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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: April 1995

- Duodenal Ulcer -Up to 98% healing within four weeks ¹⁻⁶ (Range 91-98%)
- Reflux Oesophagitis -Up to 95% healing within eight weeks 7-12 (Range 85-95%)
- Lower total treatment costs per patient symptom free than either omeprazole or ranitidine

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 (20962) 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)

SECOND GENERATION

ZOTON*

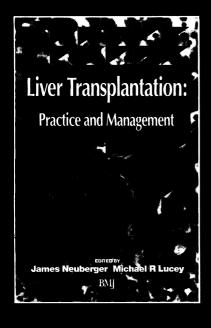
lansoprazole



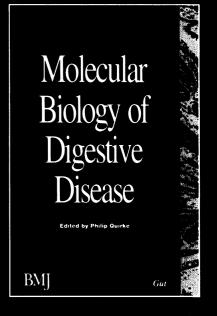


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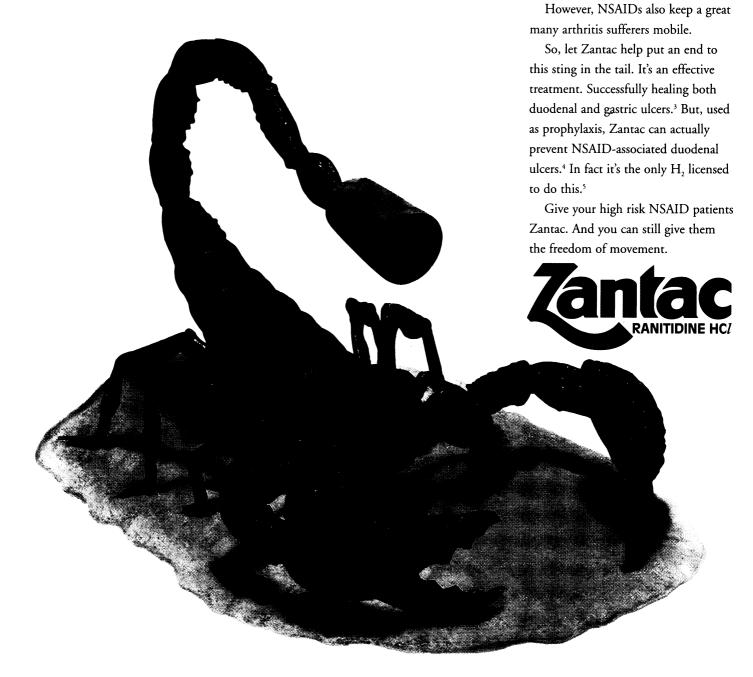
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Indications Duodenal ulcer, benign gastric ulcer, ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), prevention of NSAID-associated duodenal ulcer, oesophageal reflux disease, severe oesophagitis, long-term management of healed 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 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 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.

NSAIDs claim around 3,000 lives a

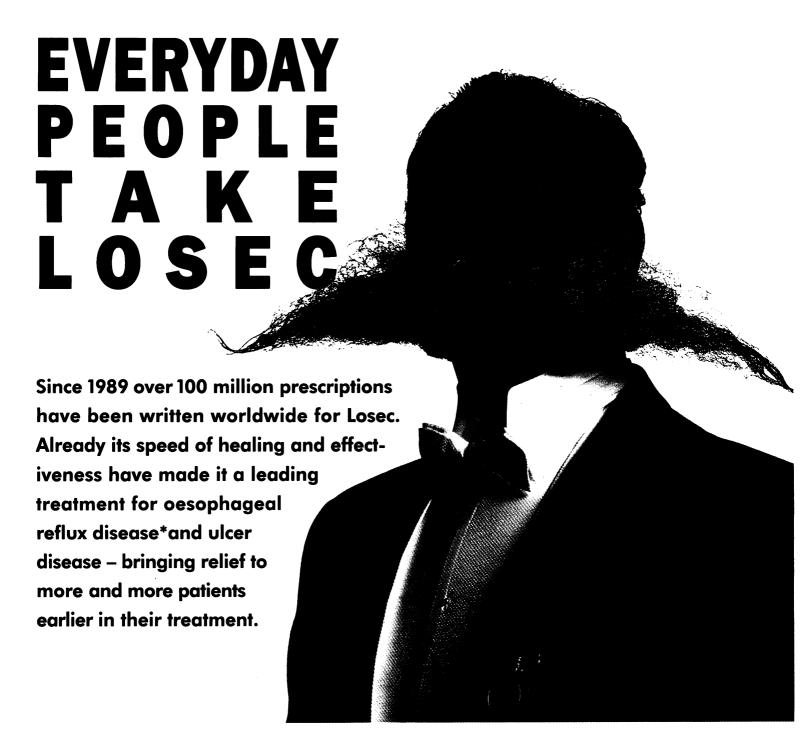
year in the UK alone.1 Patients with a

history of ulcer disease being at greatest risk of life-threatening complications.²

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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





·FOR HEALING-

In oesophageal reflux disease, duodenal and benign gastric ulcer.

LOSEC® CAPSULES (omeprazole) ABBREVIATED PRESCRIBING INFORMATION (refer to full data sheet before prescribing) PRESENTATION: LOSEC Capsules containing 10mg, 20mg or 40mg omeprazole as enteric coated granules with an aqueous based coating. USES: Oesophageal reflux disease. Duodenal and benign gastric ulcers (including NSAID-induced). Duodenal ulcer associated with Helicobacter pylori. Prophylaxis of acid aspiration. Zollinger-Ellison syndrome. DOSAGE & ADMINISTRATION: Adults (including the elderly): The usual dose in oesophageal reflux disease and peptic ulcer is 20mg once daily, increasing to 40mg once daily in severe or refractory cases, if required. Oesophageal reflux disease: Healing: 20mg daily for 4 weeks. Continue for further 4-8 weeks if required. Maintenance in acid reflux disease: LOSEC 10mg daily. Increase to 20mg daily if symptoms return. Duodenal ulcer (DU): Healing: 20mg daily for 4 weeks. DU maintenance: LOSEC 10mg daily increasing to 20mg daily if symptoms return. Duadenal ulcer (DU): Healing: 20mg daily increasing to 20mg daily if symptoms return. Du associated with 4elicobacter pylori: Usual dose is LOSEC 40mg daily with amoxycillin 1.5g daily (750mg b.d.) for 2 weeks. Up to 2g/day of amoxycillin has been used in clinical studies. Benign Gastric Ulcer: 20mg daily for 8 weeks. Prophylaxis of acid aspiration: LOSEC 40mg on the evening before surgery followed by LOSEC 40mg on the morning of surgery. Zollinger-Ellison Syndrome: 60mg

daily as long as clinically indicated. Individually adjust within range 20-120mg daily. If in excess of 80mg daily 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. Avoid in pregnancy unless no safer alternative. Discontinue breast feeding if LOSEC is considered essential. Side effects: LOSEC is well tolerated. Adverse reactions are generally mild and reversible (relationship to LOSEC not established in many cases). They include diarrhoea, headaches, skin disorders and in isolated cases, angioedema, musculoskeletal disorders, fatigue, insomnia, dizziness, blurred vision, vertigo, paraes thesia, liver enzyme and haematological changes. LOSEC can delay the elimination of diazepam, phenytoin and warfarin. Simultaneous treatment with omeprazole and digoxin may increase the bioavailability of digoxin. 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. In patients known to be allergic to amoxycillin, clarithromycin may be a useful alternative in dual therapy. Omeprazole 40mg daily, amoxycillin 1500mg daily and metronidazole 1200mg daily for 14 days achieved an overall Hp eradication rate of 89% (96% in metronidazole-sensitive isolates).

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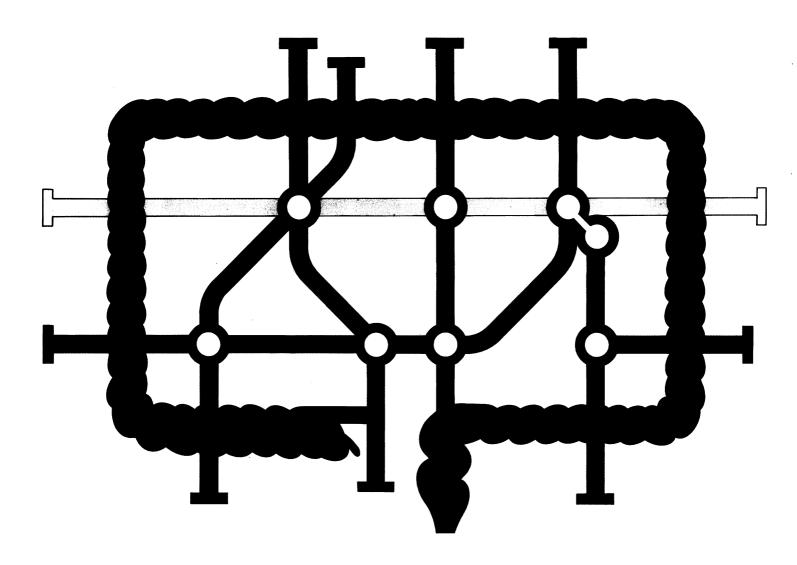
PL 0017/0337 - LOSEC Capsules 10mg. PL 0017/0238 - LOSEC Capsules 20mg. PL 0017/0320 - LOSEC Capsules 40mg.

*Oesophageal reflux disease (GORD) = symptoms and/or tissue damage attributable to reflux. Symptoms vary considerably from one sufferer to another, but the most typical are heartburn and regurgitation.

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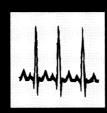
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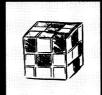


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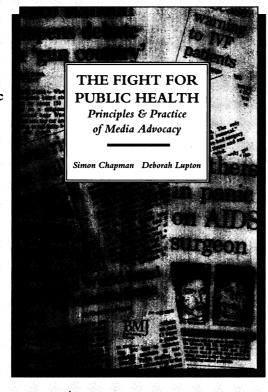


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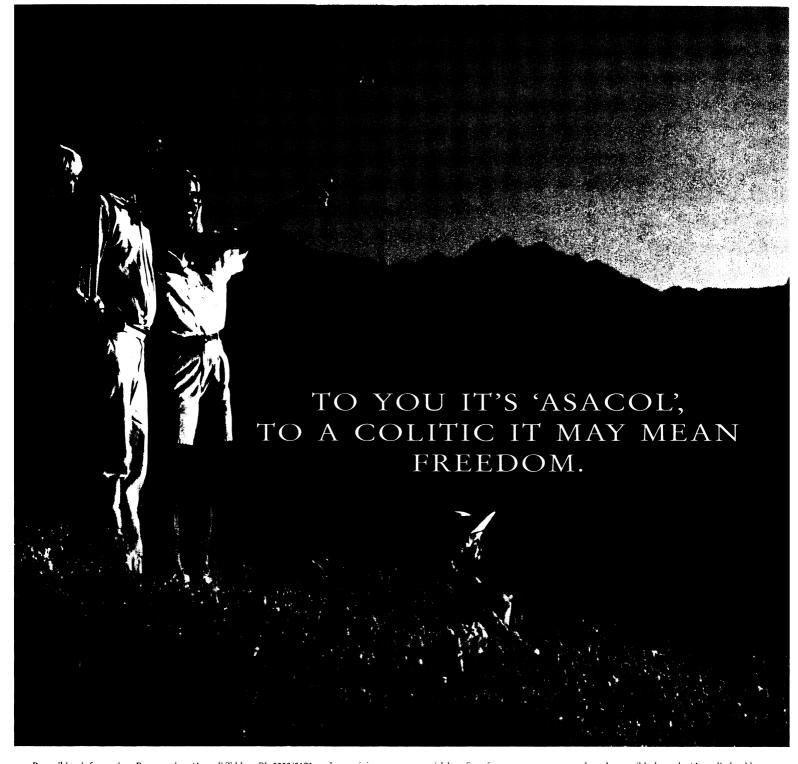
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Prescribing information: Presentation: 'Asacol' Tablets, PL 0002/0173, each containing 400 mg mesalazine (5-aminosalicylic acid) coated with a pH-dependent acrylic based resin (Eudragit S) formulated to release the active ingredient in the terminal ileum and colon. Blister packs of 120 (12 x 10), £39.62. '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. 'Asacol' Foam Enema, PL 0002/0222, 1 g mesalazine per metered dose. Carton containing can of 14 metered doses, 14 disposable applicators and 14 disposable plastic bags. £39.60. Uses: For the treatment of mild to moderate acute exacerbations of ulcerative colitis. Tablets and Suppositories for the maintenance of remission of ulcerative colitis. The suppositories and foam enema are particularly appropriate in patients with distal disease. Dosage and administration: Adults: Tablets: Acute disease: Six tablets a day in divided doses, with concomitant corticosteroid therapy where clinically indicated. Maintenance therapy: Three to six tablets a day in divided doses. Suppositories: 250 mg suppositories: Three to six suppositories a day, in divided doses, with the last dose at bedtime. 500 mg suppositories: A maximum of three suppositories a day, in divided doses, with the last dose at bedtime. Foam Enema: For disease affecting the rectosigmoid region, one metered dose 1 g a day for 4-6 weeks; for disease involving the descending colon, two metered doses 2 g once a day for 4-6 weeks. Children: There is no dosage recommendation. Contra-indications: A history of sensitivity to salicylates or renal sensitivity to sulphasalazine. Severe renal impairment (GFR <20 ml/min). Children under 2 years of age. Precautions: Renal disorder: mesalazine is excreted rapidly by the kidney, mainly as its metabolite, N-acetyl-5-aminosalicylic acid. In rats, large doses of mesalazine injected intravenously produce tubular and glomerular toxicity. 'Asacol' is best avoided in patients with established renal impairment but, if necessary, it should be used with caution. 'Asacol' Tablets should not given with lactulose or similar preparations which lower stool pH and may prevent release of mesalazine. Use in pregnancy and lactation: No information is available with

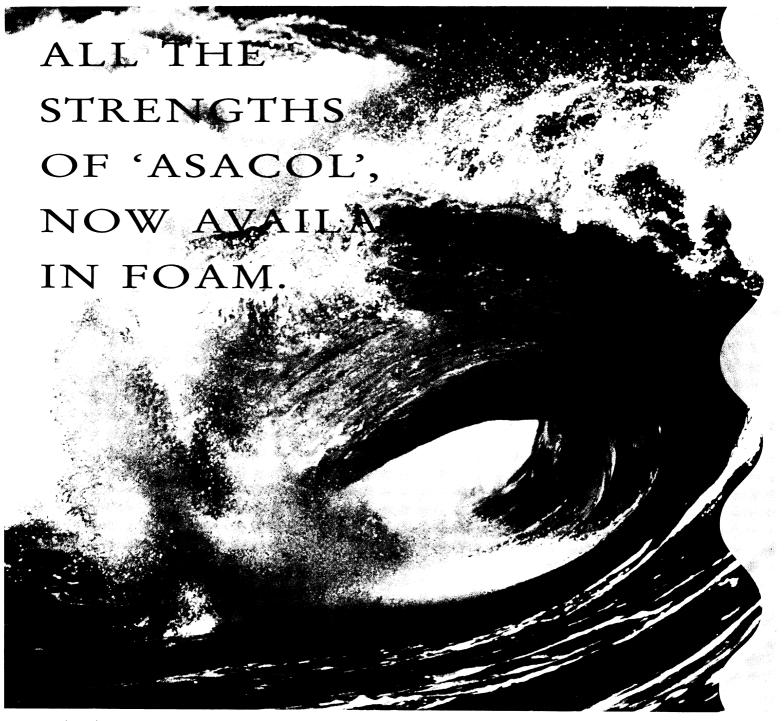
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regard to teratogenicity; however, negligible quantities of mesalazine are transferred across the placenta and are excreted in breast milk following sulphasalazine therapy. Use of 'Asacol' during pregnancy should be with caution, and only if, in the opinion of the physician, the

potential benefits of treatment are greater than the possible hazards. 'Asacol' should, unless essential, be avoided by nursing mothers. Elderly: Use in the elderly should be cautious and subject to patients having a normal renal function (see Precautions). Adverse reactions: The side effects are predominantly gastrointestinal. Nausea, diarrhoea, abdominal pain and headache have been reported. 'Asacol' may be associated with the exacerbation of the symptoms of colitis in those patients who may have previously had such problems with sulphasalazine. There have been reports of leucopenia, neutropenia, thrombocytopenia aplastic anaemia, pancreatitis, hepatitis, and nephrotic syndrome with oral treatment, usually reversible on withdrawal. Renal failure has been reported. Mesalazine-induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment. Hypersensitivity reactions to mesalazine have been reported rarely, including interstitial nephritis, allergic myocarditis, lupus-like syndrome, pulmonary symptoms and rash (including urticaria). These reactions are usually reversible on cessation of mesalazine. Other side effects observed with sulphasalazine such as depression of sperm count and function have not been reported with 'Asacol'. Treatment of overdosage: Following tablet ingestion, gastric lavage and intravenous transfusion of electrolytes to promote diuresis. There is no specific antidote. Legal category: POM. Further information: Whilst mesalazine is known to be the active component of sulphasalazine in the treatment of ulcerative colitis, the other component of sulphasalazine, sulphapyridine, is thought to be responsible for the majority of side effects. 11.8.94

Smith Kline & French Laboratories, Welwyn Garden City, Hertfordshire Al.7 1EY. Authorised user of the trade mark 'Asacol' in the UK. © 1995 Smith Kline & French Laboratories. *Mesalazine is the British approved name of 5-aminosalicylic acid.





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'Asacol' should, unless essential, be avoided by

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Asacol should, unless essential, be avoided by nursing mothers. Elderly: Use in the elderly should be cautious and subject to patients having a normal renal function (see Precautions).

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