PREDFOAM

Prednisolone Metasulphobenzoate

An ulcerative colitis management system

Predfoam is an effective local treatment for ulcerative colitis, combining clinical efficacy with simplicity presented in a pack that makes life easier for patients

- **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. Rudderl, 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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(terlipressin)

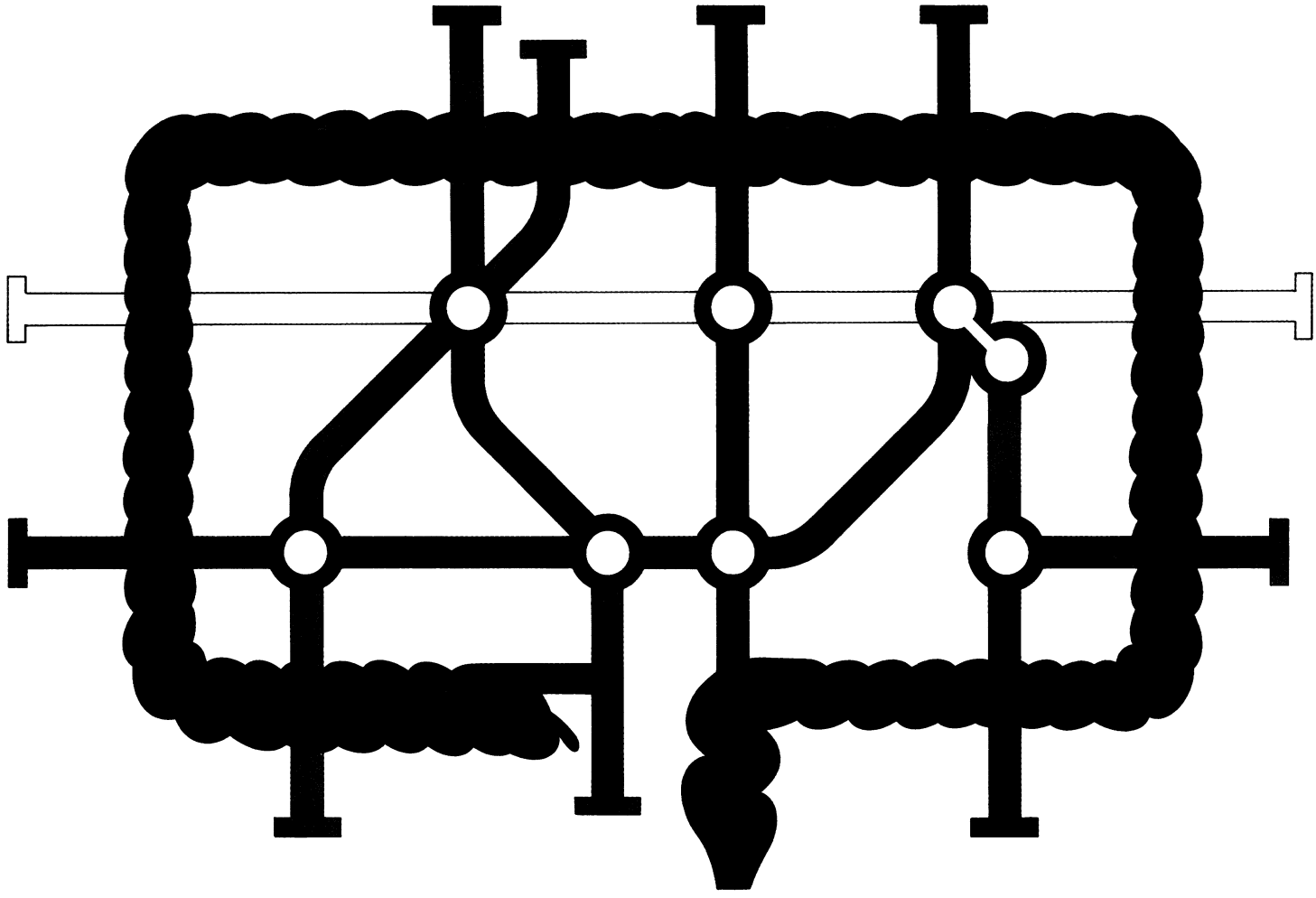
The only medical treatment which reduces B.O.V. mortality and improves survival rates[1,2]

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

GLYPRESSIN®

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: 5194/0018 **UK Product Licence holder:** Ferring Pharmaceuticals Ltd. Greville House, Hatton Road, FELTHAM, Middlesex, TW14 9PX. **Date of Preparation:** January 1994. GLYPRESSIN is a Trade Mark. **References:** 1. Soderlund 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.



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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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(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
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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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Date of preparation: March 1994. LOS/ADV 034

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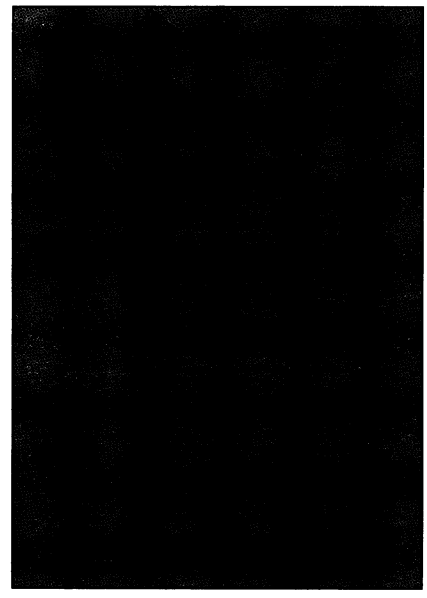

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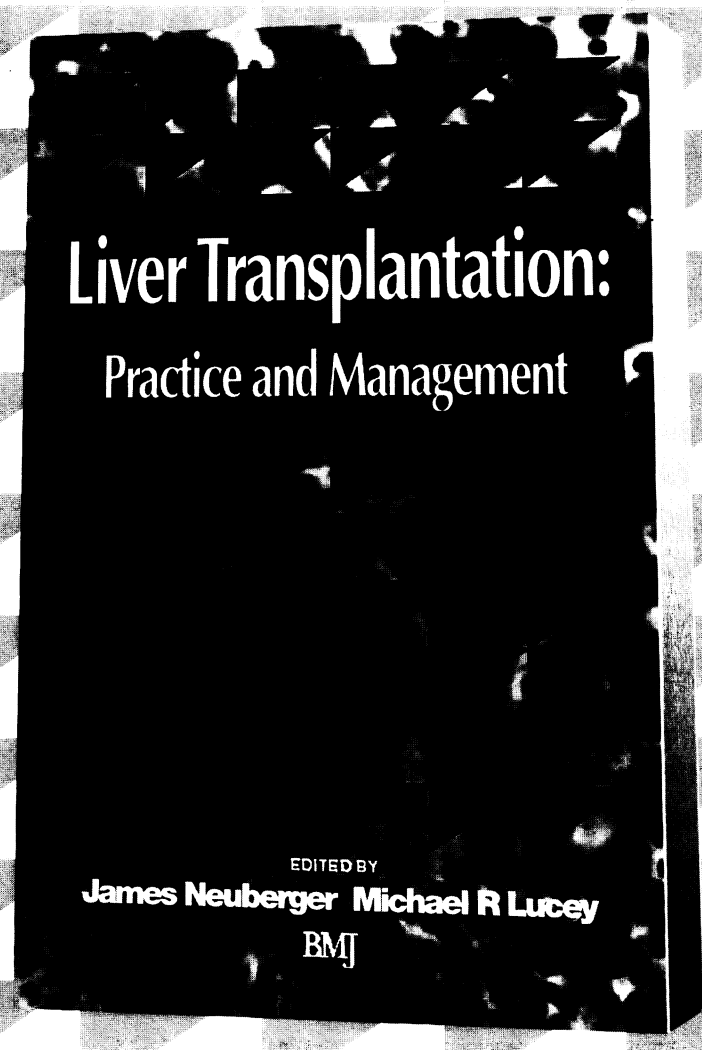

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