

I've got the power

**PRESCRIBING INFORMATION:** **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, 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. Alternatively, in duodenal ulcers, 300mg in the morning and evening for four weeks to achieve optimal healing. 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). *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. Reduce dosage in presence of severe renal failure (see data sheet). Like other drugs, use during pregnancy and lactation only if strictly necessary. **Side effects:** Headache, dizziness, skin rash, occasional hepatitis. 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 0004/0279, 60 tablets £29.76); Zantac 300 Tablets each containing 300mg ranitidine HCl (Product licence number 0004/0302, 30 tablets £27.43); Zantac Dispersible Tablets each containing 150mg ranitidine HCl (Product licence number 0004/0298, 60 tablets £31.25); Zantac Effervescent Tablets each containing 150mg ranitidine HCl/ and 14.3mEq sodium (Product licence number 0004/0392, 60 tablets £31.25); Zantac Effervescent Tablets each containing 300mg ranitidine HCl/ and 20.8mEq sodium (Product licence number 0004/0393, 30 tablets £31.25); Zantac Syrup each 10ml dose containing 150mg ranitidine HCl (Product licence number 0004/0310, 300ml bottle £22.32). **Product licence holder:** Glaxo Operations UK Limited, Greenford, Middlesex UB6 0HE. Zantac is a Glaxo trade mark. Further information is available on request from: Glaxo Laboratories Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Tel: 081 990 9000.

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## Keep up with the times—

### THE HEALTH DEBATE LIVE: 45 INTERVIEWS FOR LEADING FOR HEALTH

The BMA's document *Leading for Health: a BMA Agenda for Health*, encompasses often contrasting views and presents questions that need answering. What did people actually say in their interviews? With the interviewees permission, the *BMJ* has published the transcripts of their original comments. This collection provides a lively and provocative contribution to the health service debate.

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#### Lossec Capsules Abbreviated Prescribing Information

**Presentation:** Lossec Capsules containing 20mg omeprazole. **Uses:** Treatment of reflux oesophagitis. Symptom relief is rapid, and the majority of patients are healed after 4 weeks. Treatment of duodenal and gastric ulcers, including those complicating NSAID therapy. Zollinger-Ellison syndrome. **Dosage & administration:** **Adults (including elderly): Reflux oesophagitis:** 20mg once daily, given for 4 weeks. For those patients not fully healed after the initial course, healing usually occurs during a further 4-8 weeks treatment. Lossec has also been used in a dose of 40mg once daily in patients with reflux oesophagitis refractory to other therapy. Healing usually occurred within 8 weeks. Patients can be continued at a dosage of 20mg once daily. **Duodenal and benign gastric ulcers:** 20mg once daily. The majority of patients with duodenal ulcer are healed after 4 weeks. The majority of patients with benign gastric ulcer are healed after 8 weeks. In severe cases, the dose may be increased to 40mg Lossec once daily. Long-term therapy with Lossec in the treatment of gastric and duodenal ulcers is not currently recommended. **Zollinger-Ellison syndrome:** 60mg once daily. The dosage should be adjusted individually and treatment continued as long as clinically indicated. More than 90% of patients with severe disease and inadequate response to other therapies have been effectively controlled on doses of 20 - 120mg daily. With doses above 80mg, give twice daily. **Children:** There is no experience of the use of Lossec in children. **Impaired renal or hepatic function:** Adjustment is not required. Patients with severe liver disease should not require more than 20mg Lossec daily. **Contra-indications, warnings, etc** **Contra-indications:** No known contra-indications to the use of Lossec. When gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with Lossec is instituted, as treatment may alleviate symptoms and delay diagnosis. Avoid in pregnancy unless there is no safer alternative. Breast feeding should be discontinued if the use of Lossec is considered essential. Lossec is well tolerated. All the following adverse reactions have usually been mild and transient, and there has been no consistent relationship with treatment: Nausea, headache, diarrhoea, constipation, flatulence, skin rashes, urticaria, pruritus, dizziness, somnolence, insomnia, vertigo, malaise, paraesthesia have occurred rarely. In isolated cases the following have been reported: muscular weakness, arthralgia, myalgia, blurred vision, dysgeusia, peripheral oedema, gynaecomastia, leucopenia, thrombocytopenia, GI candidiasis and stomatitis. Reversible mental confusion, agitation, depression and hallucinations have occurred predominantly in severely ill patients. Increases in liver enzymes with or without increases in bilirubin values have been observed. Lossec can delay the elimination of diazepam, phenytoin and warfarin. Monitoring of patients receiving warfarin or phenytoin is recommended and a reduction of warfarin or phenytoin dose may be necessary when omeprazole is added to treatment. No evidence of an interaction with theophylline, propranolol, metoprolol, lidocaine, quinine, amoxicillin or antacids. The absorption of Lossec is not affected by alcohol or food. **Animal Toxicology:** Gastric Fc-cell hyperplasia and carcinoids, have been observed in life-long studies in rats treated with omeprazole or subjected to partial fundectomy. These changes are the result of sustained hypergastrinaemia secondary to acid inhibition, and not from a direct effect of any individual drug. No treatment related mucosal changes have been observed in patients treated continuously with omeprazole for periods up to 5 years. **Pharmaceutical precautions:** Use within three months of opening. Replace cap firmly after use. Dispense in original container. **Legal category:** POM **Package quantities:** Bottles of 5 capsules, £6.49; Bottles of 28 capsules, £36.36 **Product licence no:** PLO01/0238 **Product licence holder:** Astra Pharmaceuticals Ltd., Home Park, Kings Langley, Herts WD4 8DH. References: 1. Holt S & Howden CW. *Dig Dis & Sci* 1991; **36** (4): 385-93. 2. Sandmark S et al. *Scand J Gastroenterol* 1988; **23**: 625-32. 3. McFarland RJ et al. *Gastroenterol* 1990; **98**: 278-83. 4. Bate CM et al. *Gut* 1990; **31**: 968-72.

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\*Lossec compared with conventional starting courses of H<sub>2</sub>-antagonists in reflux oesophagitis, duodenal and gastric ulcers



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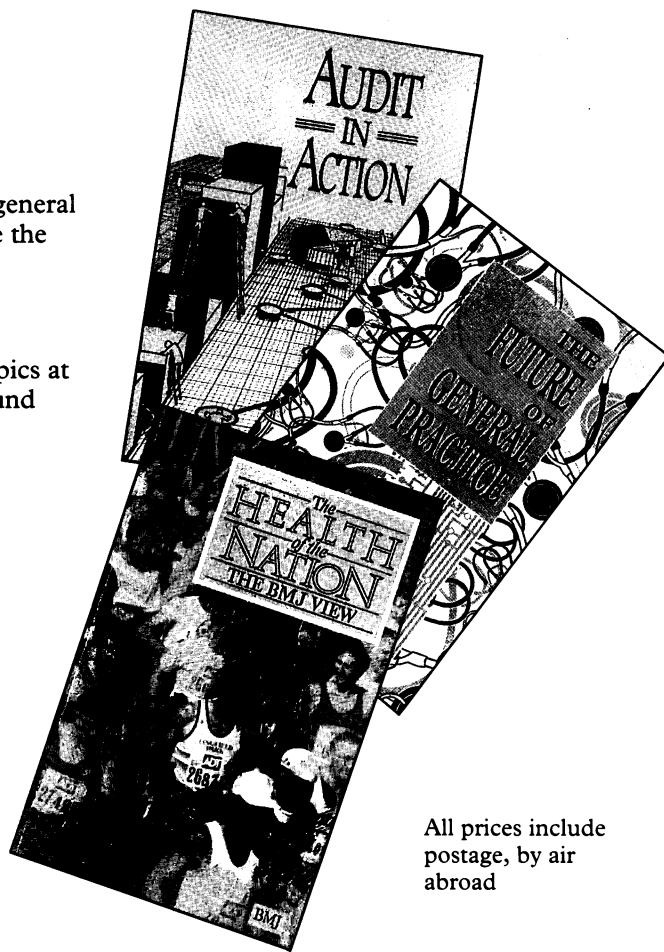
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**References:** 1. Moriga M, *Roy Soc. Med. Int. Cong. Symp. Ser.* 1981; 36: 77-79. 2. De Loose F, *Pharmatherapeutica* 1979; 2(3): 140-146. 3. Van Ganse W, *Curr. Ther. Res.* 1978; 23(6): 695-701. 4. Van Outryve M et al., *Postgrad. Med. J.* 1979; 55 (Suppl. 1): 33-35. 5. Van de Mierop L et al., *Digestion* 1979; 19: 244-250. 6. Laduron PM & Leysen JE, *Biochem. Pharmacol.* 1979; 28: 2161-2165. Motilium is a registered trade mark. Further information available from: Sanofi Winthrop Limited, 1 Onslow Street, Guildford, Surrey GU1 4YS.

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It's power

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**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 1g. Olsalazine should be taken with food. **Remission:** Adults including the Elderly. Two capsules (0.5g) twice daily taken with food.

**Contra-indications:** Hypersensitivity to salicylates. There is no experience of the 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:** Watery 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 the 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 be supportive. **Pharmaceutical Precautions:** Store at room temperature in a dry place. **Legal Category:** POM. **Package Quantities:** Containers of 100 capsules. **Further Information:** Olsalazine has been used concomitantly with glucocorticosteroids.

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1. Courtney, M.G. et al. (1992) *The Lancet*, **339**: 1279-1281  
2. Courtney, M.G. et al. (1990) *The 9th World Congress of Gastroenterology*, Sydney, Australia. Abstr. PP727.



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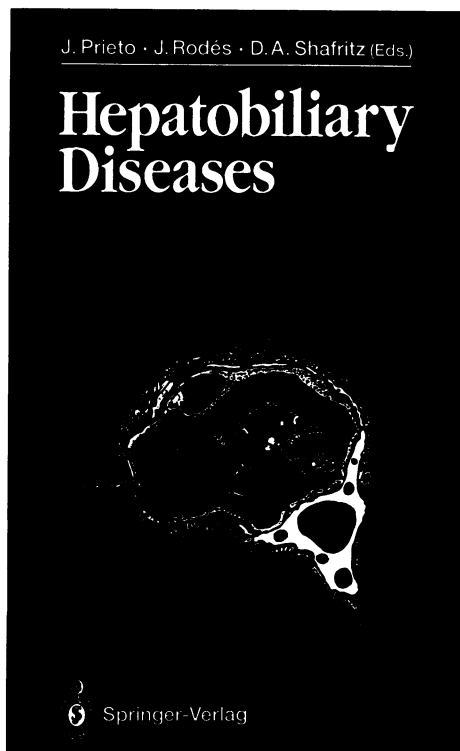
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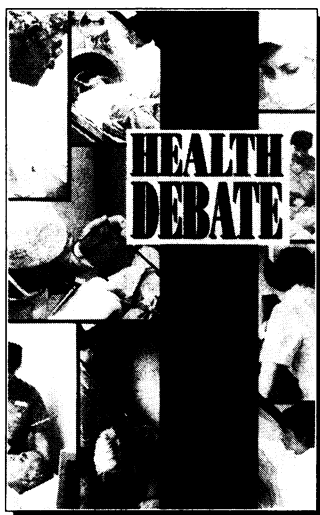


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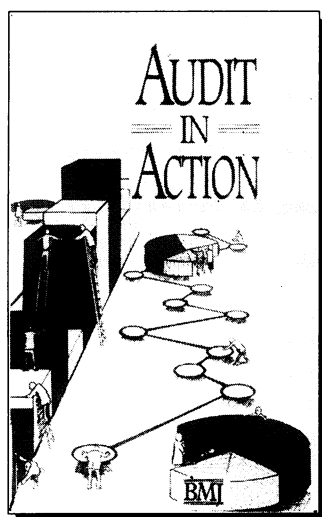
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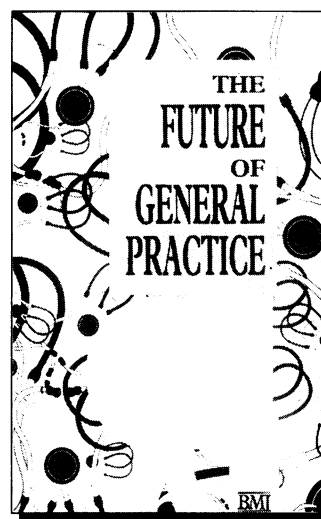
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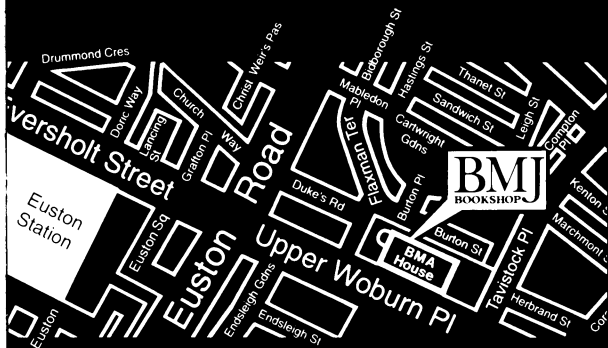
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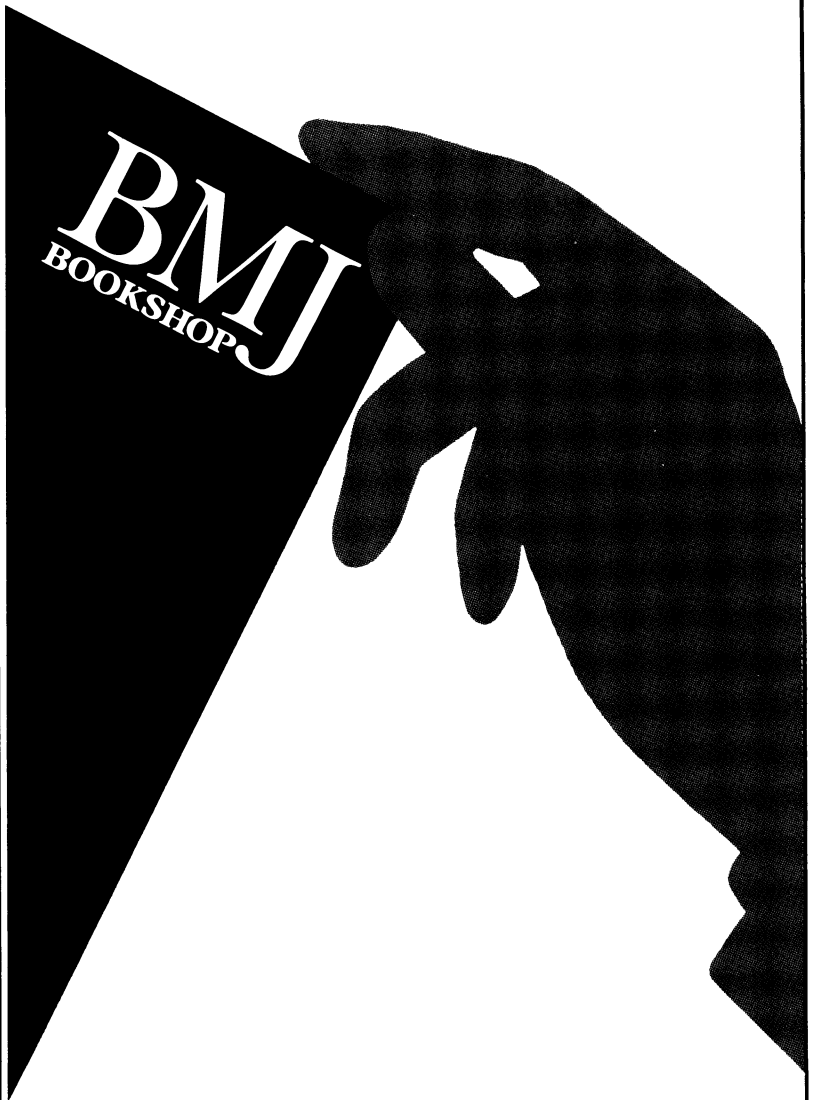
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# GASTROENTÉROLOGIE CLINIQUE ET BIOLOGIQUE

Gastroenterol Clin Biol, t. 16.

N° 10

October 1992

## CONTENTS

### LIVER AND BILIARY TRACT

#### Editorial:

- Measurement of portal blood flow by Doppler ultrasound ..... 741  
A. HADENGUE

#### Original articles:

- Evaluation of the effects of molsidomine and propranolol-molsidomine on portal hemodynamics in patients with alcoholic cirrhosis by Doppler and B-mode sonography ..... 745  
J.-L. MONNIN, J.-P. VINEL, A. LE QUELLEC, J.-P. PASCAL, P. TAUREL, J.-M. BRUEL, F. BLANC, H. MICHEL, A.-J. CIURANA
- Treatment of ascites in patients with cirrhosis: results of a randomized study comparing diuretics with paracentesis compensated by albumin ..... 751  
H. HAGÈGE, O. INK, M. DUCREUX, G. PELLETIER, C. BUFFET, J.-P. ÉTIENNE

#### Current trend:

- Non-transferrin-bound iron and hepatic iron load .. 756  
D. GUYADER, G. ZANNINELLI, P. BRISSOT

### DIGESTIF TRACT AND PANCREAS

#### View point:

- Criteria of drug-induced pancreatitis ..... 761  
R. DELCENSERIE, J.-D. GRANGE, R. LAUGIER, P. BERNADES

#### Original articles:

- Incidence of duodenal ulcer in Reims (France) in 1988. 764  
P. RENARD, S. MINAULT, J.-P. AUCOUTURIER, A. FENZY, J. DIOT, P. ZEITOUN
- Plasma cholesterol and lipoproteins in total parenteral nutrition treated patients following total small bowel removal. Effects of the amount of phospholipids infused ..... 769  
P. BEAU, J. FERZOU, T. HAJRI, C. SEROUGNE, C. MATUCHANSKY, C. LUTTON
- Bacterial translocation in Crohn's disease ..... 777  
G. LAFFINEUR, D. LESCUT, P. VINCENT, P. QUANDALLE, A. WURTZ, J.-F. COLOMBEL
- Therapeutic benefits of one-a-day mesalazine controlled-release suppository in ulcerative proctitis. A controlled double-blind randomized study ..... 782  
Y. NGÔ, J.-M. GÉLINET, A. IVANOVIC, J. KAC, G. SCHÉNOWITZ, J. VILOTTE, J.-C. RAMBAUD

- Endoscopic ultrasonography in the staging of recto-sigmoid villous adenomas ..... 787  
G. ROSEAU, L. PALAZZO, T. RAHME, J.-A. PAOLAGGI

#### Current trend:

- Expression of the multidrug resistance gene product (P-glycoprotein) in human digestive tract and liver. 791  
C. MULLER, G. STAUMONT, G. BRADLEY, F. BIBEAU, P. BROUSSET, G. LAURENT

#### Clinical cases:

- Liver damage due to Wild Germander: report of four cases ..... 798  
A. MATTEI, T. BIZOLLON, J.-D. CHARLES, P. DEBAT, T. FONTANGES, M. CHEVALLIER, C. TREPO
- Severe fatty liver: a cause of sudden death in the alcoholic patient ..... 801  
O. ROSMORDUC, J.-P. RICHARDET, A. LAGERON, C. MUNZ, P. CALLARD, M. BEAUGRAND
- Gastrobronchial fistule is a rare condition ..... 805  
F.-X. ROBERT, H. BILI, B. BOYER, L. SUC, Y. FOLL
- Lymphoepithelial cyst of the pancreas ..... 808  
B. BASTENS, M. GOLLAIRE, J. CAPPELLI, V. LAMY, J. DRYJSKI, R. MOISSE

#### Controversy:

- Acute pancreatitis induced by glicazide: does it exist?. 811  
J.-F. ROCHE, G. GAY
- Answer to the letter of J. F. Roche and G. Gay ... 811  
X. ROBLIN, A. BAZIZ, Y. ABINADER, M. KAKMOUNI

#### Letters to the editor:

- Gastric emptying after endoscopic sclerotherapy of esophageal varices in alcoholic patient with cirrhosis. 812  
S. BONVOISIN, R. SANZARI, D. GONNOT, L. DESCOS, Y. FRANÇOIS, D. SAPPEY MARINIER, J.-C. CENNI
- « Echoes » in chylous ascites associated with cirrhosis. 813  
S. SULTAN, G. BELLAICHE, Y. EL ATTAR, H. CAUGANT, B. LESGOURGUES, N. DELAS
- Cytolytic hepatitis caused by Wild Germander: a new case with rechallenge ..... 813  
J.-L. LEGOUX, F. MAITRE, D. LABARRIÈRE, D. GARGOT, D. FESTIN, X. CAUSSE
- Portal vein thrombosis associated with constitutional coagulation protein deficiencies ..... 815  
S. SCHNEIDER, B. TAILLAN, E. DRAI, G. GARNIER, J. BAYLE, D. BENCHIMOL, P. DUJARDIN
- Prevalence of hepatitis A virus antibodies among hospital staff ..... 816  
J. GERMANAUD, J.-P. BARTHEZ, X. CAUSSE
- Acute pancreatitis and dexfenfluramine (Isomeride®): a case report ..... 817  
J.-M. BORIES, P. BAURET, D. LARREY, H. MICHEL

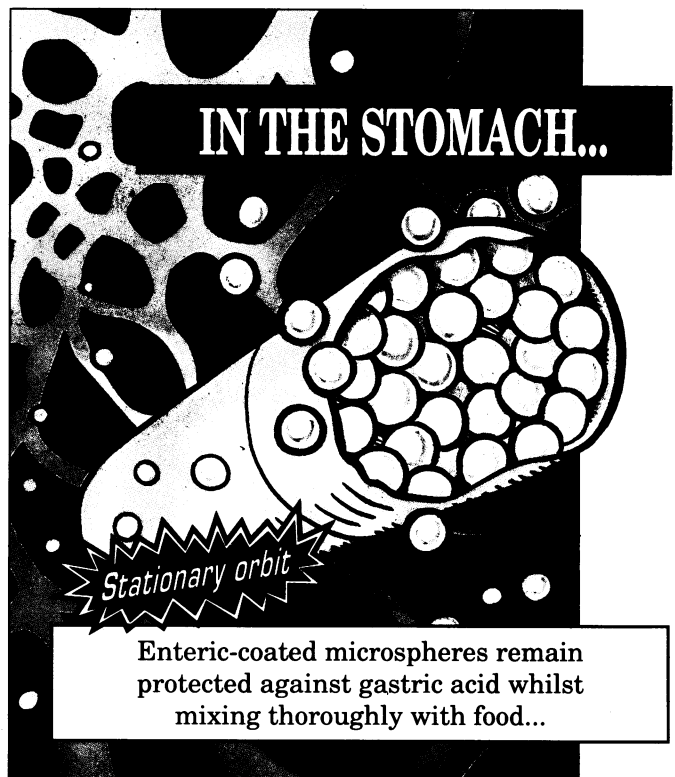
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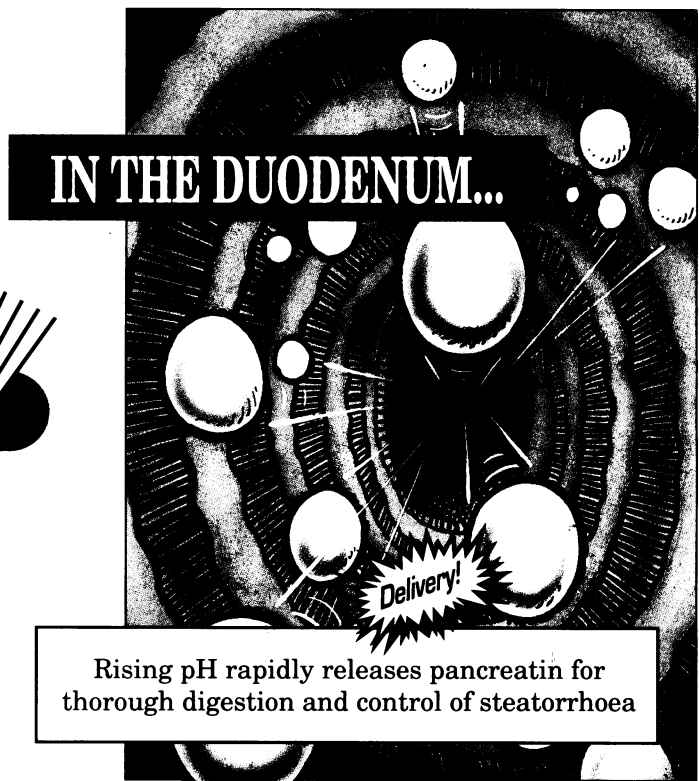
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**References**

1. Stead R J et al. *Thorax* 1987; 42: 533-37
2. Beverley D W et al. *Arch Dis Child* 1987; 62: 564-68

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