PRESCRIBING INFORMATION Properties: Prepulsid is the first of a new class of drug capable of correcting abnormal motility throughout the GI tract. **Indications:** GASTRO-OESOPHAGEAL REFLUX DISEASE: Treatment of the symptoms such as heartburn, regurgitation, and healing of mucosal lesions. Prepulsid may also be used for the maintenance treatment of reflux oesophagitis. DYSPEPSIA: Treatment of symptoms such as epigastric pain, early satiety, bloating, 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:** Take 15 minutes before food. ADULTS AND CHILDREN TWELVE YEARS AND OVER: **Gastro-Oesophageal Reflux:** 20mg Prepulsid bd (before breakfast and at bedtime). Alternatively, 10mg Prepulsid td (if necessary, night time symptoms can be treated with an extra 10mg dose at bedtime). A 12 week course is recommended for healing oesophagitis. Patients may continue long term maintenance therapy at a dose of 20mg once daily (at bedtime) or alternatively, 10mg twice daily (before breakfast and at bedtime). In patients whose lesions were initially very severe, this dose can be increased to 20mg twice daily. **Dyspepsia:** 10mg Prepulsid td. The usual course of treatment is 4 weeks. **Impaired Gastric Emptying:** 10mg Prepulsid td or qd. An initial course of 6 weeks is recommended but longer treatment may be required. **USE IN CHILDREN:** Not recommended in children under 12. **USE IN ELDERLY:** Dose as for adults, but monitor response. **ABNORMAL RENAL OR LIVER FUNCTION:** Initially the dose should be halved. **CONTRA-INDICATIONS, WARNINGS ETC. Contra-Indications:** Contra-indicated in pregnancy and in patients in whom gastrointestinal stimulation might be dangerous e.g. gastrointestinal haemorrhage, mechanical obstruction or perforation. **Warnings:** It is not advisable to take Prepulsid whilst breast feeding. **Drug Interactions:** The 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, such as anticonvulsants, it may be useful to measure their plasma concentration. In patients receiving anticoagulants, the prothrombin time may be increased. Prepulsid does not affect psychomotor performance nor does it induce sedation or drowsiness. However, the sedative effects of benzodiazepines and alcohol may be accelerated when administered concomitantly with Prepulsid. The effects of Prepulsid are antagonised by anticholinergic drugs. **Side Effects:** Abdominal cramps, borborygmi and loose stools (diarrhoea) are mainly transient and rarely require discontinuation of treatment. Should severe abdominal cramps occur with single administrations of 20mg Prepulsid, it is recommended that the dose per administration is halved and the frequency of dosing doubled. Infrequent side-effects include headaches and lightheadedness. Reports of convulsions and extrapyramidal effects have been received. Exceptionally, reversible liver function abnormalities have been reported – causal relationship not established. **Overdosage:** Treatment should include activated charcoal, close observation and general supportive measures. **Presentation and Packaging:** Prepulsid Tablets; white, biconvex, scored tablets, engraved CIS/10 on one side and Janssen on the reverse in packs of 120. Each tablet contains 10mg of cisapride. The tablets also contain lactose. Prepulsid Suspension; white, cherry-flavoured suspension containing cisapride 5mg/5ml, 500ml bottle. The suspension also contains sucrose, methyl and propyl parabens. **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). **Product Licence Number:** Prepulsid 10mg tablets PL 0242/0136. Prepulsid suspension PL 0242/0157. **Basic NHS Cost:** 120 tablets – £37.60; 500ml bottle suspension – £15.60. **Legal Category:** POM.

Further information is available from
JANSSEN PHARMACEUTICAL LTD
Grove, Wantage, Oxon, OX12 0DQ
Date of preparation: December 1993
TM=Trademark, ©JPL 212/94

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

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

Glaxo *Laboratories Limited*

ZANTAC
STING O

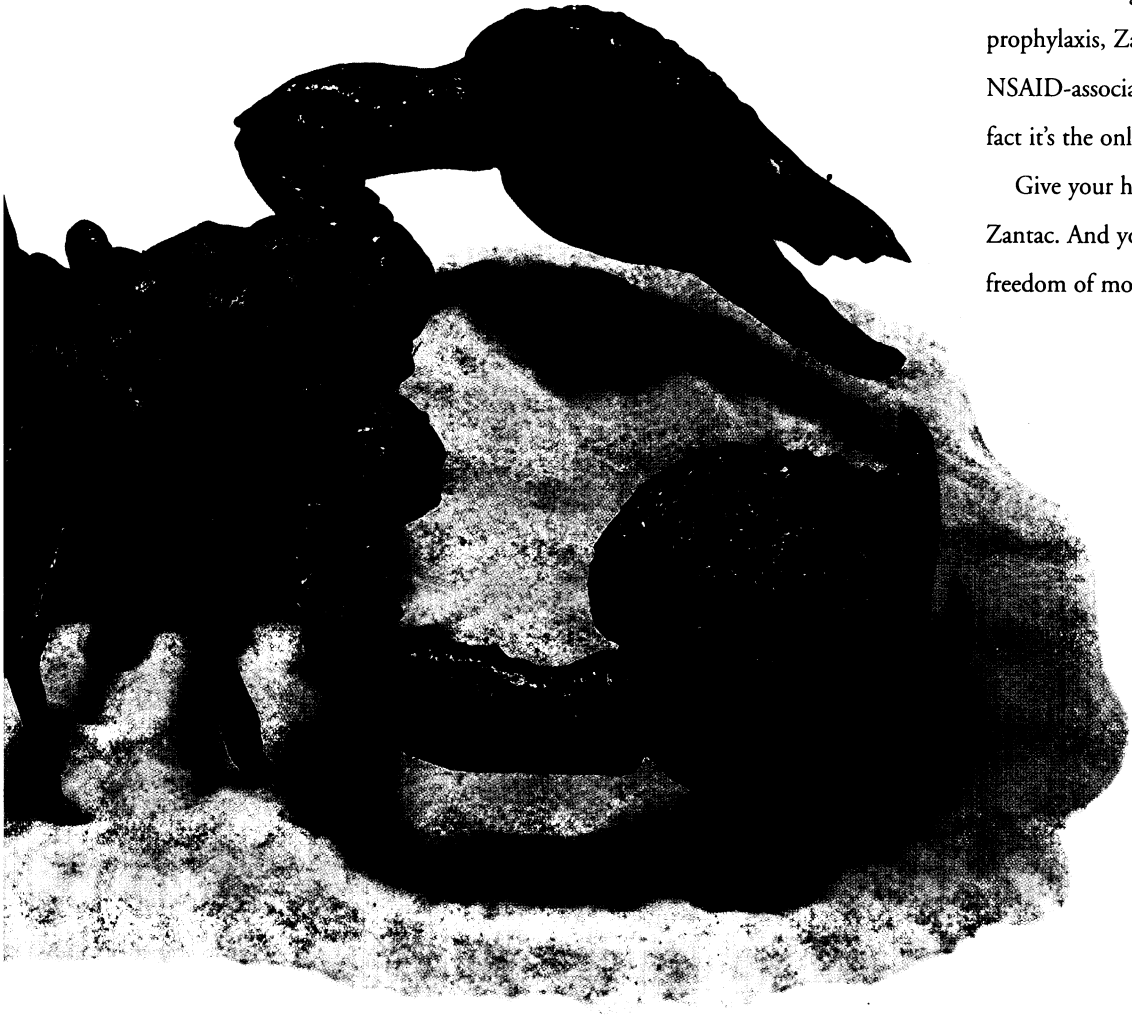
, TAKING THE UT OF NSAIDs.

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

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

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

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



Zantac
RANITIDINE HCl

PREDFOAM

Unique metered dose aerosol – providing dosage uniformity[1]

Foam formulation – easier to retain than liquid preparations and preferred by patients[2,3]

Proven clinical efficacy[4,5]

Easy to use disposable applicators – clean and convenient for patients at home or at work

A complete local management system for maximum patient compliance

Prescribing Information
Predfoam Prednisolone metasulphobenzoate sodium equivalent to 20mg prednisolone per metered dose. **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 including cleft palate and intra-uterine growth retardation. There may, therefore, be a very small risk of such effects in the human foetus. **Overdosage:** Overdosage by this route is unlikely. **Pharmaceutical Precautions:** Pressurised Container: Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn even after use. Shake before use. **Legal Category:** POM. **Product Licence Number** 0108/0101. **Product Authorisation Number** 100/40/1. **Pack and NHS Price:** Box containing 1 fourteen dose canister, 14 disposable nozzles and plastic bags £7.06. Full prescribing information is available on request. **Date of Preparation:** November 1993.

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

PHARMAX LIMITED
Bourne Road, Bexley, Kent DA5 1NX.
Telephone: 0322 550550.

PRESCRIBING INFORMATION Uses: *Adults (including the elderly):* The acute treatment of nausea and vomiting of any aetiology, for up to 12 weeks treatment of nausea and vomiting due to L-dopa and bromocriptine, and for the treatment of symptoms of functional dyspepsia. Not recommended for chronic use nor, routinely, for prophylaxis of post-operative vomiting. *Children:* Only for nausea and vomiting following cancer chemotherapy or irradiation. **Presentation:** *Motilium tablets (domperidone 10mg):* Cartons of 30 and 100 tablets in blister strips of 10. Basic NHS cost 30 tablets: £2.46, 100 tablets: £8.21. PL 11723/0055. *Motilium suspension (domperidone 1mg/ml):* Bottles of 200ml. Basic NHS cost of 200ml: £1.80. PL 11723/0054. *Motilium suppositories (domperidone 30mg):* Cartons of 10 in blister strips of 5. Basic NHS cost 10 suppositories: £2.65. PL 11723/0051. **Dosage:** Route, dose and frequency of dosaging should be adjusted according to severity and duration of symptoms. **For the treatment of nausea and vomiting** *Adults (including the elderly):* Tablets or suspension: 10-20mg at 4-8 hourly intervals. Suppositories: 1 or 2 at 4-8 hourly intervals. *Children:* Suspension: 0.2-0.4mg/kg at 4-8 hourly intervals. Suppositories: For children aged 2-12 years, 1-4 daily according to body weight (see Data Sheet). **For treatment of symptoms of functional dyspepsia** *Adults (including the elderly):* Tablets: Up to 10-20mg orally 3 times daily before meals and 10-20mg at night depending on clinical response. A course of treatment should not exceed 12 weeks. *Children:* Not recommended. **Contra-indications/Warnings, etc.:** No specific contra-indications. Safety of Motilium in pregnancy has not yet been established, therefore it should be avoided in those who are pregnant. Domperidone is excreted into breast milk but at very low levels. **Side effects:** In common with other dopamine antagonists Motilium produces a rise in serum prolactin which may be associated with e.g. galactorrhoea, and less frequently gynaecomastia, breast enlargement or soreness etc.. Domperidone does not readily cross the normally functioning blood-brain barrier. However, acute extrapyramidal dystonic reactions have been reported with Motilium, which should be treated with an anticholinergic antiparkinsonian drug, or a benzodiazepine. Occasional rashes and other allergic phenomena have been reported. Motilium is a registered trade mark. **Legal category:** POM. **Date of preparation:** March1994.

References: 1. Tatsuta M *et al. Scand J Gastroenterol* 1989; **24** (2): 251-256. 2. De Schepper A *et al. Arzneimittelforsch* 1978; **28** (7): 1196-1199. 3. Bekhti A & Rutgeerts L. *Postgrad Med J* 1979; **55** (Suppl.1): 30-32. 4. Van de Mierop L *et al. Digestion* 1979; **19:** 244-250. 5. Sarin SK *et al. Indian J Med Res* 1986; **83** (June): 623-628. 6. De Loose F *et al.* (unpublished study - July 1980). 7. Agorastos I *et al. J Int Med Res* 1981; **9** (2): 143-147.

Further information is available on request from: Sanofi Winthrop Limited, One Onslow Street, Guildford, Surrey GU1 4YS. Telephone: (0483) 505515. Fax: (0483) 35432.

sanofi WINTHROP

A major force in the battle against recurrent non-ulcer dyspepsia

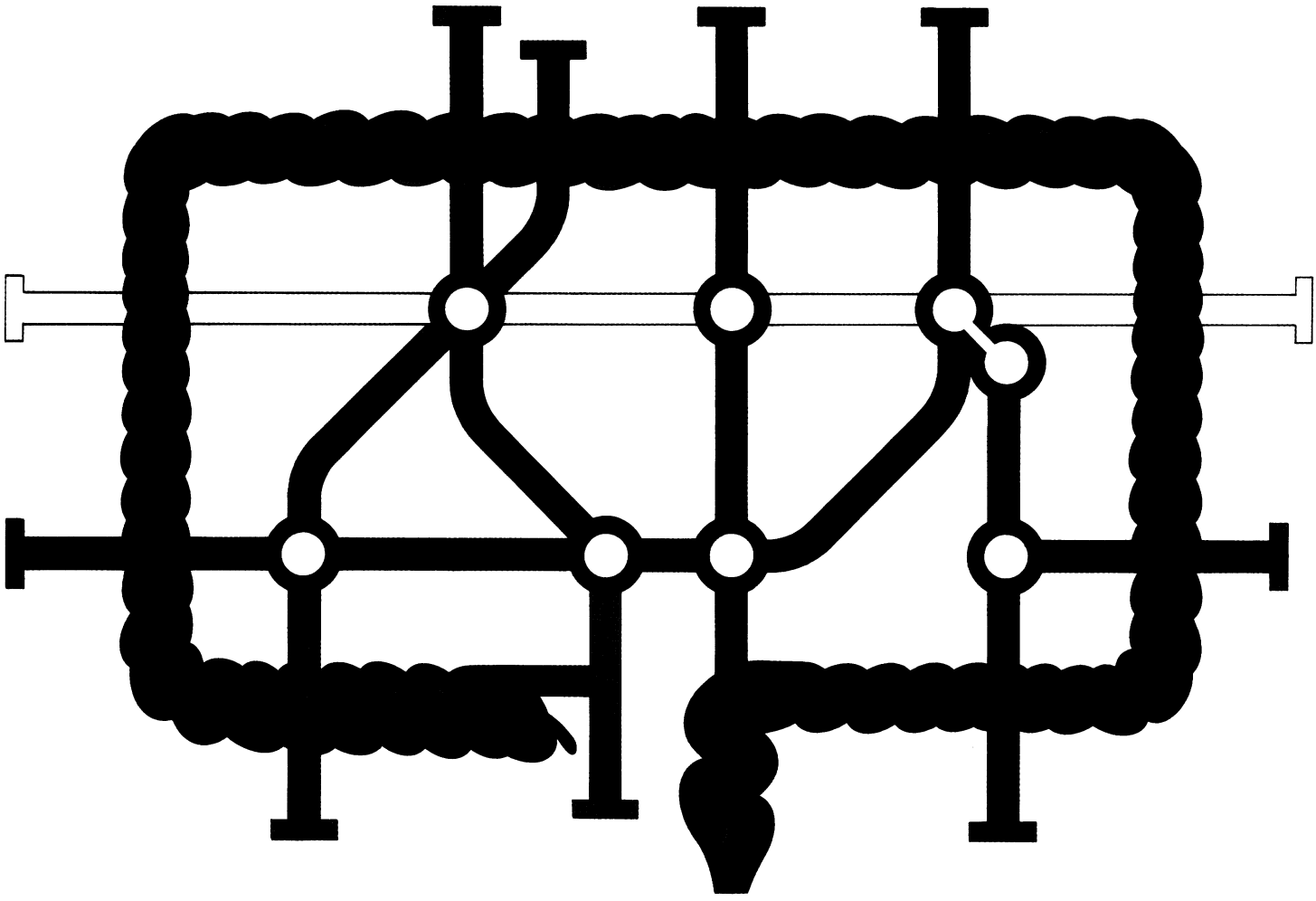
Motilium®

domperidone

Promotes gastric emptying[1,2]. Relieves dyspeptic symptoms[3-7]

NEW INDICATION

1/94/0000



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 Ph Eur 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. **Pharmaceutical precautions:** Pressurized container. Protect from sunlight and do not expose to temperatures over 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 and Basic NHS cost:** 25g canister plus applicator, £7.07. **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 Colifoam is a registered trade mark. **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. Stafford-Miller Ltd., Professional Relations Division, Broadwater Road, Welwyn Garden City, Herts. AL7 3SP. **Code:** DO2665.

GLYPRESSIN®

(terlipressin)

The only drug treatment shown to reduce B.O.V. mortality and improve survival rates.[1,2]

- Bolus doses, ideal for emergency use
- Rapidly controls bleeding
- Earlier haemostasis improves patient's prognosis

GLYPRESSIN®

Abridged Prescribing Information Name of Product: GLYPRESSIN Terlipressin. **Presentation:** GLYPRESSIN 1 mg. Freeze dried powder for injection. Supplied with 5ml ampoule of sterile diluent. **Indications:** Treatment of bleeding oesophageal varices.**Dosage and Administration:** In acute variceal bleeding, 2mg GLYPRESSIN should be administered by intravenous bolus injection followed by 1 or 2 mg every 4 to 6 hours until bleeding is controlled, up to a maximum of 72 hours. **Contraindications, Warnings and Precautions:** Glypressin is contraindicated in pregnancy. The product should be used with great caution in patients with hypertension, advanced atherosclerosis, cardiac dysrhythmias or coronary insufficiency. Constant monitoring of blood pressure, serum sodium, serum potassium and fluid balance are essential. The possibility of immunological sensitisation cannot be excluded. **Side effects:** Infrequent effects include: abdominal cramps, headache, transient blanching, increase in arterial blood pressure. **Pharmaceutical precautions:** Freeze dried powder and the diluent may be stored at room temperature, protected from direct sunlight. Each 1 mg vial of GLYPRESSIN should be reconstituted with 5 ml diluent supplied and used immediately. **Legal category:** Prescription Only Medicine. **Package quantity:** GLYPRESSIN Terlipressin 1 mg freeze dried powder: single use vial. Diluent 5 ml ampoule supplied with each vial. **Product Licence:** UK Product Licence number: 3194/0018. **UK Product Licence holder:** Ferring Pharmaceuticals Ltd, Greville House, Hatton Road, Feltham, Middlesex, TW14 9PX .**Date of Preparation:** July 1994.

GLYPRESSIN is a Trade Mark. **References:- 1.** Söderlund C et al Scand J Gastroenterol 1990;25:622-630. 2. Burroughs AK Drugs 1992;44(Suppl 2):14-23

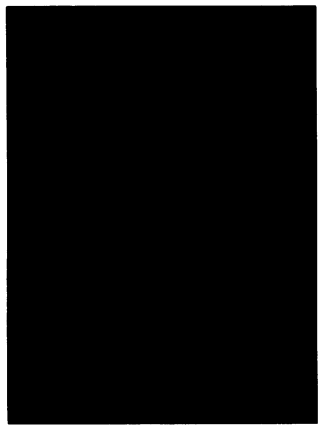
Further Information is available from:- Ferring AB, Box 30047, S-200 61 MALMÖ, Sweden.

SITZMARKS™...
(Radiopaque Markers)
When you require a definitive diagnosis for the chronically constipated patient

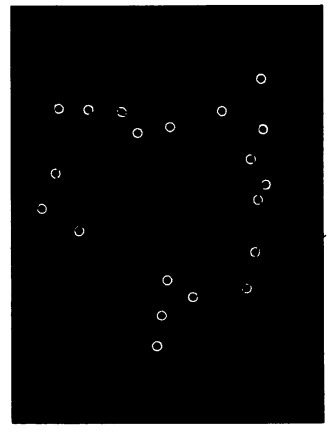
SITZMARKS™: A Soft Gelatin Capsule containing 20 Radiopaque Rings of 1 mm x 4.50 mm.

- Convenient
- Efficient Pre-Cut Radiopaque Rings
- Time Saving and Cost Effective

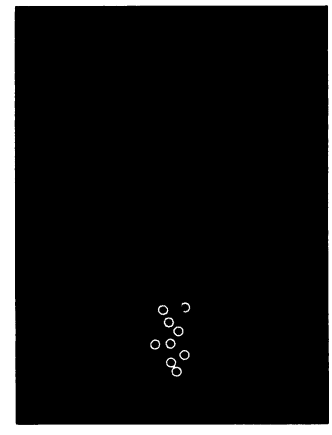
Reading the Results*:



1 Most rings have been expelled. Patient is not significantly constipated.



2 Most rings are scattered about the colon. Patient most likely has hypomotility or colonic inertia.



3 Most rings are gathered in the rectosigmoid. Patient most likely has functional outlet obstruction.

Suggested SITZMARKS™ Directions:

Step A

1. On Day 0, direct patient to take the Sitzmarks™ capsule by mouth with water.
2. On Day 5, have patient return for a flat plate abdominal X-Ray to determine the location and the extent of elimination of the markers.
3. Patients who expel all markers probably are not significantly constipated.
4. Patients who retain a large number of markers need to have follow up abdominal X-Rays every 2-3 days.
5. Patients whose markers accumulate in the rectosigmoid may require outlet defecography or manometrics.

Step B

6. Have patients take Konsyl® or Konsyl®-D daily, in double dose. Encourage liquid intake.
7. Have patients take another Sitzmarks™ capsule in 1-2 weeks and return in 5 days for another X-Ray to determine location and extent of elimination of the markers.
8. Same as direction 4 and 5 in Step A above.

TO ORDER SITZMARKS™ CONTACT:

Konsyl Pharmaceuticals

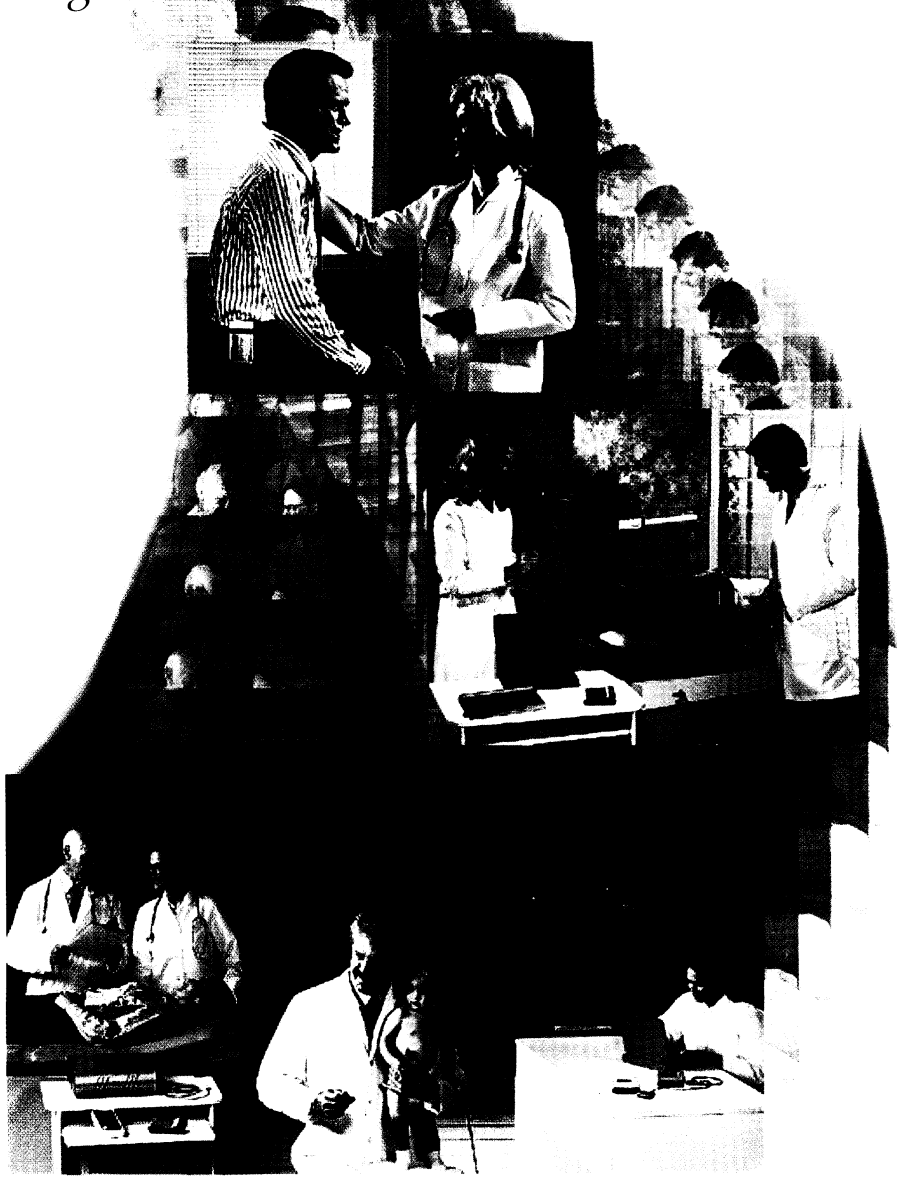
Division of Lafayette Pharmaceutical, Inc. • 4200 S. Hulen • Ft. Worth, Texas 76109 • (817) 763-8011

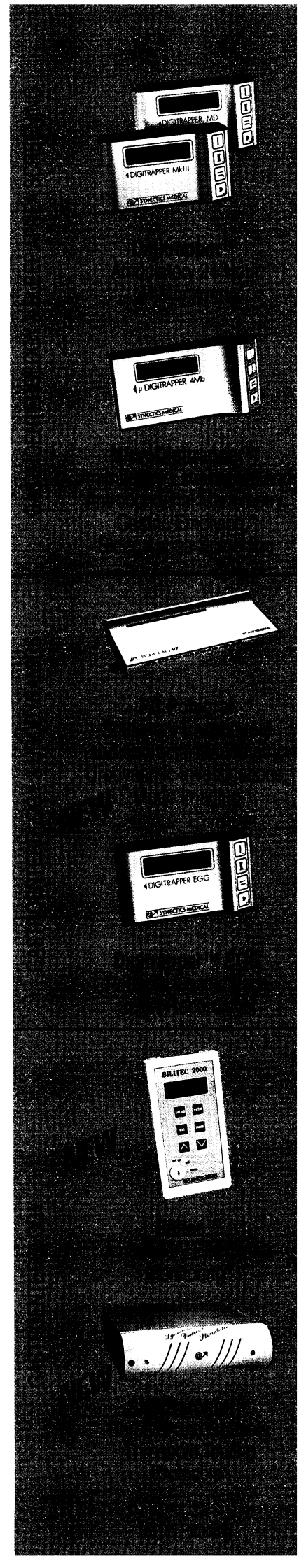
Konsyl Sample Hotline: 1-800-3-KONSYL (1-800-356-6795)

*Artists interpretation of actual X-Rays taken 5 days after patient takes SITZMARKS™.

SYSTEM THINKING

The Complete Diagnostic GI Function Testing Lab
Designed To Grow With You.





With Synectics System Thinking, you can design the ideal lab for both your present and future needs, whatever they may be. Don't get locked into an inflexible and limited system that cannot grow as your patient load and procedure variety grow. All equipment from the Synectics Diagnostic Function Testing lab, including Urodynamic and Sleep Apnea Screening equipment, are designed to complement each other to create a truly comprehensive and cost effective system.

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Since 1989 more than 75 million prescriptions have been written for Losec around the world. Already its speed of healing and effectiveness have made it one of the leading treatments for oesophageal reflux disease* and ulcer disease – bringing relief to more and more patients earlier in their treatment than ever before.

Now you can eradicate *Helicobacter pylori* with Losec and antibiotics.

Make Losec your routine treatment. It can produce far from routine results.

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(omeprazole-Astra)

TAKING CARE OF MORE PEOPLE. EVERY DAY.

LOSEC CAPSULES ABBREVIATED PRESCRIBING INFORMATION
(refer to full data sheet before prescribing)
PRESENTATION: Losec Capsules containing 20mg or 40mg omeprazole. **USES:** Oesophageal reflux disease. Duodenal and benign gastric ulcers (including NSAID-induced). Duodenal ulcer associated with *Helicobacter pylori*. Zollinger-Ellison syndrome.
DOSAGE & ADMINISTRATION: Adults (including the elderly): The usual dose in oesophageal reflux disease and peptic ulcer is 20mg once daily which can be increased to 40mg once daily in severe cases if required. **Oesophageal reflux disease:** Healing: 20mg daily for 4 weeks. Continue for further 4-8 weeks if required. Patients refractory to other therapies: 40mg daily. Maintenance: 20mg daily. **Duodenal ulcer (DU):** Healing: 20mg daily for 4 weeks. Maintenance (recurrent DU): 20mg daily is recommended. **DU associated with *Helicobacter pylori*:** Usual 2 week course is Losec 40mg daily with amoxycillin 1.5g daily (750mg b.d). Up to 2g/day of amoxycillin has been used in clinical studies. **Benign Gastric Ulcer:** 20mg daily for 8 weeks. **Zollinger-Ellison Syndrome:** 60mg daily as long as clinically indicated. Individually adjust within range 20-120mg daily. If in excess of 80mg 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 as Losec treatment may alleviate symptoms and delay diagnosis. Avoid in pregnancy unless there is no safer alternative. Discontinue breast feeding if Losec is considered essential. Losec is well tolerated. Adverse reactions are generally mild and reversible. The following adverse events (relationship to Losec not established in many cases) have been reported. Skin rash, urticaria, pruritus, dizziness, light-headedness, feeling faint, arthritic and myalgic symptoms usually resolving on cessation of therapy. Isolated cases of photosensitivity, bullous eruption, erythema multiforme, angioedema, alopecia, stomatitis, candidiasis, blurred vision, taste disturbance, peripheral oedema, sweating, gynaecomastia, leucopenia, thrombocytopenia, malaise, fever, bronchospasm, encephalopathy in patients with pre-existing severe liver disease, hepatitis, jaundice, interstitial nephritis and hepatic failure. Increases in liver enzymes have been observed. Diarrhoea and headache have been reported and may require treatment discontinuation in a small number of patients with resolution of symptoms in most. Other reactions include constipation, nausea/vomiting, flatulence, abdominal pain, somnolence, insomnia, vertigo and paraesthesia. Reversible mental confusion, agitation, depression and hallucinations have been reported in severely ill patients. Losec can delay the elimination of diazepam, phenytoin and warfarin and may increase the bioavailability of digoxin. Patients on warfarin or phenytoin should be monitored and the dose reduced if necessary when Losec is added in. There is no evidence of interactions with theophylline, propranolol, metoprolol, lidocaine, quinidine, amoxycillin 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 following partial fundectomy. These are not direct effects of any individual drug but result from sustained hypergastrinaemia due to acid inhibition. No treatment related mucosal changes have been observed in patients treated continuously with omeprazole for up to 5 years.
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. Recent evidence suggests a link between *Helicobacter pylori* and gastric carcinoma. Losec with amoxycillin eradicates >50% of Hp isolates irrespective of metronidazole sensitivity. In patients known to be allergic to amoxycillin, clarithromycin may be a useful alternative. Useful effects on Hp have also been shown in clinical trials using omeprazole in combination with amoxycillin and metronidazole. Such treatments may lower DU recurrence and thus the need for prolonged anti-secretory therapies. **PACKAGE QUANTITIES:** 20mg: bottles of 7 capsules, £8.86, bottles of 28 capsules, £36.36; 40mg: bottles of 7 capsules £17.72, bottles of 14 capsules £36.36. **PRODUCT LICENCE NO:** PL 0017/0238 – Losec Capsules 20mg. PL 0017/0320 – Losec Capsules 40mg. **PRODUCT LICENCE HOLDER:** Astra Pharmaceuticals Ltd, Home Park, Kings Langley, Herts WD4 8DH.
*Oesophageal reflux disease = symptoms and or tissue damage attributable to reflux. Symptoms vary considerably from one sufferer to another, but the most typical are heartburn and regurgitation.

ASTRA
Astra Pharmaceuticals

For further information contact the product licence holder: Astra Pharmaceuticals Ltd, Home Park, Kings Langley, Herts WD4 8DH. Tel: (0923) 266191.

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