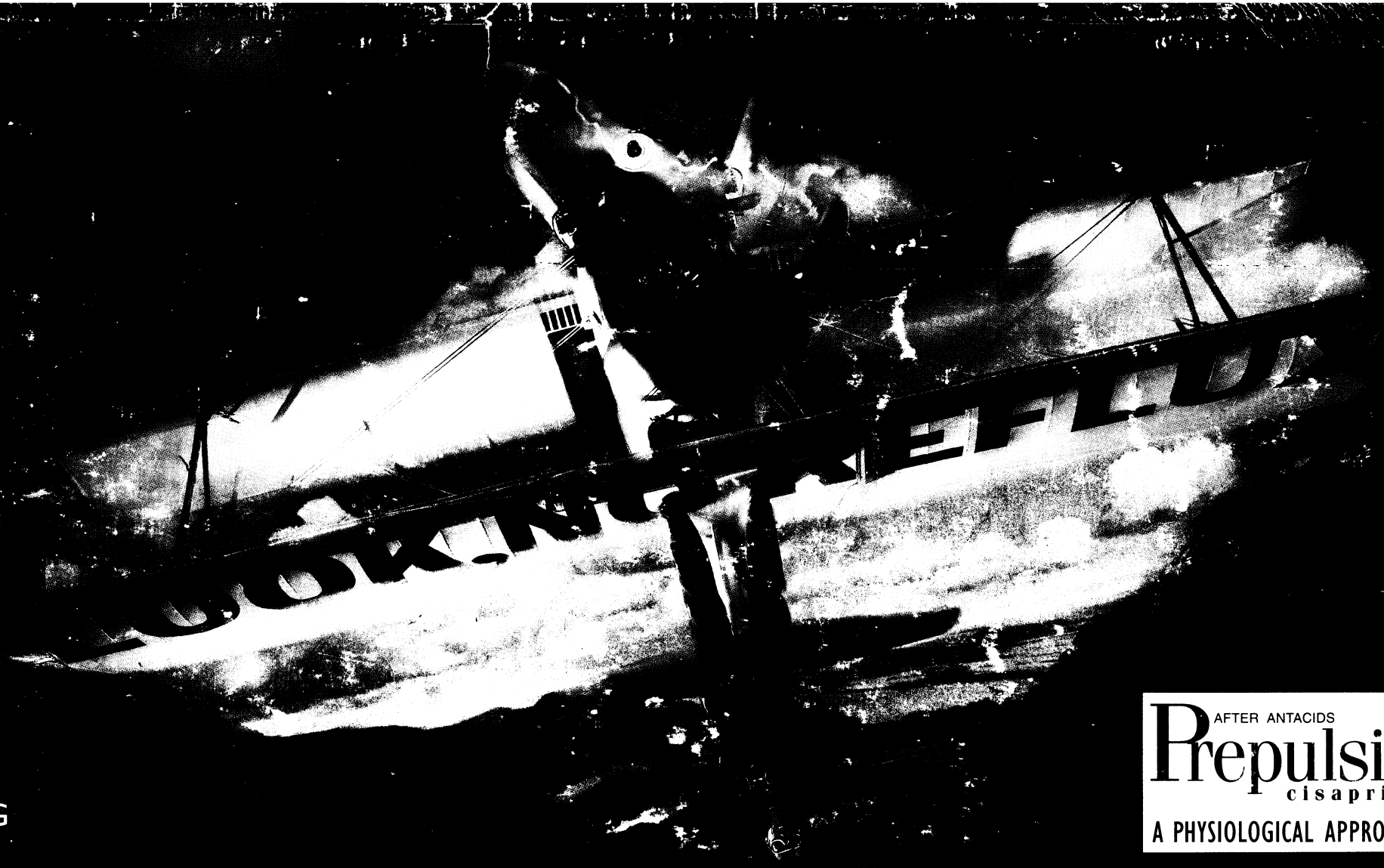
BLOATING

NO

BELCHING

NO

PROBLEM



AFTER ANTACIDS

Prepulsid™

cisapride

A PHYSIOLOGICAL APPROACH

ABBREVIATED PRESCRIBING INFORMATION Please refer to data sheet before prescribing. **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 symptoms such as epigastric pain, early satiety, anorexia, bloating and nausea associated with delayed gastric emptying secondary to diabetes, systemic sclerosis and autonomic neuropathy. **Dosage and Administration:** Adults and children twelve years and over: Take 15 minutes before food. REFLUX: 20mg Prepulsid b.d. (before breakfast and at bedtime) or 10mg Prepulsid t.i.d. (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 b.d. (before breakfast and at bedtime) increasing to 20mg b.d. in patients whose lesions were initially very severe. DYSPEPSIA: 10mg Prepulsid t.i.d. Usual course of treatment is 4 weeks. IMPAIRED GASTRIC EMPTYING: 10mg Prepulsid t.i.d. or q.i.d. 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; concomitant oral or parenteral ketoconazole, itraconazole or miconazole, fluconazole, erythromycin and clarithromycin; hypersensitivity to Prepulsid. **Warnings:** In view of reports of isolated cases of QT-interval prolongation and/or torsade de pointes (causal relationship not established), the recommended dose of Prepulsid should not be exceeded and it should be used with caution in patients with conditions leading to QT-interval prolongation, congenital QT-interval prolongation or in patients taking medication known to prolong QT-interval. 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. Prepulsid is metabolised mainly via the cytochrome P450 3A4 enzyme. Oral ketoconazole significantly inhibits the metabolism of Prepulsid; on the basis of *in vitro* data, itraconazole and miconazole may also have this effect. Co-administration with oral ketoconazole can result in QT-interval prolongation, which can lead to ventricular arrhythmias (see warnings). Concomitant administration with oral or parenteral ketoconazole, itraconazole, miconazole, fluconazole, erythromycin and clarithromycin, is therefore contra-indicated. Concomitant administration with cimetidine increases peak plasma levels and the AUC of Prepulsid, while the absorption of cimetidine and ranitidine is accelerated when co-administered with Prepulsid. The level of change is unlikely to be clinically significant. **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 light-headedness. 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:** The most frequently-reported symptoms are abdominal cramping and increased stool frequency. Treatment includes activated charcoal and close observation. Patients should also be evaluated for possible QT-interval prolongation and for factors that can predispose to the occurrence of torsade de pointes. **Presentation:** Prepulsid Tablets: pack 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 PL 0242/0136. Prepulsid Suspension PL 0242/0157. **Product Licence Holder:** Janssen-Cilag Ltd., Saunderton, High Wycombe, Bucks, HP14 4HJ. **Basic NHS Cost:** 120 tablets £37.60; 500 ml bottle suspension £15.60. **Legal Category:** POM. **Date of preparation:** April 1996

JANSSEN-CILAG