

# COLIFOAM

10% hydrocortisone acetate

## FIRST CLASS TREATMENT WHICH TRAVELS TO WORK

- ☛ Colifoam is highly effective for distal ulcerative colitis.<sup>(1)</sup>
- ☛ The retrograde spread of Colifoam increases with the extent of disease.<sup>(2)</sup>
- ☛ Colifoam is easier to retain than liquid enemas and causes less interference with social, sexual and occupational activities.<sup>(1,3)</sup>

PRESCRIBED WITH CONFIDENCE FOR OVER 20 YEARS.



**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. **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 from Stafford-Miller Ltd., Broadwater Road, Welwyn Garden City, Herts. AL7 3SP. **Code:** DO2665.

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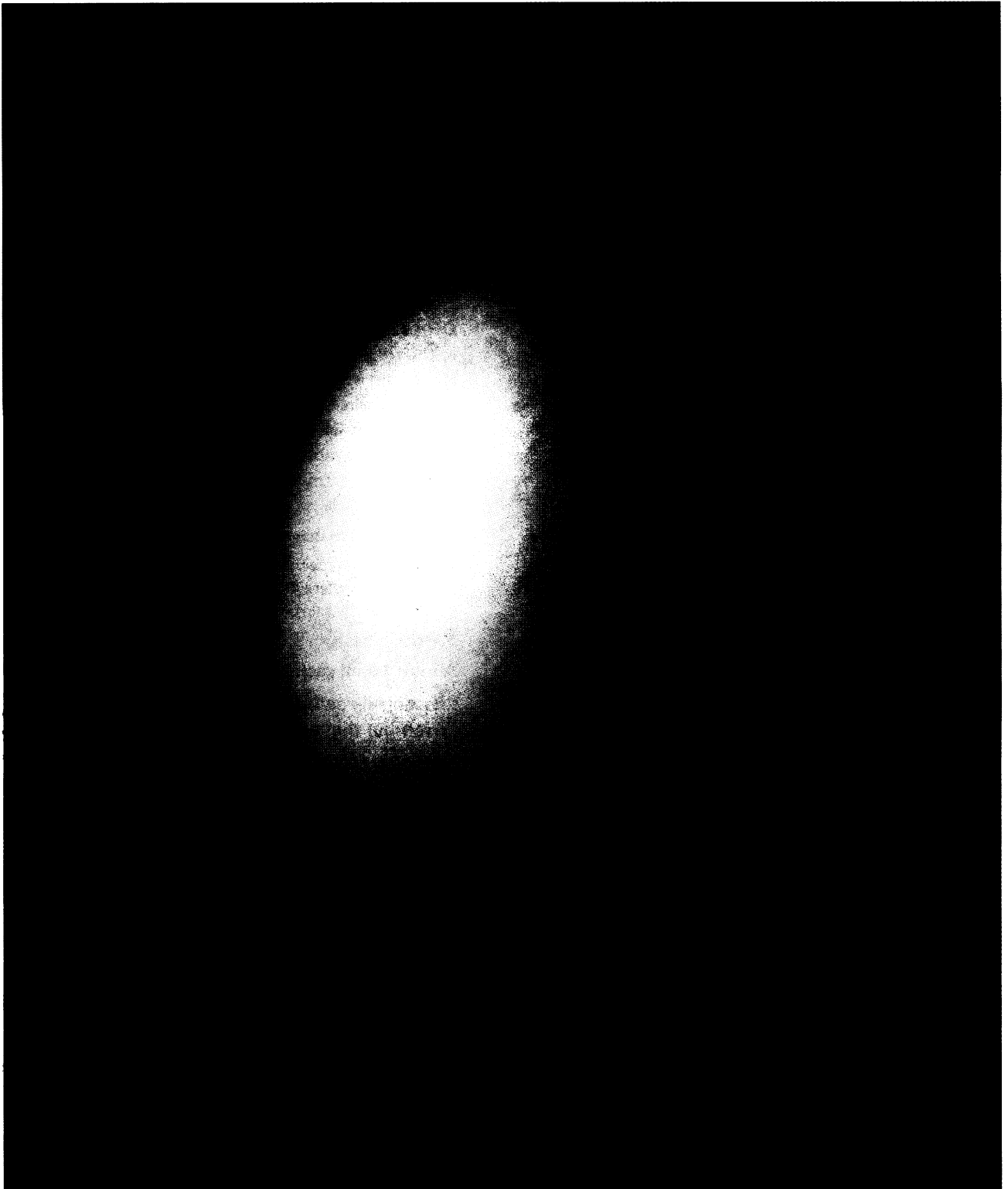
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#### PRESCRIBING INFORMATION:

**Indications** Duodenal ulcer (including those associated with *H. pylori* infection), benign gastric ulcer, postoperative ulcer, oesophageal reflux disease, Zollinger Ellison Syndrome, prophylaxis of gastrointestinal haemorrhage from stress ulcer, recurrent haemorrhage from bleeding peptic ulcer, acid aspiration (Mendelson's Syndrome). Tablets, Syrup, Effervescent Tablets only, ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), prevention of NSAID-associated duodenal ulcer, chronic episodic dyspepsia, severe oesophagitis, long-term management of healed oesophagitis. **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 ulcer, 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. Duodenal ulcers associated with *H. pylori*, 300mg at bedtime or 150mg twice daily with oral amoxicillin 750mg three times daily and metronidazole 500mg three times daily for 2 weeks. Zantac therapy then continued for a further 2 weeks. Ulcers following 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. Long-term treatment of healed oesophagitis: 150mg twice daily. Obstetric patients at commencement of labour; oral dose of 150mg may be followed by 150mg at six-hourly intervals (see data sheet). Those at risk of acid aspiration syndrome; oral dose of 150mg two hours before induction of general anaesthesia with preferably 150mg the previous evening. Alternatively, Zantac Injection 50mg intramuscularly or by slow intravenous injection 45 to 60 minutes before general anaesthesia. Zantac Injection may be given every six to eight hours either as slow (over a period of at least two minutes) intravenous injection of 50mg, after dilution to a volume of 20ml per 50mg dose, or as intermittent intravenous infusion at a rate of 25mg per hour for two hours; alternatively, as intramuscular injection of 50mg (2ml) every six to eight hours. Prophylaxis of haemorrhage from stress ulceration or from bleeding peptic ulceration: parenteral administration may be continued until oral feeding commences. If still at risk, Zantac Tablets or Syrup 150mg may be given twice daily. Prophylaxis of haemorrhage from stress ulceration: priming dose of 50mg as a slow intravenous injection followed by continuous intravenous infusion of 0.125 to 0.250mg/kg/hr

# cellent

# Zantac

RANITIDINE HCl

*Zantac is now healing ulcers  
in over 100 countries<sup>1</sup>*

may be preferred. **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** Caution when using Effervescent Tablets in sodium-restricted patients. Exclude 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 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. Rapid administration of injection may rarely cause bradycardia; recommended rates of administration should not be exceeded. Like other drugs, use during pregnancy and lactation only if strictly necessary. **Side effects** Headache, dizziness, skin rash, occasional hepatitis, rarely arthralgia, myalgia, and with antibiotics, diarrhoea. 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<sub>2</sub>-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 10949/0137, 60 tablets £27.89); Zantac Effervescent Tablets each containing 300mg ranitidine HCl and 20.8mEq sodium (Product licence number 10949/0138, 30 tablets £27.43); Zantac Syrup each 10ml dose containing 150mg ranitidine HCl (Product licence number 10949/0108, 300ml bottle £22.32); Zantac Injection each 2ml dose containing 50mg ranitidine HCl (product licence number 10949/0109, 5 x 2ml £3.21). **Product licence holders** Glaxo Laboratories, Stockley Park West, Uxbridge, Middlesex UB11 1BT. [POM] Zantac is a trade mark of the Glaxo Wellcome Group of Companies. Further information is available on request from Glaxo Wellcome UK Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Telephone 0181-990 9444. Date of preparation: September 1995


#### Reference

1. Data on file. GlaxoWellcome UK Limited 1995.

**GlaxoWellcome**

#### Prescribing information

##### Klaricid 500

**Presentation:** Yellow ovaloid film coated tablets containing 500mg of clarithromycin. Each tablet is engraved with  on one side. **Indications:** Klaricid in the presence of acid suppression effected by omeprazole is indicated for the eradication of *H. pylori* in patients with duodenal ulcers. **Dosage and Administration:** Adults: Clarithromycin 500mg t.d.s. for 14 days plus oral omeprazole 40mg o.d. The pivotal study was carried out with omeprazole 40mg o.d. for 28 days, whilst supportive studies were carried out with omeprazole 40mg o.d. for 14 days. See omeprazole data sheet for further information on omeprazole dosing. **Contra-**

##### indications, Warnings etc:

**Contraindications:** Known hypersensitivity to macrolide drugs. Do not administer with ergot derivatives. **Precautions:** Caution in adults with impaired hepatic and renal function. Do not administer to paediatric patients with hepatic or renal failure. Prolonged or repeated use of clarithromycin may result in an overgrowth of non-susceptible bacteria or fungi. If superinfection occurs, clarithromycin should be discontinued and appropriate therapy instituted. Caution in patients taking drugs metabolised by the cytochrome P450 system as there may be elevations in their serum levels. *H. pylori* organisms may develop resistance to clarithromycin in a small number of patients.

**Interactions:** Potentiation of terfenadine, astemizole, theophylline, digoxin, warfarin and carbamazepine. Interaction of Klaricid tablets with simultaneously administered zidovudine in adults. No interaction with oral contraceptives. **Side-effects:** Klaricid is generally well tolerated. Side-effects include nausea, vomiting, diarrhoea and rarely pseudomembranous colitis, abdominal pain, headache, taste perversion, reversible tongue discoloration, glossitis and stomatitis. Allergic reactions including anaphylaxis and Stevens-Johnson syndrome, and transient central nervous system side-effects have been reported. Hepatic dysfunction has also been reported. **Use**

##### in Pregnancy and Lactation:

The safety of Klaricid during pregnancy and breast feeding has not been established, and therefore if a patient becomes pregnant Klaricid should only be used if benefits outweigh risks. Clarithromycin has been found in the milk of lactating animals and humans.

**Overdose:** Should be treated with gastric lavage and supportive measures. **Basic NHS Price:**

£4.82 per day. **Legal Category:**

POM. **Marketing Authorisation Number:** PL 0037/0254:

42 tablet calendar blister pack.

Further information is available on request from Abbott Laboratories Ltd., Norden Road, Maidenhead, Berkshire SL6 4XE. Date of Preparation December 1995.

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\* Klaricid 500mg t.d.s. plus omeprazole 40mg o.d.

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## LOSEC® CAPSULES (omeprazole) ABBREVIATED PRESCRIBING INFORMATION (refer to full data sheet before prescribing)

**PRESENTATION:** LOSEC Capsules containing 10mg, 20mg or 40mg omeprazole (O) as enteric coated granules with an aqueous based coating. **USES:** Oesophageal reflux disease. Duodenal and benign gastric ulcers (including NSAID-induced). *Helicobacter pylori* eradication: Relief of associated dyspeptic symptoms in combination treatment with antibiotics. 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. **Benign Gastric Ulcer:** 20mg daily for 8 weeks. ***Helicobacter pylori* eradication: DU disease: Triple therapies:** LOSEC 40mg daily with amoxicillin (A) 500mg and metronidazole (M) 400mg, both three times a day for 1 week. Or clarithromycin (C) 250mg and metronidazole 400mg (or tinidazole 500mg) both bd for 1 week. **Dual therapies:** LOSEC 40mg daily

with amoxicillin 750mg to 1g bd or clarithromycin 500mg tid, both for 2 weeks. **GU disease:** LOSEC 40mg daily with amoxicillin 750mg to 1g bd for 2 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, dry mouth, vertigo, paraesthesia, liver enzyme and haematological changes. **Interactions:** LOSEC can delay the elimination of diazepam, phenytoin and warfarin. Plasma concentrations of omeprazole and clarithromycin are increased when used concomitantly. 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. Eradication of Hp with omeprazole and antibiotics gives rapid symptom relief, high healing rates and long-term remission of ulcer disease.

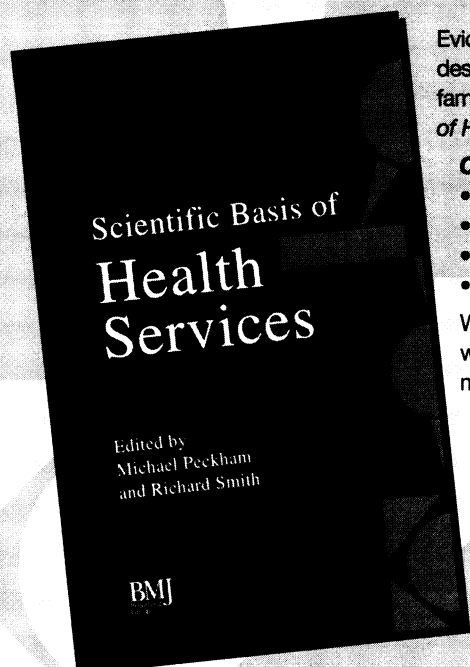
**Quality of life.** In recent clinical data, in patients with acute peptic ulcer disease, omeprazole Hp eradication therapy improved patients' quality of life. **PACKAGE QUANTITIES:** 10mg: bottles of 7\* capsules £4.99, bottles of 28 capsules £19.95. 20mg: bottles of 7\* capsules, £8.86, bottles of 28 capsules, £35.45; 40mg: bottles of 7\* capsules £17.72, bottles of 14 capsules £35.45. (\*Hospital pack only). **MARKETING AUTHORIZATION NO:** PL 0017/0337. LOSEC Capsules 10mg. PL 0017/0238 - LOSEC Capsules 20mg. PL 0017/0320 - LOSEC Capsules 40mg.



For further information contact the **MARKETING AUTHORIZATION HOLDER:** Astra Pharmaceuticals Ltd, Home Park, Kings Langley, Herts WD4 8DH. Tel: (01923) 266191.

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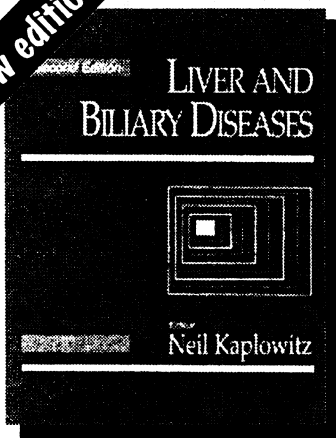
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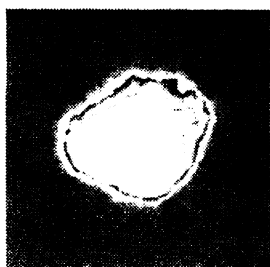


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Entocort® CR 3mg Capsules (budesonide)

PRESCRIBING INFORMATION (Refer to full Summary of Product Characteristics before prescribing). **Presentation:** Capsules containing 3mg budesonide **Use:** Induction of remission of mild to moderate Crohn's disease affecting the ileum and/or ascending colon. **Dosage and Administration: Adults:** 9mg once daily in the morning before breakfast for up to 8 weeks. When treatment is to be discontinued, the dose should normally be reduced for the last 2 to 4 weeks of therapy. **Children:** Not recommended. **Elderly:** No special dose adjustment, though limited experience in elderly. **Contra-Indications:** Bacterial, fungal or viral infections. Known hypersensitivity. **Precautions:** Treatment with Entocort CR Capsules results in lower systemic steroid levels than conventional oral

# We've re-shaped steroid delivery for Crohn's -



steroid therapy. However, in common with all oral steroids use with caution in patients with tuberculosis, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts, chicken pox and measles or patients with a family history of diabetes or glaucoma. Corticosteroids may cause suppression of HPA axis and reduce the stress response. As with any glucocorticoid steroids, blood levels may increase in patients with compromised liver function. **Interactions:** Cholestyramine may reduce uptake.

**Pregnancy and lactation:** Use during pregnancy should be avoided unless essential. It is not known whether budesonide passes into breast milk.

**Adverse Events:** Those characteristic of systemic corticosteroid therapy. Others include (most classed as mild to moderate) - dyspepsia, muscle cramps, tremor, palpitations, nervousness, blurred vision, skin reactions and menstrual disorders. In clinical studies adverse event incidence was similar to placebo. **Legal Category:** POM. **Packs and prices:** Polyethylene bottles of 100 capsules. Price: £90.00. **Pharmacological Properties:** Budesonide has a high local anti-inflammatory effect and a significantly lower effect on HPA axis and adrenal function than prednisolone. **Marketing Authorization No:** PL0017/0359.

References: 1. Edsbäcker S, Wollmer P, Nilsson A, et al. Abstract. *Gastroenterol* 1993; **104** (4pt 2): A695. 2. Rutgeerts P, Löfberg R, Malchow H, et al. *N Engl J Med* 1994; **331**: 842-845. 3. Jewell DP, Campieri M, Järnerot G, et al. *Gastro Int* 1993; **6**: 1-4. 4. Campieri M, Ferguson A, Doe W, and The International Budesonide Study Group. Abstract. *Gastroenterol* 1995; **108** (4 suppl.): A790.

Further information available from the **Marketing Authorization Holder:** Astra Pharmaceuticals Limited, Kings Langley, Herts, WD4 8DH. Tel: (01923) 266191.

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**Date of preparation:** May 1996

ENT/ADV 1047

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With efficacy and low steroid side effects,<sup>2,4</sup> Entocort CR is tailor-made for Crohn's disease.

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Capsules  
budesonide

A tried and trusted steroid, adapted for Crohn's disease.



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References: 1. Edsbäcker S, Wollmer P, Nilsson A, et al. Abstract. *Gastroenterol* 1993; **104** (4pt 2): A695. 2. Rutgeerts P, Löfberg R, Malchow H, et al. *N Engl J Med* 1994; **331**: 842-845. 3. Jewell DP, Campieri M, Järnerot G, et al. *Gastro Int* 1993; **6**: 1-4. 4. Campieri M, Ferguson A, Doe W, and The International Budesonide Study Group. Abstract. *Gastroenterol* 1995; **108** (4 suppl.): A790.

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TO A COLITIC IT MAY MEAN  
FREEDOM.

**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. **Contraindications:** 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. Serious blood dyscrasias have been reported very rarely with mesalazine. Haematological investigations should be performed if the patient develops unexplained bleeding, bruising, purpura, anaemia, fever or sore throat. Treatment should be stopped if there is suspicion or evidence of blood dyscrasia. 'Asacol' Tablets should not be 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 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, including nausea, diarrhoea and abdominal pain. Headache has also been reported. Mesalazine may be associated with an exacerbation of the symptoms of colitis in those patients who have previously had such problems with sulphasalazine. There have been rare reports of leucopenia, neutropenia, agranulocytosis, aplastic anaemia and thrombocytopenia, pancreatitis, hepatitis, allergic lung reactions, lupus erythematosus-like reactions and rash (including urticaria), interstitial nephritis and nephrotic syndrome with oral mesalazine treatment, usually reversible on withdrawal. Renal failure has been reported. Mesalazine-induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment. Other side effects observed with sulphasalazine such as depression of sperm count and function, have not been reported with 'Asacol'. **Treatment of overdose:** 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. 24.6.95.

Smith Kline & French Laboratories, Welwyn Garden City, Hertfordshire AL7 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.

**ASACOL**  
MESALAZINE\* (5-AMINOSALICYLIC ACID)  
FIVE STAR, 5-ASA COLITIS CONTROL



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STRENGTH  
OF 'ASACOL',  
NOW AVAILABLE  
IN FOAM.

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**ASACOL**  
MESALAZINE\* (5-AMINOSALICYLIC ACID)

FIVE STAR, 5-ASA  
COLITIS CONTROL

**SB** SmithKline Beecham  
Pharmaceuticals  
Healthy Alliance  
partnership beyond prescription

NO

REFLUX

NO

BLOATING

NO

BELCHING

NO

PROBLEM

**ABBREVIATED PRESCRIBING INFORMATION** Please refer to data sheet before prescribing. **Indications:** GASTRO-OESOPHAGEAL REFLUX DISEASE: Treatment of symptoms and healing of mucosal lesions; maintenance treatment of reflux oesophagitis. **DYSPEPSIA:** Treatment of symptoms such as epigastric pain, early satiety, bloating and belching where organic disease has been excluded. **IMPARED GASTRIC EMPTYING:** Relief of symptoms such as epigastric pain, early satiety, anorexia, bloating and nausea associated with delayed gastric emptying secondary to diabetes, systemic sclerosis and autonomic neuropathy. **Dose and Administration:** Adults and children twelve years and over: Take 15 minutes before food. **REFLUX:** 20mg Prepidid b.d. before breakfast and at bedtime for 10mg Prepidid t.i.d. if necessary, night time symptoms can be treated with a fourth 10mg dose at bedtime for 12 weeks to heal oesophagitis. For long term maintenance therapy, 20mg once daily (at bedtime) or 10mg b.d. (before breakfast and at bedtime) increasing to 20mg b.d. in patients whose lesions were initially very severe. **DYSPEPSIA:** 10mg Prepidid t.i.d. Usual course of treatment is 4 weeks. **IMPARED GASTRIC EMPTYING:** 10mg Prepidid t.i.d. or q.i.d. An initial course of 6 weeks is recommended but longer treatment may be required. **CHILDREN:** Not recommended in children under 12. **ELDERLY:** As for adults, but monitor response. **ABNORMAL RENAL/LIVER FUNCTION:** Initially dose should be halved. **Contra-indications:** Pregnancy; patients in whom gastrointestinal stimulation might be dangerous; concomitant oral or parenteral ketoconazole, itraconazole or miconazole, fluconazole,

erythromycin and clarithromycin hypersensitivity to Prepidid. **Warnings:** In view of reports of isolated cases of QT-interval prolongation and/or torsade de pointes (causal relationship not established), the recommended dose of Prepidid should not be exceeded and it should be used with caution in patients with conditions leading to QT-interval prolongation, congenital QT-interval prolongation or in patients taking medication known to prolong QT-interval. Not recommended whilst breast feeding. **Drug Interactions:** 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, e.g. anticonvulsants, it may be useful to measure plasma concentrations. In patients receiving anticoagulants, check prothrombin time as it may be increased. The sedative effects of benzodiazepines and alcohol may be accelerated when given with Prepidid. The effects of Prepidid are antagonised by anticholinergic drugs. Prepidid is metabolised mainly via the cytochrome P450 3A4 enzyme. Oral ketoconazole significantly inhibits the metabolism of Prepidid; on the basis of *in vitro* data, itraconazole and miconazole may also have this effect. Co-administration with oral ketoconazole can result in QT-interval prolongation, which can lead to ventricular arrhythmias (see Warnings). Concomitant administration with oral or parenteral ketoconazole, itraconazole, miconazole, fluconazole, erythromycin and clarithromycin, is therefore contra-indicated. Concomitant administration with cimetidine increases peak plasma levels and the AUC of Prepidid, while the absorption of cimetidine and

ranitidine is accelerated when co-administered with Prepidid. The level of change is unlikely to be clinically significant. **Side Effects:** Abdominal cramps, boorborgmi and loose stools are mainly transient. Should severe abdominal cramps occur with single administrations of 20mg Prepidid halve the dose per administration and double the frequency of dosing. Less frequent side effects include headaches and light-headedness. Reports of hypersensitivity, convulsions, extrapyramidal effects and increased urinary frequency have been received. Exceptionally reversible liver function abnormalities have been reported - causal relationship not established. **Overdosage:** The most frequently reported symptoms are abdominal cramping and increased stool frequency. Treatment includes activated charcoal and close observation. Patients should also be evaluated for possible QT-interval prolongation and for factors that can predispose to the occurrence of torsade de pointes. **Presentation:** Prepidid Tablets, pack of 120 tablets each containing 10mg cispripide. Prepidid Suspension, 500ml bottles containing cispripide 5mg/ml. **Pharmaceutical Precautions:** Prepidid Tablets: store at room temperature in a dry place and protect from light. Prepidid Suspension: store at room temperature (below 25°C). **PL Nos:** Prepidid Tablets PL 02471036. Prepidid Suspension PL 02472057. **Product Licence Holder:** Janssen-Cilag Ltd, Sanderson High Wycombe Bucks, HP14 4JH. **Basic NHS Cost:** 120 tablets £37.60; 500 ml bottle suspension £15.60. **Legal Category:** POM. **Date of preparation:** April 1996. **TM=Trademark.** Copyright 0098154

AFTER ANTACIDS  
**Prepidid**<sup>TM</sup>  
cispripide  
A PHYSIOLOGICAL APPROACH

JANSSEN-CILAG