



**I've got the power**

**PRESCRIBING INFORMATION: INDICATIONS:** Duodenal ulcer, benign gastric ulcer, ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), oesophageal reflux disease, severe 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. Alternatively, in duodenal ulcers, 300mg in the morning and evening for four weeks to achieve optimal healing. 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. 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. Severe oesophagitis: 300mg four times daily for up to eight weeks (see data sheet for full dosage instructions). **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 and Granules. 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 with peptic ulcer and on NSAID therapy is recommended especially if elderly. Reduce dosage in the presence of severe renal failure (see data sheet). Like other drugs, use during pregnancy and lactation only if strictly necessary. **SIDE EFFECTS:** Headache, dizziness, skin rash, occasional hepatitis. 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<sub>2</sub>-receptor antagonists rare cases of bradycardia, A-V block and asystole (see data sheet). **PRESENTATIONS:** Zantac 150 Tablets each containing 150mg ranitidine (Product licence number 0004/0279, 60 tablets £29.76); Zantac 300 Tablets each containing 300mg ranitidine (Product licence number 0004/0302, 30 tablets £27.43); Zantac Dispersible Tablets each containing 150mg ranitidine (Product licence number 0004/0298, 60 tablets £31.25); Zantac Effervescent Tablets each containing 150mg ranitidine and 14.3mEq sodium (Product licence number 0004/0392, 60 tablets £31.25); Zantac Effervescent Tablets each containing 300mg ranitidine and 20.8mEq sodium (Product licence number 0004/0393, 30 tablets £31.25); Zantac Effervescent Granules each containing 150mg ranitidine and 10.2mEq sodium (Product licence number 0004/0394, 30 sachets £15.63); Zantac Effervescent Granules each containing 300mg ranitidine and 20.4mEq sodium (Product licence number 0004/0395, 30 sachets £31.25); Zantac Syrup each 10ml dose containing 150mg ranitidine (Product licence number 0004/0310, 300ml bottle £22.32). **PRODUCT LICENCE HOLDER:** Glaxo Operations U.K. Limited, Greenford, Middlesex UB6 0HE. Zantac is a Glaxo trade mark. Further information is available on request from: Glaxo Laboratories Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Tel: 081 990 9000.

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### Losec Capsules Abbreviated Prescribing Information

**Presentation:** Losec Capsules containing 20mg omeprazole. **Uses:** Treatment of reflux oesophagitis. Symptom relief is rapid, and the majority of patients are healed after 4 weeks. Treatment of duodenal and gastric ulcers, including those complicating NSAID therapy. Zollinger-Ellison syndrome. **Dosage & administration:** **Adults (including elderly):** Reflux oesophagitis: 20mg once daily, given for 4 weeks. For those patients not fully healed after the initial course, healing usually occurs during a further 4-8 weeks treatment. Losec has also been used in a dose of 40mg once daily in patients with reflux oesophagitis refractory to other therapy. Healing usually occurred within 8 weeks. Patients can be continued at a dosage of 20mg once daily. **Duodenal and benign gastric ulcers:** 20mg once daily. The majority of patients with duodenal ulcer are healed after 4 weeks. The majority of patients with benign gastric ulcer are healed after 8 weeks. In severe cases, the dose may be increased to 40mg Losec once daily. Long-term therapy with Losec in the treatment of gastric and duodenal ulcers is not currently recommended. **Zollinger-Ellison syndrome:** 60mg once daily. The dosage should be adjusted individually and treatment continued as long as clinically indicated. More than 90% of patients with severe disease and inadequate response to other therapies have been effectively controlled on doses of 20 - 120mg daily. With doses above 80mg, give twice daily. **Children:** There is no experience of the use of Losec in children. **Impaired renal or hepatic function:** Adjustment is not required. Patients with severe liver disease should not require more than 20mg Losec daily. **Contra-indications, warnings, etc:** **Contra-indications:** No known contra-indications to the use of Losec. When gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with Losec is instituted, as treatment may alleviate symptoms and delay diagnosis. Avoid in pregnancy unless there is no safer alternative. Breast feeding should be discontinued if the use of Losec is considered essential. Losec is well tolerated. All the following adverse reactions have usually been mild and transient, and there has been no consistent relationship with treatment: Nausea, headache, diarrhoea, constipation, flatulence, skin rashes, urticaria, pruritus, dizziness, somnolence, insomnia, vertigo, malaise, paraesthesia have occurred rarely. In isolated cases the following have been reported: muscular weakness, arthralgia, myalgia, blurred vision, dysgeusia, peripheral oedema, gynaecomastia, leucopenia, thrombocytopenia, GI candidiasis and stomatitis. Reversible mental confusion, agitation, depression and hallucinations have occurred predominantly in severely ill patients. Increases in liver enzymes with or without increases in bilirubin values have been observed. Losec can delay the elimination of diazepam, phenytoin and warfarin. Monitoring of patients receiving warfarin or phenytoin is recommended and a reduction of warfarin or phenytoin dose may be necessary when omeprazole is added to treatment. No evidence of an interaction with theophylline, propranolol, metoprolol, lidocaine, quinidine, amoxicillin or antacids. The absorption of Losec is not affected by alcohol or food. **Animal Toxicology:** Gastric ECL-cell hyperplasia and carcinoids, have been observed in life-long studies in rats treated with omeprazole or subjected to partial fundectomy. These changes are the result of sustained hypergastrinaemia secondary to acid inhibition, and not from a direct effect of any individual drug. No treatment related mucosal changes have been observed in patients treated continuously with omeprazole for periods up to 5 years. **Pharmaceutical precautions:** Use within three months of opening. Replace cap firmly after use. Dispense in original container. **Legal category:** POM **Package quantities:** Bottles of 5 capsules, £6.49; Bottles of 28 capsules, £36.36 **Product licence no:** PL0017/0238 **Product licence holder:** Astra Pharmaceuticals Ltd., Home Park, Kings Langley, Herts WD4 8DH.

#### References

1. Holt S & Howden CW. *Dig Dis & Sci* 1991; **36** (4): 385-93. 2. Sandmark S et al. *Scand J Gastroenterol* 1988; **23**: 625-32. 3. McFarland RJ et al. *Gastroenterol* 1990; **98**: 278-83. 4. Bate CM et al. *Gut* 1990; **31**: 968-72.

**ASTRA** For further information contact the product licence holder:  
Astra Pharmaceuticals Ltd., Home Park, Kings Langley, Herts WD4 8DH.  
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\*Losec compared with conventional starting courses of H<sub>2</sub>-antagonists in reflux oesophagitis, duodenal and gastric ulcers







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**Presentation:** White, sugar-coated tablets each containing 135mg mebeverine hydrochloride. Available in packs of 100. Basic NHS price £8.35. Yellow, banana-flavoured sugar-free suspension containing mebeverine pamoate equivalent to 50mg mebeverine hydrochloride per 5ml. Available in bottles of 300ml. Basic NHS price £3.50.  
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intestinal spasm secondary to organic diseases.

**Dosage and Administration:** Tablets: Adults and children ten years and over: One tablet three times a day, preferably 20 minutes before meals. Suspension: Adults and children ten years and over: 15ml (150mg) three times a day, preferably 20 minutes before meals. **Contra-indications, warnings, etc:** Animal experiments have failed to show any terato-

genic effects. However, the usual precautions concerning the administration of any drug during pregnancy should be observed. **Product Licence Number:** Tablets: 0512/0044. Suspension: 0512/0061. Further information is available on request to the Company. Duphar Laboratories Limited, Gaters Hill, West End, Southampton, SO3 3JD. Telephone: 0703 472281

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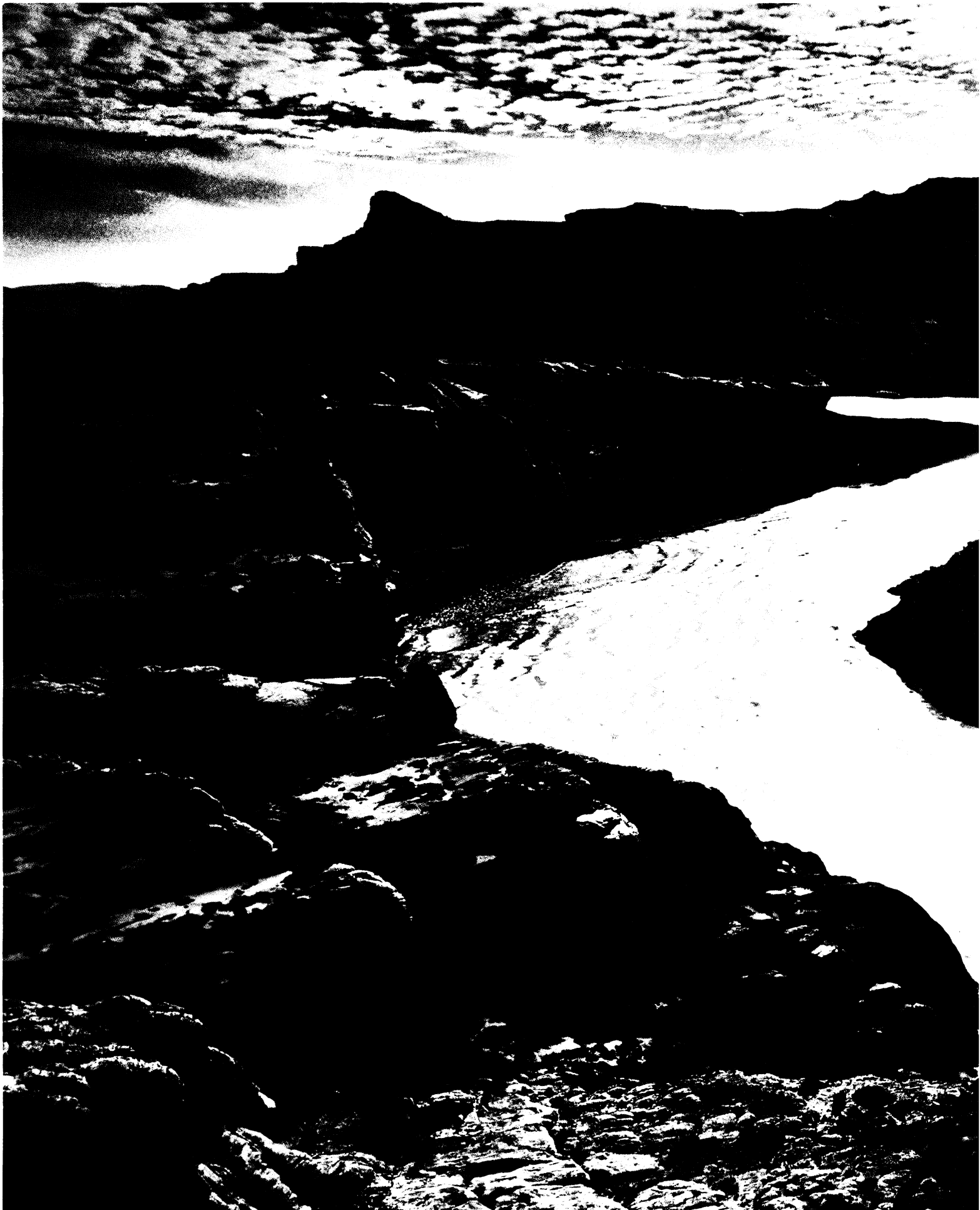
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Rarely, reversible mental confusion states, usually in very ill or elderly patients. Rare cases of leucopenia and thrombocytopenia, usually reversible, agranulocytosis and pancytopenia. Hypersensitivity reactions, anaphylactic shock. Rare cases of breast symptoms in men. As with other H<sub>2</sub>-receptor antagonists rare cases of bradycardia, A-V block and asystole (see data sheet). **PRESENTATIONS:** Zantac 150 Tablets each containing 150mg ranitidine (Product licence number 0004/0279, 60 tablets £29.76); Zantac 300 Tablets each containing 300mg ranitidine (Product licence number 0004/0302, 30 tablets £27.43); Zantac Dispersible Tablets each containing 150mg ranitidine (Product licence number 0004/0298, 60 tablets £31.25); Zantac Effervescent Tablets each containing 150mg ranitidine and 14.3mEq sodium (Product licence number 0004/0392, 60 tablets £31.25); Zantac Effervescent Tablets each containing 300mg ranitidine and 20.8mEq sodium (Product licence number 0004/0393, 30 tablets £31.25); Zantac Effervescent Granules each containing 150mg ranitidine and 10.2mEq sodium (Product licence number 0004/0394, 30 sachets £15.63); Zantac Effervescent Granules each containing 300mg ranitidine and 20.4mEq sodium (Product licence number 0004/0395, 30 sachets £31.25); Zantac Syrup each 10ml dose containing 150mg ranitidine (Product licence number 0004/0310, 300ml bottle £22.32). **PRODUCT LICENCE HOLDER:** Glaxo Operations U.K. Limited, Greenford, Middlesex UB6 0HE. Zantac is a Glaxo trade mark. Further information is available on request from: Glaxo Laboratories Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Tel: 081 990 9000.

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## CYTOTEC

### Abbreviated Prescribing Information

**Presentation:** Tablet containing misoprostol 200 micrograms.

**Uses:** Healing of duodenal and gastric ulcer induced by non-steroidal anti-inflammatory drugs (NSAID) in arthritic patients at risk, whilst continuing NSAID therapy. Prophylaxis of NSAID-induced ulcers. Healing of duodenal and gastric ulcer.

**Dosage: Adults including the elderly.**

**Healing of duodenal and gastric ulcer:** 800 micrograms daily in four divided doses taken with food.

**Prophylaxis of NSAID-induced ulcer:** Usual dose 200 micrograms twice daily taken with food. Higher frequency NSAID use – 200 micrograms three times a day. Refer to data sheet for additional information.

**Contraindications:** Pregnant women, women planning a pregnancy, patients allergic to prostaglandins.

**Warnings:** Pre-menopausal women should use effective contraception and be advised of the risks of taking Cytotec if pregnant.

**Precautions:** Cytotec does not produce hypotension in clinical studies at ulcer-healing doses, nevertheless exercise caution in disease states where hypotension might precipitate severe complications. Cytotec should not be administered during breast feeding.

**Adverse effects:** Diarrhoea, abdominal pain, dyspepsia, flatulence, nausea, vomiting, dizziness, skin rashes.

In women – menorrhagia, intermenstrual bleeding, vaginal bleeding.

**Basic NHS Price:** £13 per 56 tablets.

**Product Licence Number:** 0020. 0115.

Data sheet with full prescribing information is available on request.

## SEARLE

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**References:** 1. Moriga M. *Roy. Soc. Med. Int. Cong. Symp. Ser.* 1981; 36: 77-79. 2. De Loosse F. *Pharmatherapeutica* 1979; 2(3): 140-146. 3. Van Ganse W. *Curr. Ther. Res.* 1978; 23(6): 695-701. 4. Van Outryve M *et al.*, *Postgrad. Med. J.* 1979; 55 (Suppl. 1): 33-35. 5. Van de Mierop L *et al.*, *Digestion* 1979; 19: 244-250. 6. Laduron PM & Leysen JE. *Biochem. Pharmacol.* 1979; 28: 2161-2165. Motilium is a registered trade mark. Further information available from: Sanofi Winthrop Limited, 1 Onslow Street, Guildford, Surrey GU1 4YS.

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## PRESCRIBING INFORMATION: Dipentum

**Presentation:** Caramel coloured capsules containing 250mg olsalazine sodium. **Uses:** Oral treatment of acute mild ulcerative colitis and the maintenance of remission. Olsalazine consists of two molecules of 5-aminosalicylic acid (5-ASA) joined through an azo-bond. The systemic absorption of olsalazine is minimal. 99% of an oral dose will reach the colon. Olsalazine is activated in the colon where it is converted into 5-ASA. The release of 5-ASA is neither pH nor time dependent. 5-ASA acts topically on the colonic mucosa and local colonic concentrations of 5-ASA are more than 1000 times that found in the serum. **Dosage and Administration:** **Acute Mild Disease:** Adults including the Elderly. Commence on 1g daily in divided doses and, depending upon the patient response, titrate the dose upwards to a maximum of 3g daily over 1 week. A single dose should not exceed 1g. Olsalazine should be taken with food. **Remission:** Adults including the Elderly. Two capsules (0.5g) twice daily taken with food. **Contra-indications: Warnings etc:** **Contra-indications:** Hypersensitivity to salicylates. There is no experience of the use of olsalazine in patients with significant renal impairment. Olsalazine is contra-indicated in patients with significant renal impairment. **Pregnancy:** Reproduction studies performed in mice, rats and rabbits have revealed no evidence of impaired fertility, harm to the foetus or teratogenic effects due to olsalazine administration. However, the experience of use in pregnant women is limited. Dipentum should not be used during pregnancy unless the clinician considers that the potential benefit outweighs the possible risk to the foetus. **Lactation:** There are no data on the excretion of olsalazine in breast milk. **Adverse Reactions:** Watery diarrhoea has been recorded in 15% of patients treated. In half of these patients the diarrhoea was either transient or overcome by dose reduction. In patients who do not respond to dose reduction the drug should be stopped. As with sulphasalazine and mesalazine gastrointestinal side-effects are the most common. The most frequently reported adverse reactions are diarrhoea, abdominal cramps, headache, nausea, dyspepsia, arthralgia and rash. **Treatment of Overdose:** There is no specific antidote to olsalazine. Treatment should be supportive. **Pharmaceutical Precautions:** Store at room temperature in a dry place. **Legal Category:** POM. **Package Quantities:** Containers of 100 capsules. **Further Information:** Olsalazine has been used concomitantly with glucocorticosteroids. **Product Licence Number:** 0009/0069. **Product Licence Holder:** Pharmacia Biosystems Ltd, Davy Avenue, Knowlhill, Milton Keynes MK5 8PH. **Distributed by:** Kabi Pharmacia Ltd., Davy Avenue, Knowlhill, Milton Keynes MK5 8PH. **References:** 1. Courtney, M.G. et al. (1992) *The Lancet*; **339**: 1279-1281 2. Courtney, M.G. et al. (1990) *The 9th World Congress of Gastroenterology*, Sydney, Australia; Abstr. PP727.



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sion when you can achieve 76%?<sup>1</sup>

Ulcerative colitis can ruin lives with its distressing cycle of relapses. Surely the most rewarding strategy, once you've done the job of controlling the acute phase of this disease, is to maintain remission as effectively as possible.



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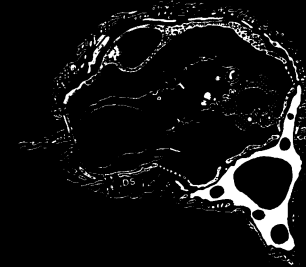
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10% Hydrocortisone acetate foam.

The leading topical treatment for ulcerative colitis.

**PRESCRIBING INFORMATION:** Presentation: White odourless aerosol containing hydrocortisone acetate PhEur 10%. 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. Pharmaceutical precautions: Pressurized container. Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn even after use. Do not refrigerate. Keep out of reach of children. For external use only. Legal category: POM. Package Quantity & Basic NHS cost: 25g canister plus applicator, £7.25. Further Information: One applicatorful of Colifoam provides a dose of approximately 125mg of hydrocortisone acetate, similar to that used in a retention enema, for the treatment of ulcerative colitis, sigmoiditis and proctitis. Product Licence No.: 0036/0021. References 1. Somerville KW et al. British Medical Journal 1985; 291:866. 2. Ruddell WSJ et al. Gut 1980; 21:885-889. 3. Independent Research Audit. Data on File. Further information is available on request. Stafford-Miller Ltd., Professional Relations Division, Broadwater Road, Welwyn Garden City, Herts. AL7 3SP.

# THE BENEFIT

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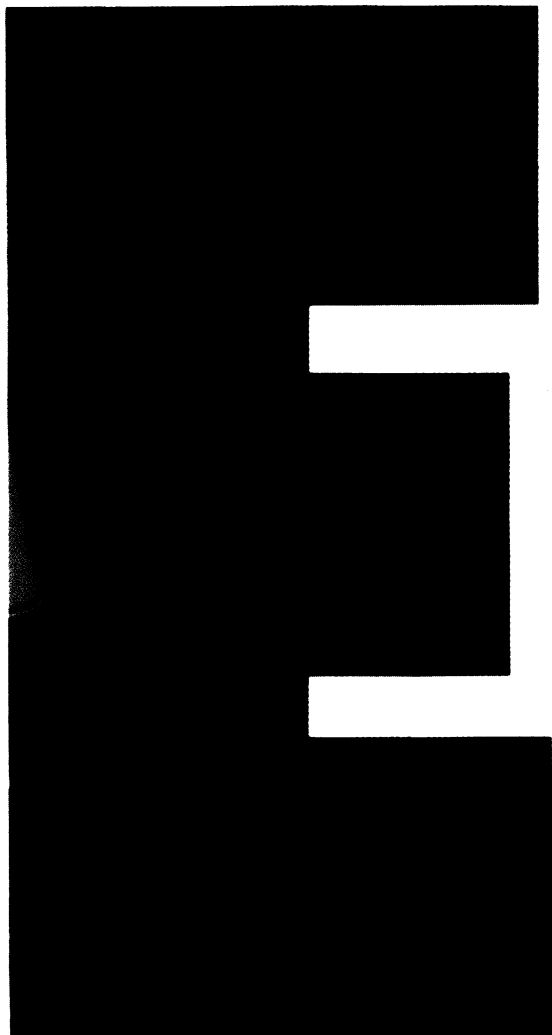
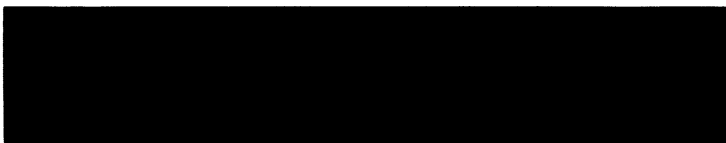


# MOLECULE OF

**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), £34.30 '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. **Uses** Treatment of mild to moderate acute exacerbations of ulcerative colitis. Maintenance of remission of ulcerative colitis. Suppositories particularly appropriate for distal disease. **Dosage and administration** **Tablets:** *Adults: 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. **Children:** No dosage recommendation. **Suppositories:** *Adults: 250 mg strength:* 3 to 6 a day, in divided doses, with the last dose at bedtime. *500 mg strength:* A maximum of 3 a day, in divided doses, with the last dose at bedtime. **Children:** No dosage recommendation. **Contraindications** A history of sensitivity to salicylates. 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. Avoid during pregnancy and lactation. Caution in elderly and only where renal function is normal. Do not give tablets with lactulose or similar preparations which lower stool pH. **Adverse reactions** Nausea, diarrhoea,

# 'S OF



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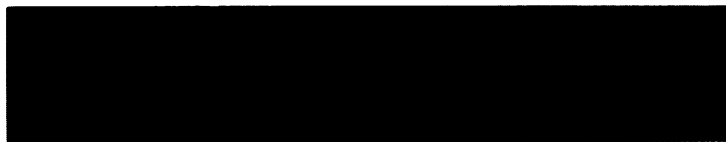
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**References** 1. Dew MJ *et al.* Colonic release of 5-aminosalicylic acid from an oral preparation in active ulcerative colitis. *Br J Clin Pharmacol* 1983;16:185-7. 2. Riley SA *et al.* Comparison of delayed release 5-aminosalicylic acid (mesalazine) and sulphasalazine in the treatment of mild to moderate ulcerative colitis relapse. *Gut* 1988;29(5):669-74. 3. Riley SA *et al.* Comparison of delayed-release 5-aminosalicylic acid (mesalazine) and

sulfasalazine as maintenance treatment for patients with ulcerative colitis. *Gastroenterology* 1988;94:1383-9. 4. Birnie GG *et al.* Incidence of sulphasalazine-induced male infertility. *Gut* 1981;22:452-5. 5. Riley SA *et al.* Sulphasalazine induced seminal abnormalities in ulcerative colitis: results of mesalazine substitution. *Gut* 1987;28:1008-12. 6. Robinson M *et al.* Olsalazine in the treatment of mild to moderate ulcerative colitis. *Gastroenterology* 1988;94:A381.

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June/July 1992

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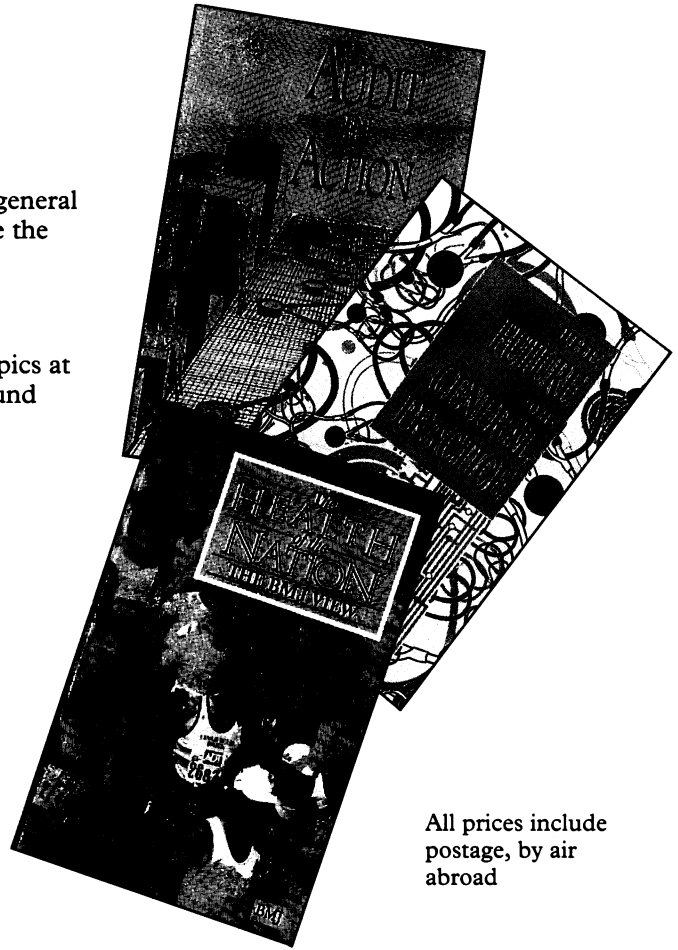
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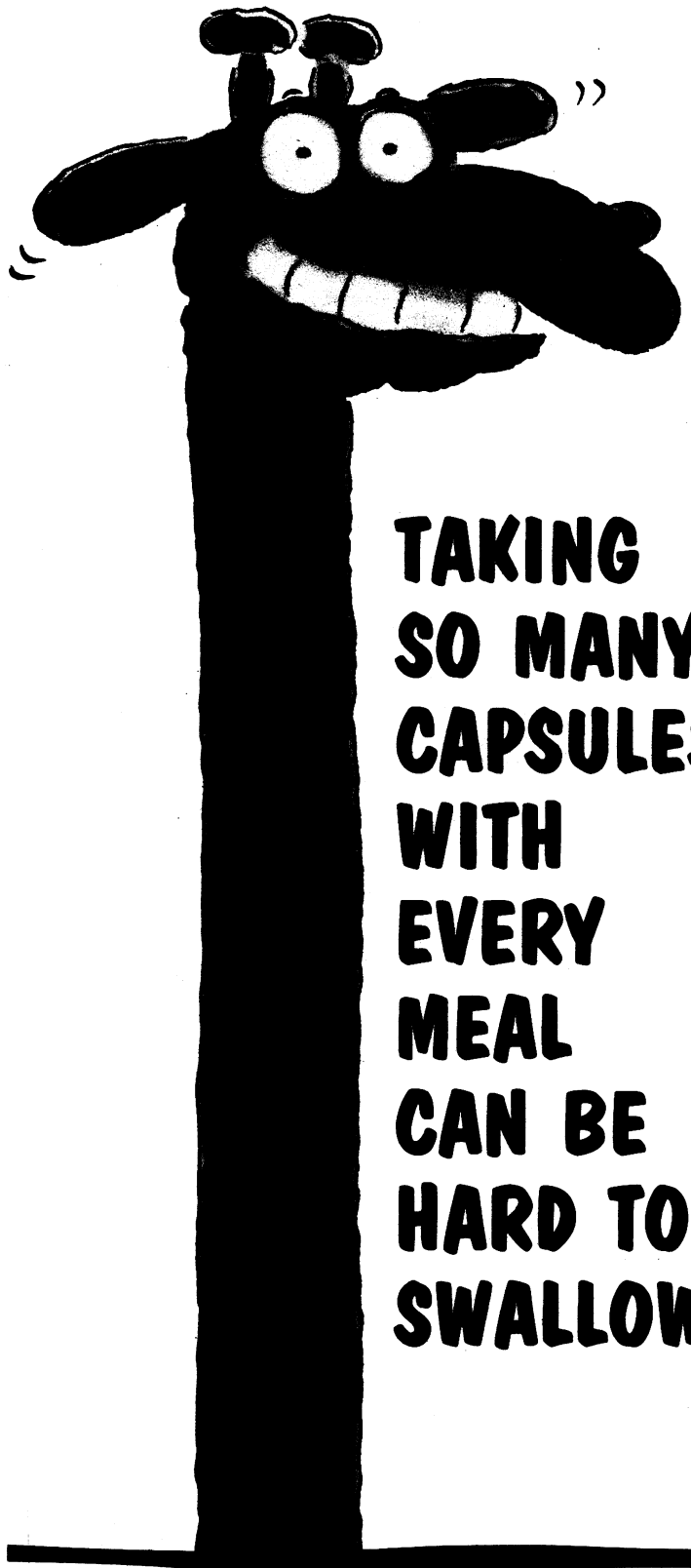
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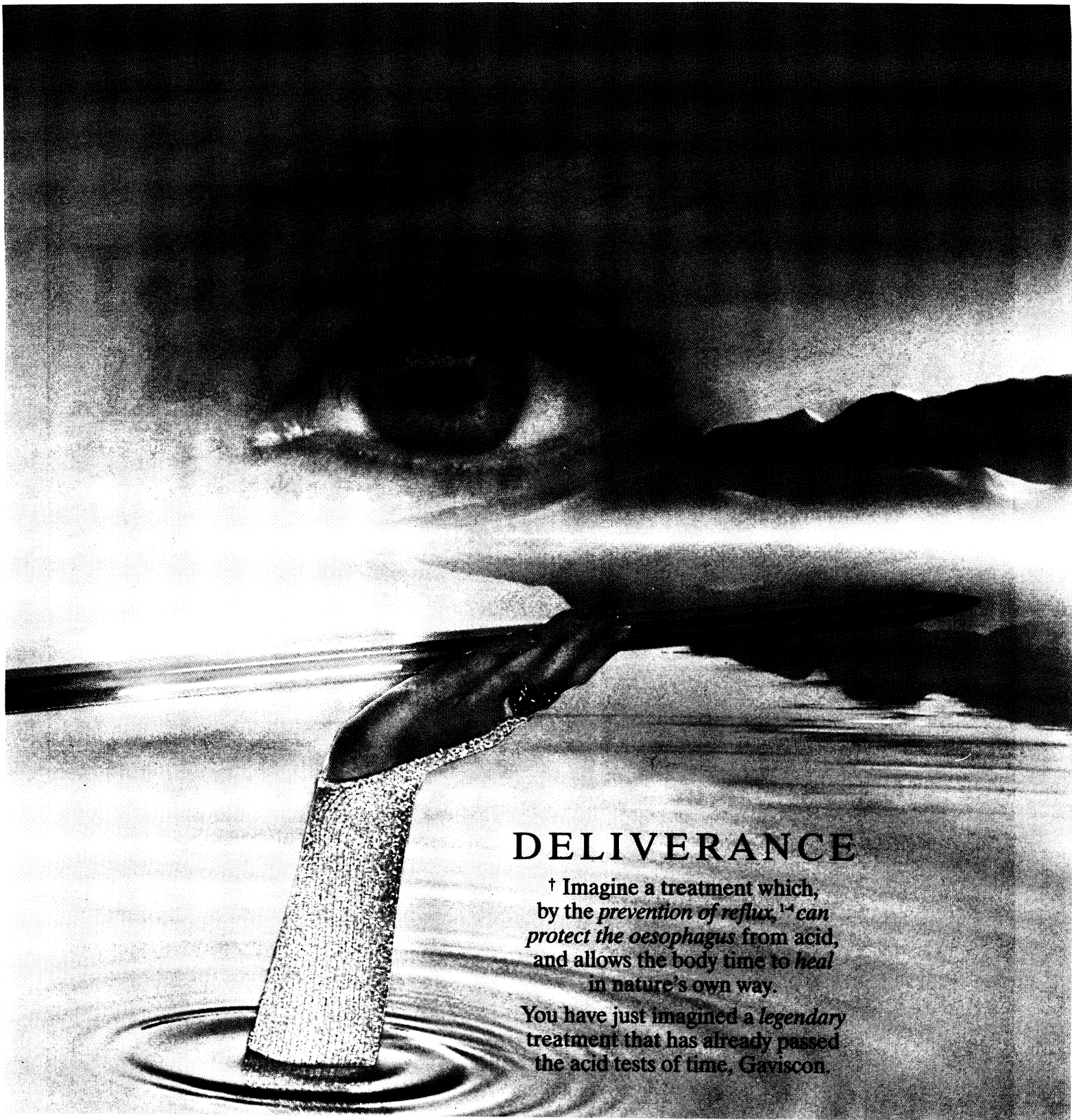


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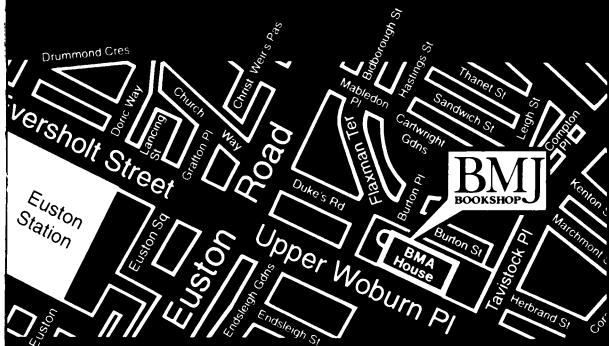
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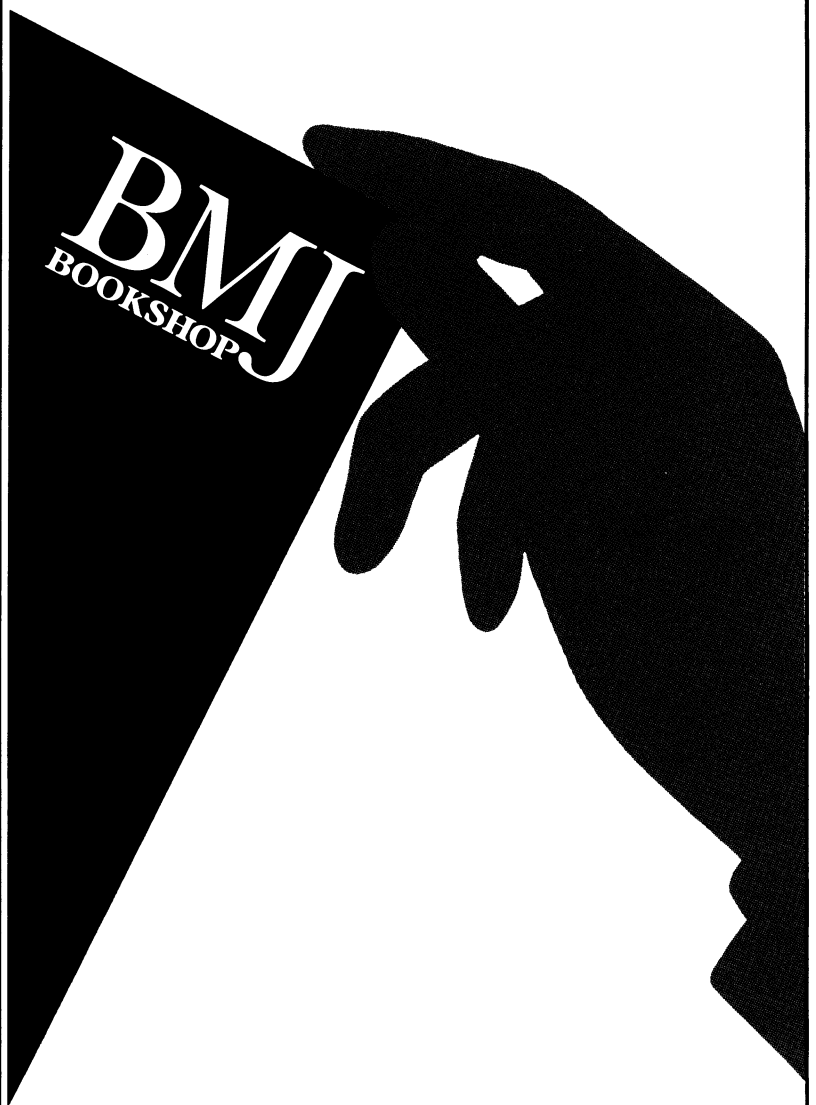
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#### Prescribing Information

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**Uses:** Treatment of proctitis and ulcerative colitis. **Dosage and administration:** Adults and elderly patients: One metered dose inserted rectally once or twice daily for two weeks, extending treatment for a further two weeks when a good response is obtained. Use should be discontinued at the discretion of the physician once the disease is stable and under control. Children: Not recommended. **Contra-Indications, warnings etc.:** Contra-indications: Local conditions where infection might be masked or healing impaired, e.g. peritonitis, fistulae, intestinal obstruction, perforation of the bowel. **Precautions:** The product should be used with extreme caution in the presence of severe ulcerative colitis. The possible occurrence of masking of local or systemic infection should be borne in mind when using this product. For rectal use only. **Side-effects:** The consequences of systemic absorption should be considered with extensive use over prolonged periods. As with all rectal corticosteroids, prolonged continuous use is undesirable. **Use in pregnancy and lactation:** There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development

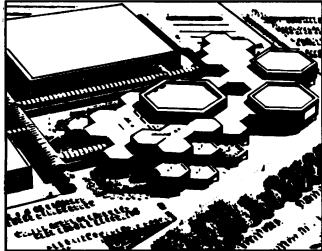
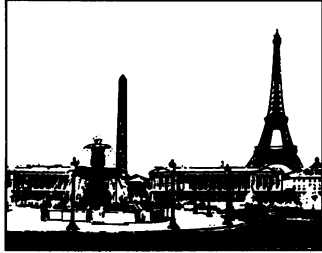
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#### References

1. Data on file, Pharmax. 2. K.W. Somerville, et al (1985) BMJ, 291-866. 3. W.S.J. Ruddell, et al (1980) Gut, 885-889. 4. C. Rodrigues, et al (1987), The Lancet, i, 1497. 5. Data on file, Pharmax.



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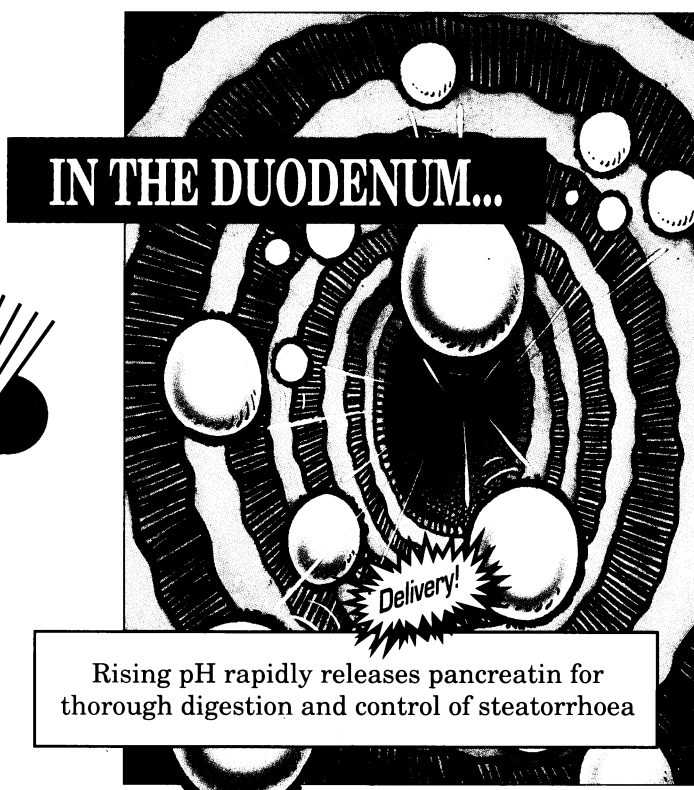
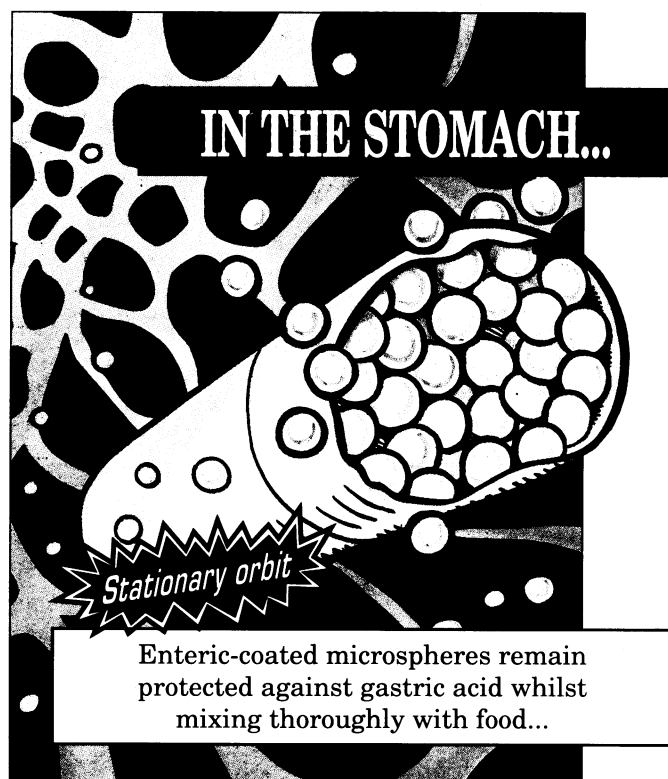
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