

# **COLIFOAM**

10% hydrocortisone acetate

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- Colifoam is highly effective for distal ulcerative colitis. (1)
- The retrograde spread of Colifoam increases with the extent of disease. (2)
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PRESCRIBING INFORMATION: Presentation: White odourless aerosol containing hydrocortisone acetate PhEur 10% w/w. Uses: Ulcerative colitis, proctosigmoiditis and granular proctitis. Dosage and administration: One applicatorful inserted into the rectum once or twice daily for two or three weeks and every second day thereafter. Shake can vigorously before use (illustrated instructions are enclosed with pack). Contra-indications, warnings etc: Local contra-indications to the use of intrarectal steroids include obstruction, abscess, perforation, peritonitis, fresh intestinal anastomoses and extensive fistulae. General precautions common to all corticosteroid therapy should be observed during treatment with Colifoam. Treatment should be administered with caution in patients with severe ulcerative disease because of their predisposition to perforation of the bowel

wall. Safety during pregnancy has not been fully established. Although uncommon at this dosage, local irritation may occur. **Pharmaceutical precautions:** Pressurised container containing flammable propellant. Protect from sunlight and do not expose to temperatures above 50°C. Keep away from sources of ignition. Do not pierce or burn even after use. Do not refrigerate, store below 25°C. Keep out of reach of children. For external use only. **Legal category:** POM. **Package quantity & basic NHS cost:** 20.8g canister plus applicator, £7.07. Provides approximately 14 doses. **Product Licence No:** 0036/0021. Further information is available on request from Stafford-Miller Ltd, Broadwater Road, Welwyn Garden City, Herts. AL7 3SP. **Code:** D02665.

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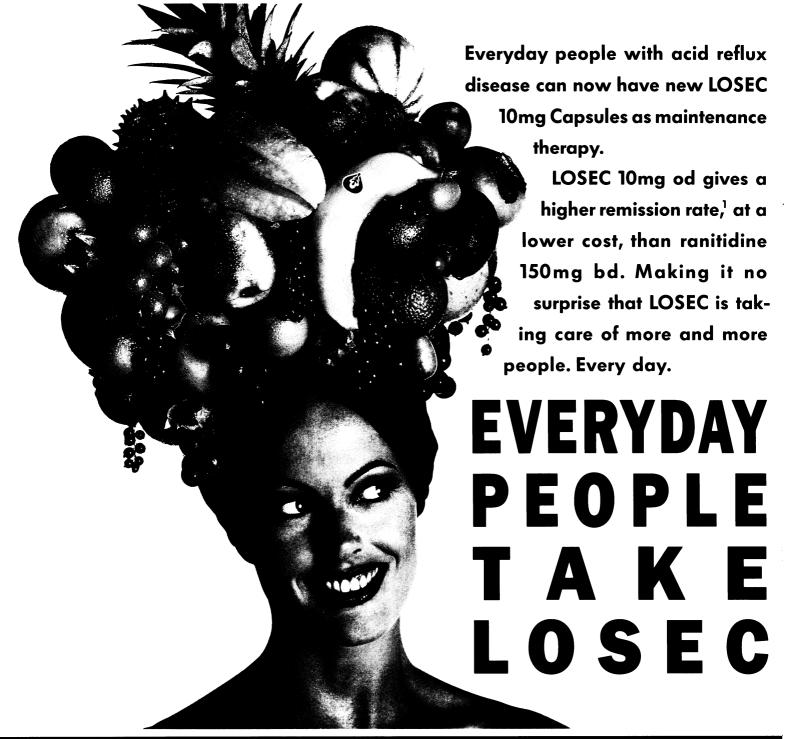
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### Reference:

1. Hallerbäck B, et al. 9th Asian-Pacific Congress of Gastroenterology & 6th Asian-Pacific Congress of Digestive Endoscopy, Bangkok, Thailand. Nov 29-Dec 3 1992; 90: Abstract FP-88

# ASTRA

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: September 1994

LOS/ADV 044

# Duodenal Ulcer -

# ZOTON\* ▼ Lansoprazole: Abbreviated Prescribing Information

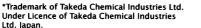
Presentation: Two tone lilac/purple hard gelatin capsule containing 30 mg Lansoprazole as enteric coated granules. Indications: Healing of duodenal ulcer, benign gastric ulcer, and reflux oesophagitis. Also benign peptic lesions including reflux oesophagitis unresponsive to H2 receptor antagonists. Dosage and Administration: Lansoprazole should be administered once daily. Duodenal ulcer. 30 mg daily for 4 weeks. Reflux oesophagitis: 30 mg daily for 4-8 weeks. Benign gastric ulcer: 30 mg daily for 8 weeks. Do not chew or crush capsules. Swallow whole. No dosage adjustment is necessary in the elderly, or patients with renal or hepatic impairment. There is no experience with Lansoprazole in children. Long term treatment cannot be recommended at this time. Contraindications: No known contra-indications to Lansoprazole. Warnings and Precautions: As with other anti-ulcer therapies the possibility of malignancy should be excluded when gastric ulcer is suspected. There is no experience with the use of Lansoprazole in pregnancy, and its use should be avoided. Animal studies indicate Lansoprazole is excreted into breast milk, there is no information on secretion into breast milk in humans. Breast feeding should be discontinued if the use of Lansoprazole is considered essential. Side effects: Generally transient and self-limiting, including gastro-intestinal disturbances, headache, dizziness, dry mouth, fatigue, rashes, and increases in liver function tests. Arthralgia, peripheral oedema, and haematological changes have been reported rarely. Legal Category: POM. Package Quantities: Original Packs: Blister packs of 56, 28, 14 and 7 (hospital starter pack) capsules. Product Licence No: PL 0095/0264. Cost: 7's £9.09 (hospital starter pack), 14's £18.18, 28's £33.36, 56's £66.72. Full prescribing information is available on request. Date of preparation: December 1994

- Up to 98% healing within **four weeks** 1-6 (Range 91-98%)
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REFERENCES 1. Licht, H., Gastroenterology, 1990, 98 (5), Pt 2, A78 (21065) 2. Petite, J.P., Journées Francophones de Pathologies Digestives, 1991 (20969) 3. Londong, W., Aliment Pharmacol Therap, 1991, 53 245-254 (19818) 4. Hawkey, C.J., Gut, 1993, 34 (10), 1458-1462 (20982) 5. Hotz, J., Aliment Pharmacol Therap, 1992, 6, 87-95 (20027) 6. Ekstrom, P., Scand J Gastroenterol, 1992, 27 (Supp 190) A34 (20341) 7. Bardhan, K.D., Gastroenterology, 1991, Vol 100 (5), A30 (19804) 8. Petite, J.P., Data on file, Lederle Laboratories (20502) 9. Dorsch, E., Am J Gastroenterol, 1991, 86 (9), A15 (20009) 10. Robinson, M., Gastroenterology, 1992, 102 (4, Pt 2 of 2), A153 (20225) 11. Benhaim, M.C., Gastroenterology, 1990, 98 (5), A20 (20164) 12. Hatlebakk, J. G., Scand J Gastroenterol, 1993, 28, 224-228 (20986) 13. Jones, R. and Bosanquet, N. et al, Br J Med Econ, 1994, 7, 99-114 (100983)

lansoprazole









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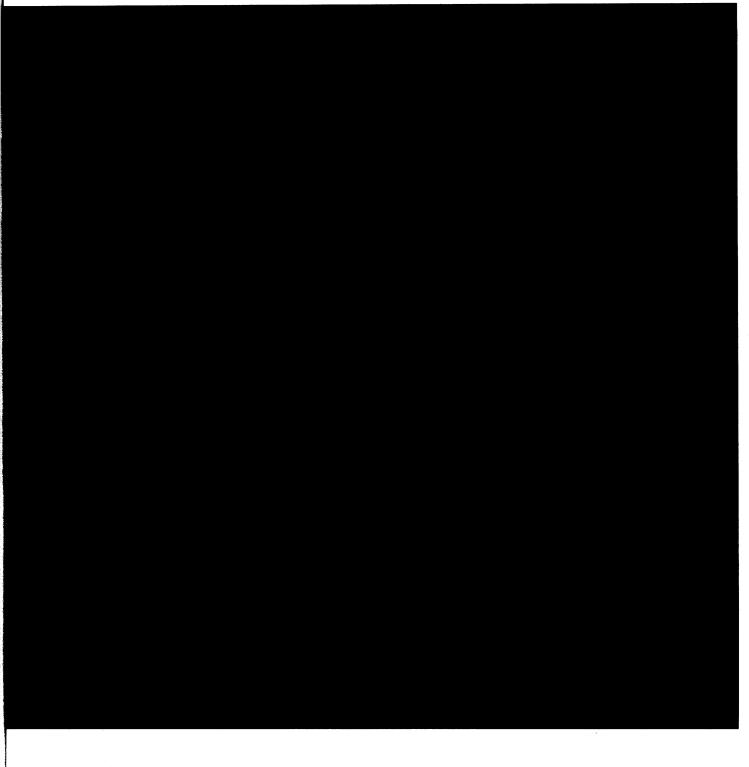
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# Keeps acid in its natural environment

None known. Dosage and Administration: Adults and children over 12: 1 or 2 tablets after meals and at bedtime. Children 6-12: 1 tablet after meals and at bedtime. Note: 1 tablet contains 2.1mmol sodium. Tablets should be thoroughly chewed. Basic NHS Cost: 60 tablets £2.25. PL: 44/0021 Gaviscon Tablets, 44/0141 Gaviscon Tablets Lemon Flavour. Legal Category: GSL. (PO). Holder of product licences: Reckitt & Colman Products Limited, Dansom Lane, Hull, HU8 7DS. Gaviscon and the sword and circle symbol are registered trademarks. Date of preparation: 20/9/94.

References 1. Ball C.S. et al. (1988) GUT, Vol. 29 (part 10) A 1449. 2. Cadiot G. et al. (1994) Gastrointest. Res. 22: 209-222. 3. Chevrel B. (1980) J. Int. Med. Res. 8: 300. 4. Ward A.E. (1989) Br. J. Clin. Pract. 43 (2) Suppl. 66: 52. 5. Williams D.L. et al. (1979) J. Int. Med. Res. 7: 551.

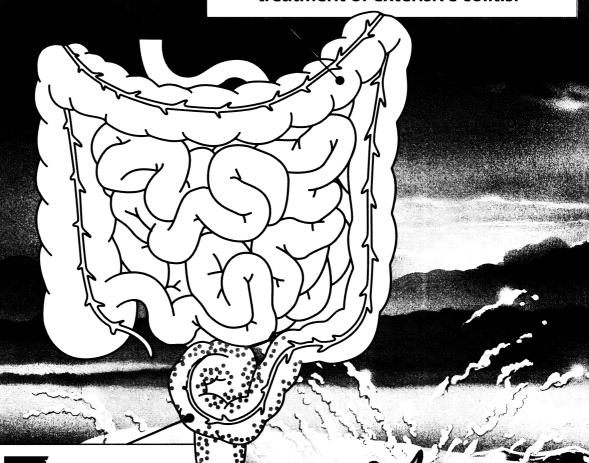


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Abbreviated Prescribing Information

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Predenema: Presentation: Disposable enema 100ml aqueous solution containing prednisolone metasulphobenzoate sodium equivalent to 20 mg of prednisolone. A long tube version is available. Uses: Local treatment of ulcerative colitis. Dosage and Administration: Adults only: 1 enema nightly for two to four weeks extending the course where a good response is being obtained. Contraindications, Warnings etc: Conditions where infection might be masked or healing impaired. Prolonged continuous use is undesirable. There is inadequate evidence of safety in human pregnancy. Legal categories and Product Licence Numbers: POM PL 0108/5018 PA 100/7/1. Packs and NHS **Price:** Pack of 7 enemas long tube £9.45. Pack of 10 enemas, standard tube £8.00. Full prescribing information is available on request.

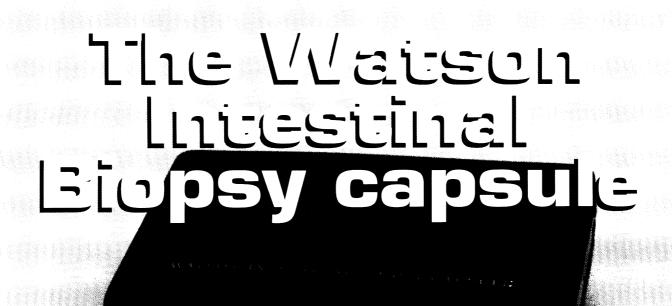
Predfoam Presentation: A foam enema containing prednisolone metasulphobenzoate sodium equivalent to 20mg of prednisolone per metered dose. Uses: Treatment of proctitis and ulcerative colitis. Dosage and Administration: Adults and Elderly patients: Once or

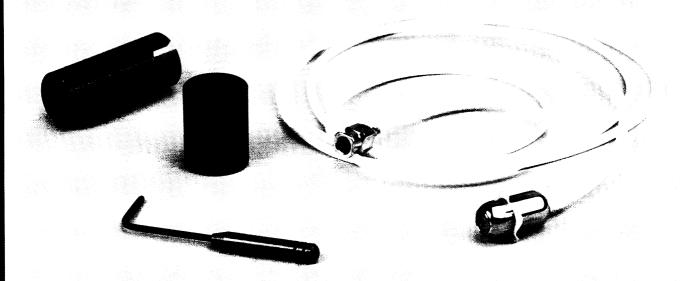
twice daily for two weeks, extending treatment for a further two weeks when a good response is obtained. Children: Not recommended. Contraindications, Warnings etc: Conditions where infection might be masked or healing impaired. Prolonged continuous use is undesirable. There is inadequate evidence of safety in human pregnancy. Legal categories and Product Licence Numbers POM PL 0108/0101 PA 100/40/1. Packs and NHS Price Box containing one 14 dose canister, 14 disposable nozzles and 14 plastic bags:£7.06.Full prescribing information is available on request. Date of preparation: October 1994

**References. 1.** Lee DAH, et al. Rectally administered prednisolone - evidence for a predominantly local action. 1980 Gut;21:215-218. **2.** Foster P, Atkinson M. Clinical evaluation of a prednisolone metasulphobenzoate rectal foam in the treatment of acute distal ulcerative colitis. Data on file.



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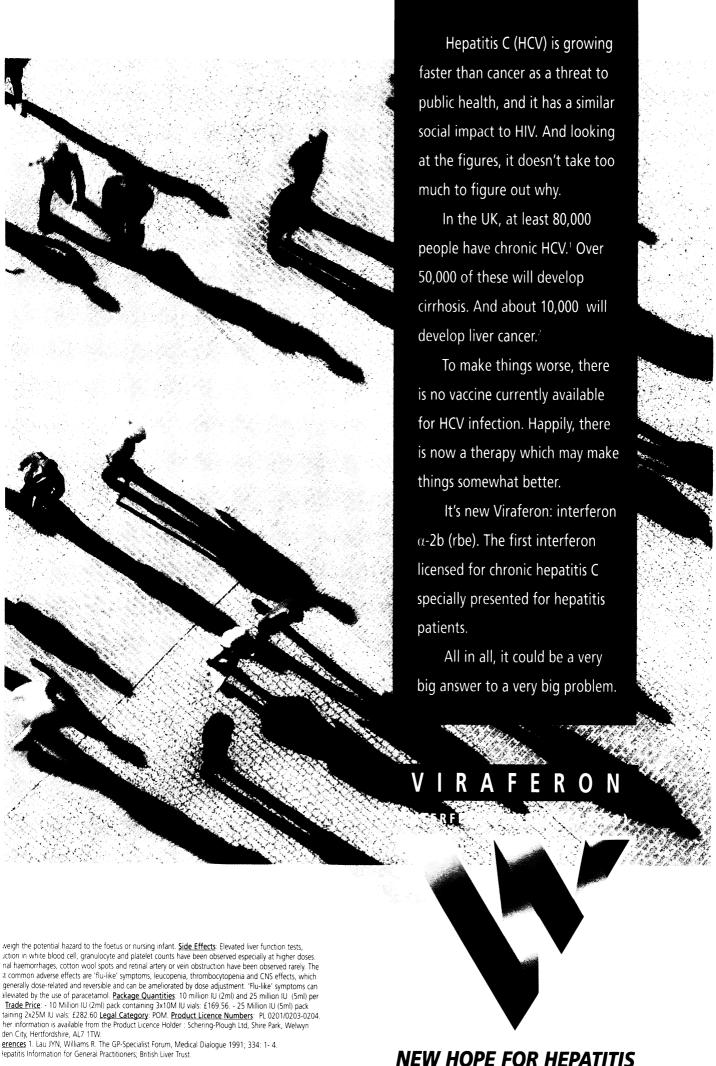
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# VIRAFERON ABBREVIATED PRESCRIBING INFORMATION

Before prescribing Viraferon please refer to full Data sheet. Presentation: 10 million or 25 million IU/vial of Interferon Alfa-2b(rbe) in solution. Uses: Treatment of Chronic Active Hepatitis B; reduction of disease activity in Chronic Hepatitis C/ Non-A, Non-B. Dosage and Administration: Chronic Active Hepatitis B: The recommended dosage is usually in the range of 2.5 million IU to 5.0 million IU/m<sup>5</sup> of body surface area administered subcutaneously three times per week for a period of four to six months. Chronic Hepatitis C/Non-A, Non-B: The recommended dose is 3 million IU administered three times a week. Most patients who respond demonstrate improvement in ALT levels within 12-16 weeks. In those patients, therapy should be continued with 3 million IU three times a week for up to 18 months. Contraindications, Warnings, Precautions, etc.: Contraindications: A history of hypersensitivity to recombinant Interferon Alfa-2b(rbe) or components of VIRAFERON Injection contraindicates its use; severe pre-existing cardiac disease, severe renal or hepatitic dysfunction; epilepsy and/or compromised central nervous system function; chronic hepatitis with advanced decompensated cirrhosis of the liver; chronic hepatitis patients who are being or have been recently treated with immunosuppressive agents

excluding short-term corticosteroid withdrawal. Autoimmune hepatitis or history of autoimmune disease, pre-existing thyroid disease not controlled by conventional therapy. <u>Warnings and Precautions</u>: Use with caution in patients with a history of pulmonary disease, diabetes mellitus, coagulation disorders or severe myelosuppression. Moderate to severe adverse experiences may require reduction of dosage or termination of VIRAFERON therapy. Patients with chronic Hepatitis B with evidence of decreasing hepatic synthetic function may be at increased risk of clinical decompensation if a flare up of aminotransferases occurs during treatment. Patients with a recent history of cardiovascular events should be closely monitored as adverse cardiovascular events including hypotension and cardiac arrhythmias have been observed. Adequate hydration of patients should be maintained during treatment. Pulmonary infiltrates, pneumonitis and pneumonia, including fatality, have been observed rarely. Reversible CNS effects commonly manifested by confusion have been seen, usually at high doses. Infrequently, patients treated for chronic Hepatitis C/Non-A, Non-B developed thyroid abnormalities, either hypothyroid or hyperthyroid. VIRAFERON may exacerbate pre-existing psoniatic disease. Ocular adverse events have been reported. Concomitant narcotics or sedatives should be administered with caution. Patients taking xanthine derivatives should be monitored and dosage adjusted as necessary. No information is available on the use of interferon in human pregnancy or its effect on human lactation. VIRAFERON should only be given if the benefits clearly



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