

Zantac has changed the way both ulcer and reflux diseases are managed. Zantac has brought relief and significant improvement to patients' lives throughout the world.

It continues to do so...

Zantac
RANITIDINE HCl

PRESCRIBING INFORMATION:

INDICATIONS Duodenal ulcer, benign gastric ulcer, ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), prevention of NSAID-associated duodenal ulcer, oesophageal reflux disease, severe oesophagitis, long-term management of healed oesophagitis, chronic episodic dyspepsia. **DOSAGE Adults:** Duodenal ulceration and gastric ulceration: A single 300mg dose at bedtime or 150mg twice daily in the morning and evening for four weeks. 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. 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. 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 H₂-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 0004/0310, 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. November 1993.



THE SQUEEZE THAT RELIEVES

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.

treatment is 4 weeks. **Impaired Gastric Emptying:** 10mg Prepulsid tid 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

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 REFUX 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 bid (before breakfast and at bedtime). Alternatively, 10mg Prepulsid tid (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 tid. The usual course of



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Further information is available from
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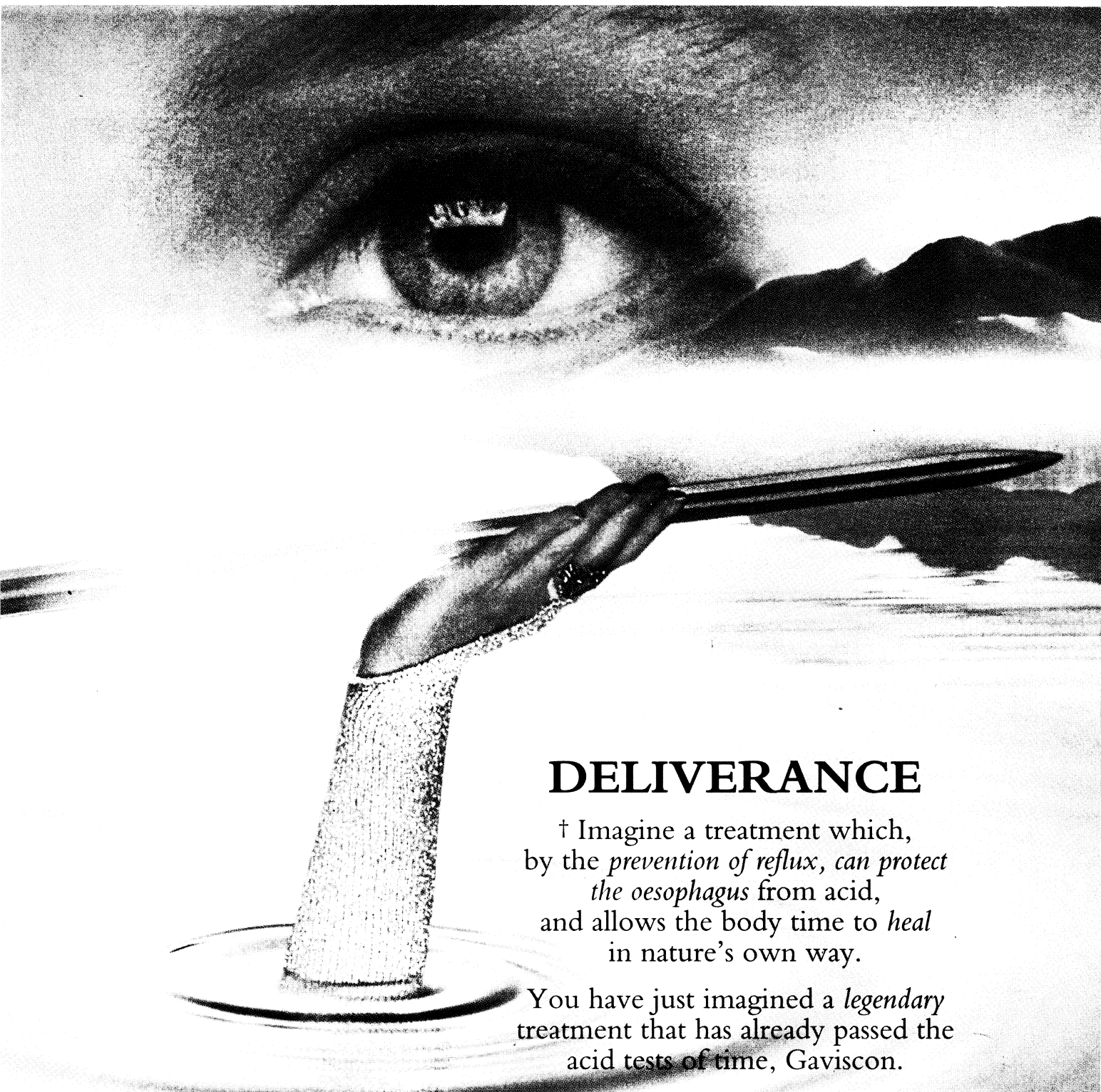
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liquid: sodium alginate BP, sodium bicarbonate Ph.Eur.
sodium bicarbonate Ph Eur., aluminium

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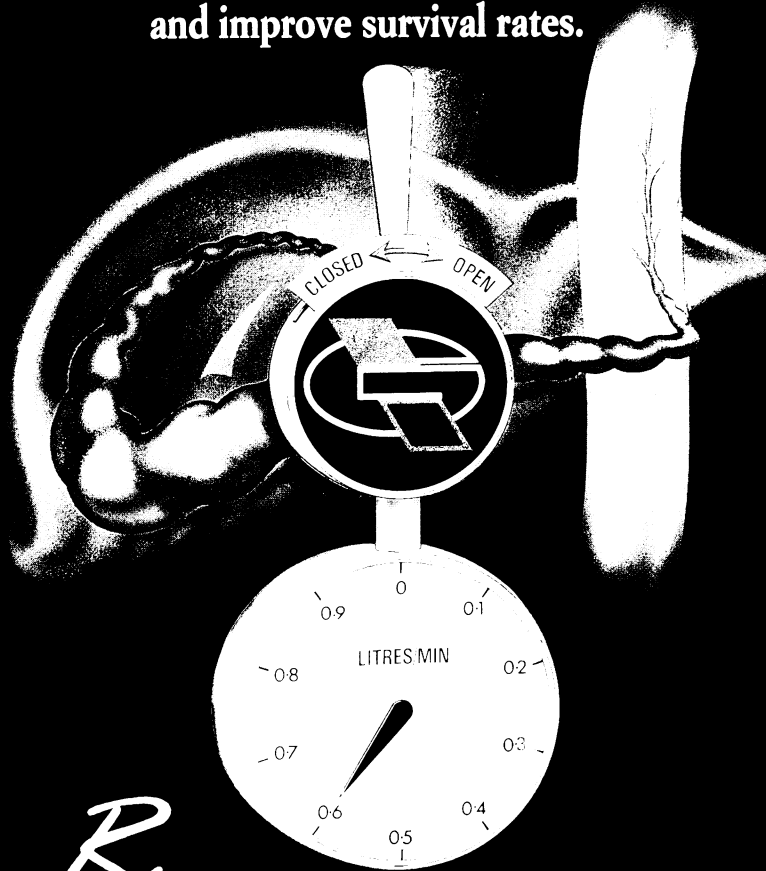
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Bleeding Oesophageal Varices

To reduce portal flow, lower variceal pressure
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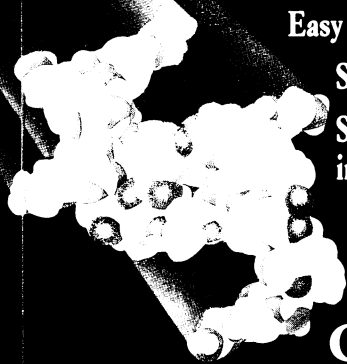
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Immediately controls bleeding¹

Easy to use in any emergency department

Single iv bolus injection²

Significant decrease in hospital mortality with
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GLYPRESSIN
(terlipressin)

“The preferred treatment for bleeding oesophageal varices”¹

Abridged Prescribing Information

Name of Product: GLYPRESSIN Terlipressin (INN/BAN) **Presentation:** GLYPRESSIN 1 mg. Freeze dried powder for injection. Supplied with 5ml ampoule of sterile diluent. **Indications:** GLYPRESSIN is indicated in the 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:** Due to its effect on smooth muscle GLYPRESSIN is contraindicated in pregnancy. **Warnings and Precautions:** The pressor and antidiuretic effects of GLYPRESSIN are reduced (compared with lysine or arginine vasopressin) but the product should still 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:** Because the severity of pressor and antidiuretic activities are reduced, few side effects have been recorded. 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:** January 1999. GLYPRESSIN is a Trade Mark. **References:** 1. Söderlund C et al Scand. J Gastroenterol 1990; 25: 622-630. 2. Lin HC et al J Hepatology 1990; 10: 370-374.

Further Information is available from:- Ferring AB, Box 30561, S-200 62 MALMÖ, Sweden.

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: £2.52, 100 tablets: £8.42. Pl. 0071/0287. Motilium suspension (domperidone 1mg/ml): Bottles of 200ml. Basic NHS cost of 200ml: £1.85. Pl. 0071/0292. Motilium suppositories (domperidone 30mg): Cartons of 10 in blister strips of 5. Basic NHS cost 10 suppositories: £2.72. Pl. 0071/0290. **Dosage:** Route, dose and frequency of dosing 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:** September 1993. **References:** 1. Tatsuia M *et al.* *Scand 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 Loosse 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.



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Relieves dyspeptic symptoms³⁻⁷**

**ABRIDGED PRESCRIBING INFORMATION
CIPROXIN® TABLETS**

(Refer to data sheet before prescribing)

Presentation White tablets containing the equivalent of either 250mg, 500mg or 750mg ciprofloxacin. **Uses** Ciprofloxacin is indicated for the treatment of single or mixed infections caused by susceptible organisms. Also indicated for prophylaxis against infection in elective upper gastro-intestinal surgery and endoscopy where there is an increased risk of infection. **Dosage and administration** The tablets should be swallowed whole with liquid. **Adults:** 250-750mg twice daily. In surgical prophylaxis a single 750mg tablet administered 60-90 minutes before the procedure (but see interactions with oral premedicants). **Duration of treatment** For acute infections the usual treatment period is 5 to 10 days, except in cases of acute uncomplicated cystitis where treatment is 250mg twice daily for 3 days. Generally, in acute and chronic infections where sensitivity is proven, treatment should be continued for at least 3 days after the signs and symptoms of infection have disappeared. **Elderly** No dose adjustment. **Contra-indications** Hypersensitivity to ciprofloxacin or other quinolones; also in children and growing adolescents except where the benefits of treatment outweigh the risks. **Warnings and precautions** Use with caution in epileptics and patients with a history of CNS disorders. Treatment could result in impairment of ability to drive or operate machinery. Crystalluria has been reported so patients should be well hydrated and excessive urine alkalinity avoided. As haemolytic reactions with ciprofloxacin are possible in patients with latent and actual defects in glucose-6-phosphate dehydrogenase activity, use with caution. **Drug interactions** Increased plasma levels of theophylline have been observed following concurrent administration with ciprofloxacin. The dose of theophylline should be reduced and plasma levels of theophylline monitored. Where monitoring of plasma levels is not possible, avoid the use of ciprofloxacin in patients receiving theophylline. Particular caution is advised in those patients with convulsive disorders. Interactions have also been noted with anticoagulants and cyclosporin. The tablets should not be administered within 4 hours of medications containing magnesium, aluminium or iron salts. High doses of quinolones have shown an interaction with NSAIDs in animals leading to convulsions. Administration of quinolones and glibenclamide simultaneously can potentiate the effect of glibenclamide, resulting in hypoglycaemia. Opiate premedicants or regional anaesthetic agents must not be administered concomitantly with ciprofloxacin when used for surgical prophylaxis. **Use in pregnancy and lactation** Not recommended. **Side-effects** Gastro-intestinal, CNS, hypersensitivity/skin reactions, musculoskeletal and special sense disturbances. Renal and hepatic disturbances. Effects on haematological parameters. Also reported: vasculitis, pseudomembranous colitis, Stevens-Johnson Syndrome, Lyell Syndrome, haemolytic anaemia, granulocytopenia, intracranial hypertension, petechiae, haemorrhagic bullae, tenosynovitis and tachycardia. **Overdosage** Serum levels of ciprofloxacin are reduced by dialysis. **Legal category** POM. **Package quantities** Blister strips of 10 in packs of 10, 20, and 100 tablets. **Product licence numbers** PL0010/0146-0148. **Basic NHS cost** 250mg x 10 tablets £7.50, 500mg x 10 tablets £13.75, 750mg x 10 tablets £20.00. **Date of preparation** July 1993.



Bayer plc, Pharmaceutical Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG13 1JA.

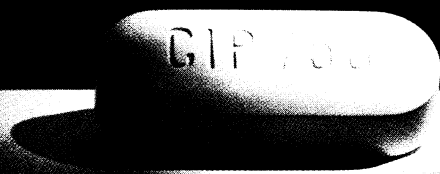
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GI Surgical Prophylaxis



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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 metasulphobenzozate 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

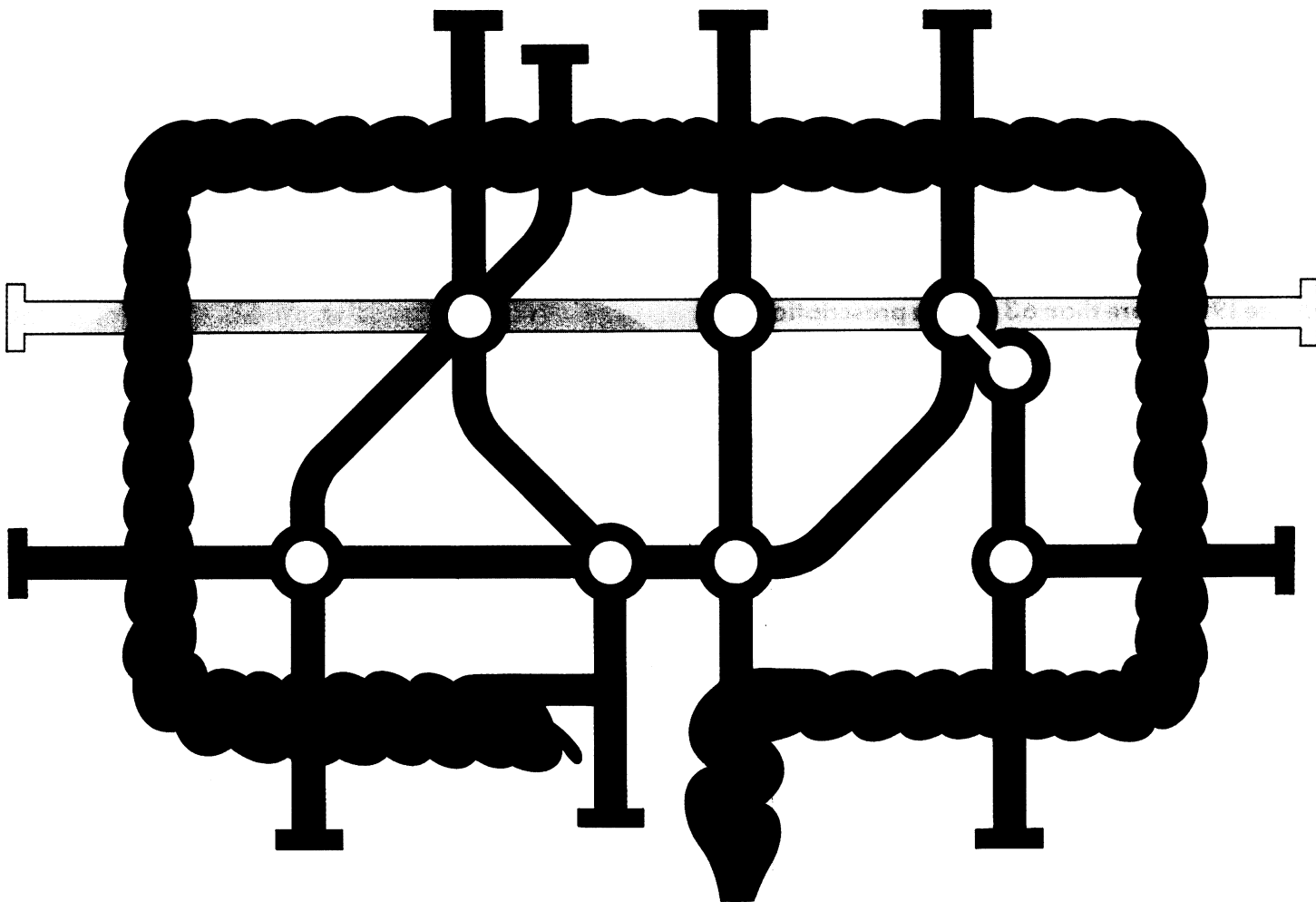
foetus. **Overdosage:** Overdosage by this route is unlikely. **Pharmaceutical Precautions:** Pressurised container. Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn even after use. Shake before use. **Legal Category:** POM. **Product Licence Number:** 0108/0101. **Product Authorisation Number:** 100/40/1. **Pack and NHS Price:** Box containing 14 fourteen dose canisters, 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. Ruddle, 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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COLIFOAM

10% hydrocortisone acetate

FIRST CLASS TREATMENT WHICH TRAVELS TO WORK

-  Colifoam is highly effective for distal ulcerative colitis.⁽¹⁾
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-  Colifoam is easier to retain than liquid enemas and causes less interference with social, sexual and occupational activities.^(1,3)

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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. **Date of Preparation:** December 1993 DO2516. **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.

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**TAKING CARE
OF MORE PEOPLE.
EVERY DAY.**

LOSEC Abbreviated Prescribing Information

Presentation: Losec Capsules containing 20mg or 40mg omeprazole. **Uses:** Treatment of oesophageal reflux disease. In reflux oesophagitis the majority of patients are healed after 4 weeks. Symptom relief is rapid. 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 for patients with a history of recurrent duodenal ulcer is recommended at a dosage of 20mg once daily. 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 function:** Adjustment is not required. **Impaired hepatic function:** As bioavailability and half life can increase in patients with impaired hepatic function, the dose requires adjustment with a maximum daily dose of 20mg. **Contra-indications, warnings, etc:** 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 and adverse reactions have generally been mild and reversible. The following have been reported as adverse events in clinical trials or reported from routine use but in many cases a relationship to treatment with omeprazole has not been established. Skin rash, urticaria and pruritus have been reported, usually resolving after discontinuation of treatment. In addition photosensitivity, bullous eruption, erythema multiforme, angioedema and alopecia have been reported in isolated cases. Diarrhoea and headache have been reported and may be severe enough to require discontinuation of therapy in a small number of patients. In the majority of cases the symptoms resolved after discontinuation of therapy. Other gastrointestinal reactions have included constipation, nausea/vomiting, flatulence and abdominal pain. Stomatitis and candidiasis have been reported as isolated cases. Paraesthesia has been reported. Dizziness, light-headedness and feeling faint have been associated with treatment, but all usually resolve on cessation of therapy. Also reported are somnolence, insomnia and vertigo. Reversible mental confusion, agitation, depression and hallucinations have occurred predominantly in severely ill patients. Arthritic and myalgic symptoms have been reported and have usually resolved when therapy is stopped. In isolated cases, the following have been reported: blurred vision, taste disturbance, peripheral oedema, increased sweating, gynaecomastia, leucopenia, thrombocytopenia, malaise, fever, bronchospasm, encephalopathy in patients with pre-existing severe liver disease, hepatitis with or without jaundice, rarely interstitial nephritis and hepatic failure. Increases in liver enzymes 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. The bioavailability of digoxin may be increased. There is 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:** 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.

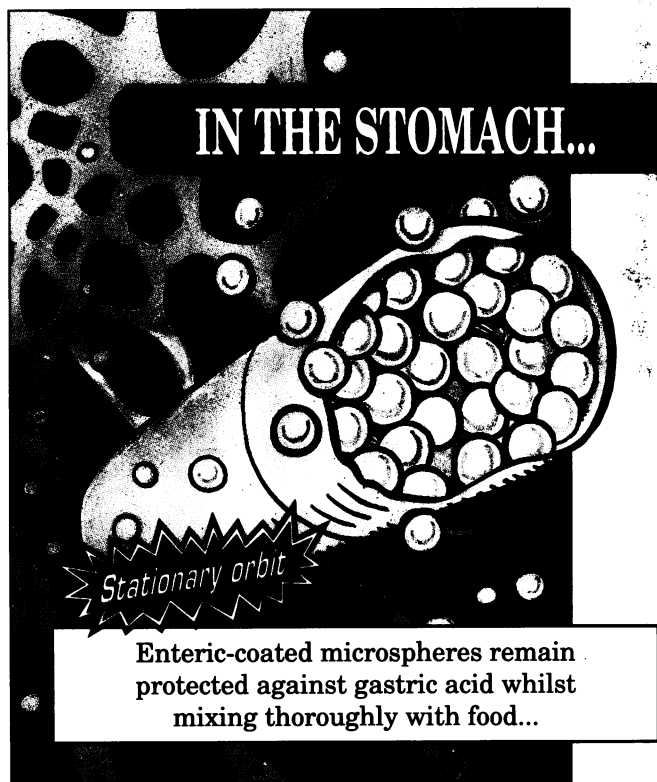
For further information contact the product licence holder:
Astra Pharmaceuticals Ltd, Home Park, Kings Langley, Herts WD4 8DH.

Tel: (0923) 266191.

LOSEC is a registered trademark.
Date of preparation: January 1994.

ASTRA
Astra Pharmaceuticals

A REAL FORCE IN PANCREATIC EXOCRINE INSUFFICIENCY



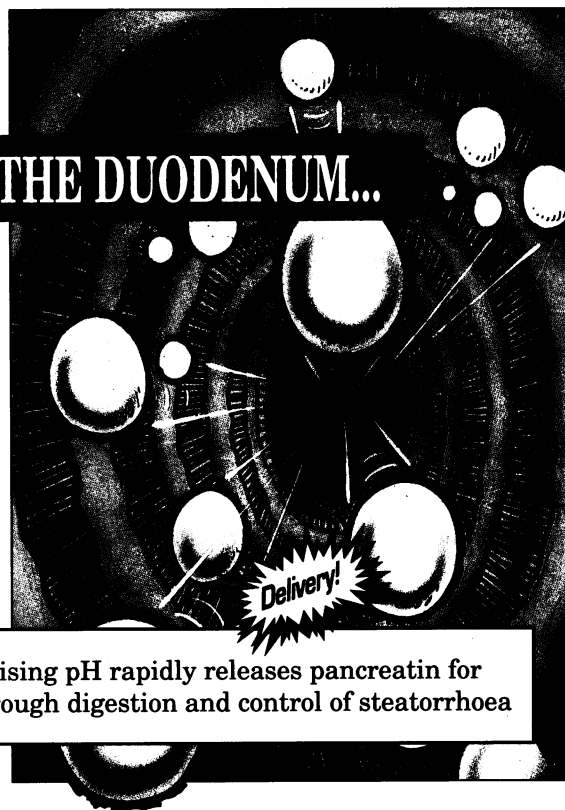
Enteric-coated microspheres remain protected against gastric acid whilst mixing thoroughly with food...

creon[®]
pancreatin
25000



Superior control of steatorrhoea[†]

IN THE DUODENUM...



Rising pH rapidly releases pancreatin for thorough digestion and control of steatorrhoea

[†] Compared with standard enteric-coated tablets in pancreatic insufficiency^{1,2}

Prescribing Information

Presentation Opaque orange/yellow hard gelatin capsules containing brownish coloured enteric coated pellets of pancreatin equivalent to: 25,000 PhEur units of lipase 18,000 PhEur units of amylase 1,000 PhEur units of protease

Uses Replacement therapy in pancreatic enzyme deficiency states.

Indications For the treatment of pancreatic exocrine insufficiency.

Dosage and administration Adults (including the elderly) and children: Initially one capsule with meals. Dose increases, if required, should be added slowly with careful monitoring of response and symptomatology. It is important to ensure adequate hydration of patients at all times whilst dosing Creon 25,000. The capsules can be swallowed whole, or for ease of administration they may be opened and the granules taken with fluid or soft food, but without chewing. If the granules are mixed with food, it is important that they are taken immediately, otherwise dissolution of the enteric coating may result.

Contra-indications, Warnings, etc Contra-indications: Substitution with pancreatic enzymes is contra-indicated in the early stages of acute pancreatitis. Patients with known hypersensitivity to porcine proteins. Use in pregnancy: There is inadequate evidence of safety in use during pregnancy. **Warnings:** The product is of porcine origin. Rarely cases of hyper-uricosuria and hyper-uricaemia have been reported with very high doses of pancreatin. Perianal irritation, and rarely, inflammation, could occur when large doses are used. Stricture formation in the ileo-caecal region and/or ascending colon has been reported in cystic fibrosis patients treated with high potency enzyme supplements. If symptoms suggestive of gastrointestinal obstruction occur, the possibility of bowel strictures should be considered (see Precautions). **Precautions** Until the

risk of bowel stricture has been fully investigated (see Warnings), patients with cystic fibrosis should not be prescribed this product unless there are special reasons for doing so. Patients continue to use it should be reviewed regularly. **Overdosage** Most cases respond to measures, including stopping enzyme therapy ensuring adequate rehydration.

Pharmaceutical precautions Store below 20°C

Legal Category P

Package Quantities Available in packs of 50 capsules. **Basic NHS Price** £19.50

Further Information For lipase and amylase PhEur units=BP units

For protease 1,000 PhEur units=467 BP units

Product Licence Number 5727/0006

Name and address of Licence Holder: Kali Chemie Pharma GmbH, Hans-Bockler-Allee 2, 3000, Hannover 1, Germany

Date of last review: December 1993

References:

1. Stead R J et al. *Thorax* 1987; 42: 533-37.
2. Beverley DW et al. *Arch Dis Child* 1987; 62: 564-68.

Further information is available from:
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