

### NEW & LOSEC 10 mg

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. 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. **DU associated with** Helicobacter 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. Benian 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 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, fatique, insomnia, dizziness, blurred vision, vertigo, paraesthesia, liver enzyme and haematological changes. LOSEC can delay the elimination of phenytoin and warfarin. **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). **PACKAGE QUANTITIES:** 10mg: bottles of 7 capsules £4.99, bottles of 28 capsules £19.95. 20mg: bottles of 7 capsules, £8.64, bottles of 28 capsules, £35.45; 40mg: bottles of 7 capsules £17.28, bottles of 14 capsules £35.45

#### PRODUCT LICENCE NUMBERS:

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

#### 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 Astra Pharmaceuticals

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

Prescribing information:

Dipentum Presentation: Caramel coloured capsules containing 250 mg olsalazine sodium. Uses: Oral treatment of acute mild ulcerative colitis and the maintenance of remission. Olsalazine consists of two molecules of 5-aminosalicylic acid (5-ASA) joined through an azo-bond. The systemic absorption of olsalazine is minimal. 99% of an oral dose will reach the colon. Olsalazine is activated in the colon where it is converted into 5-ASA. The release of 5-ASA is neither pH nor time dependent.5-ASA acts topically on the colonic mucosa and local colonic concentrations of 5-ASA are more than 1000 times that found in the serum. Dosage and Administration: Acute Mild Disease: Adults including the Elderly. Commence on 1g daily in divided doses and, depending upon the patient response, titrate the dose upwards to a maximum of 3g daily over 1 week. A single dose should not exceed la Olsalazine should be taken with food. Remission: Adults including the Elderly. Two capsules (0.5g) twice daily taken with food. Contra-indications: Warnings etc: Contra-indications: Hypersensivity to salicylates, there is no experience of use of olsalazine in patients with significant renal impairment. Olsalazine is contra-indicated in patients with significant renal impairment. Pregnancy: Reproduction studies performed in mice, rats and rabbits have revealed no evidence of impaired fertility, harm to the foetus or teratogenic effects due to olsalazine administration. However, the experience of use in pregnant women is limited. Dipentum should not be used during pregnancy unless the clinician considers that the potential benefit outweighs the possible risk to the foetus. Lactation: There are no data on the excretion of olsalazine in breast milk. Adverse Reactions: Waterv diarrhoea has been recorded in 15% of patients treated. In half of these patients the diarrhoea was either transient or overcome by dose reduction. In patients who do not respond to dose reduction the drug should be stopped. As with sulphasalazine and mesalazine gastrointestinal side-effects are most common. The most frequently reported adverse reactions are diarrhoea. abdominal cramps, headache, nausea, dyspepsia, arthralgia and rash. Treatment of Overdose: There is no specific antidote to olsalazine. Treatment should supportive. Pharmaceutical Precautions: Store at room temperature in a dry place. Legal Category: POM. Package Quantities: Containers of 100 capsules. NHS Price: 100 capsules £23.30. Further Information: Olsalazine has been used concomitantly with glucocorticosteroids. Product Licence Number: 0022/0134. Product Licence Holder: Pharmacia Ltd., Davy Avenue, Milton Keynes MK5 8PH. Distributed by: Pharmacia Ltd., Davy Avenue, Milton Keynes MK5 8PH.

References: 1. Bjarnason J., McPherson A.J. (1993) Inflammopharmacology; 2: 277-287. 2. Raimundo A.H. et al. (1992) Gut; 33(1): S63. 3. Data sheet. 4. Staerk Laursen L. et al. (1990) Gut; 31(11): 1271-1276. 5. Courtney M.G. et al. (1992) Lancet; 339: 1279-81. 6. Sandberg-Gertzen H. et al. (1988) Scand J Gastroenterol; 23: Suppl. 148, 48-50.

\*coated mesalazine (Eudragit S). P/1918/494



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#### PRESCRIBING INFORMATION:

Indications Duodenal ulcer, benign gastric ulcer, ulcers associated with non-steroidal antiinflammatory 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 nonsteroidal anti-inflammatory drugs: 150mg twice daily for up to eight weeks. Prevention of NSAIDassociated 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 sodiumcontaining 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 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 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 .\_ June 1994. UB11 1BT. Telephone 081-990 9444.

References

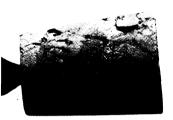
Safety 1992; 7(2): 86-105. 2. Rodriguez LAG, Jick H. The Lancet 1994. Vol 343: 769-772. 3. Lancaster-Smith ML, Jaderberg ME, Jackson DA. Gut 1991; 32: 252-255. 4. Robinson MG, Griffin JW, Bowers J et al. Dig Dis Sci 1989; 34(3): 424-428. 5. Zantac Data Sheet.

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Overdosage: Overdosage by this route is unlikely Pharmaceutical Precautions: Pressurised

R Data on file. Pharmax. 2. K.W. Somerville. et al. (1985) BMJ, 291-866, 3. W.S.J. Ruddell, et al. (1980) Gut. 885-889, 4. C. Rodrigues, et al. (1987). The Lancet. II, 1497, 5. Data on file. Pharmax.



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RESCRIBING 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 with the control of t ged 2-12 years, 1-4 daily according to body weight (see Data Sheet). For treatment of symptoms of functional dyspopatia Adults (including the elderly): Toboles: Up to 10/20mg and 35 times daily before meals and 10-20mg at night lepending 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, nerefore 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 productin which may be associated with e.g. alactorrhoea, 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 e 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: March 1994. Leferences: 1. Tatsuta M et al. Scand J 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 Alierop L et al. Digestion 1979; 19: 244-250. 5. Sarin SK et al. Indian J Med Res 1986; 83 (June): 623-628. 6. De Loose F et al. (unpublished study - July 1980). 7. Agorastos I et al. J Int Med Res 1981; 9 (2): 143-147. sanofi WINTHOP urther information is available on request from: Sanofi Winthrop Limited, One Onslow Street, Guildford, Surrey GU1 4YS. Telephone: (0483) 505515. Fax: (0483) 35432. MHHH ... 1991111. "INDIGESTION **BLOATING BELCHING FLATULENCE** ABDOMINAL DISCOMFORT MOVE IT, **YOU 'ORRIBLE LOT"** XXXXXXX A major force in the battle against recurrent non-ulcer dyspepsia Motilium Promotes gastric emptying". Relieves dyspeptic symptoms<sup>37</sup> 1/94/0000

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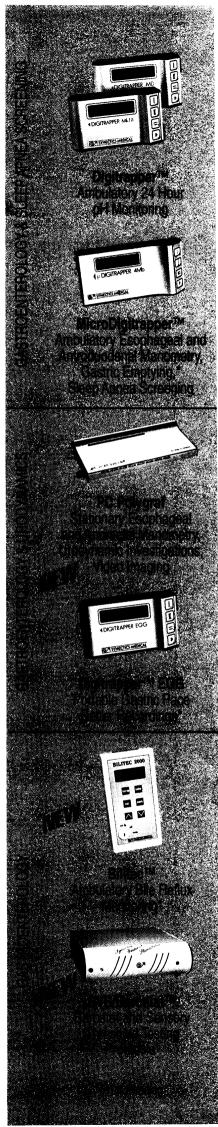


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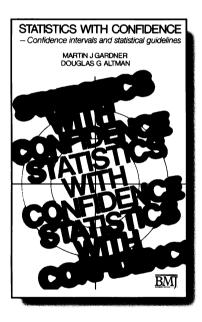
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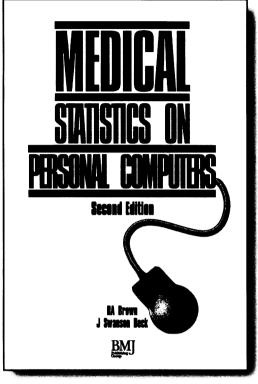
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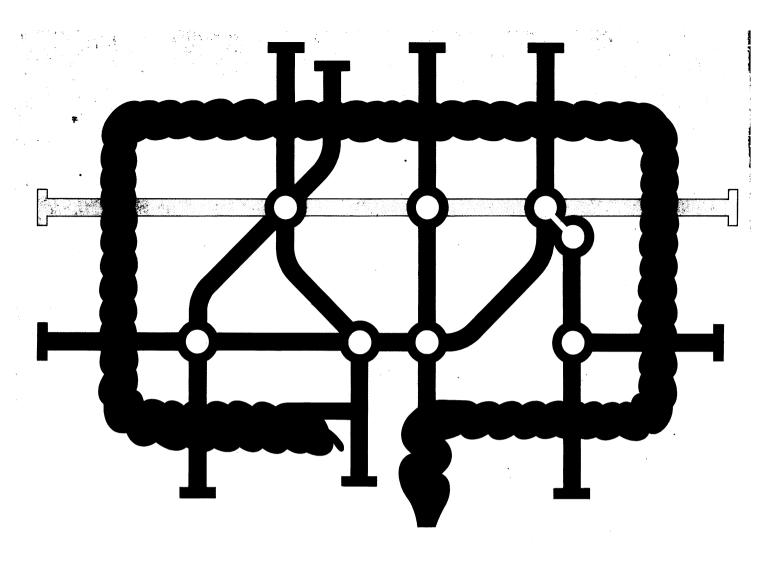
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#### PRESCRIBED WITH CONFIDENCE FOR OVER 20 YEARS.

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. 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. Code: D02665.