

Ursofalk®

ursodeoxycholic acid

The simple approach to gallstone dissolution

- * effective^{1,2,3}
- * lack of side effects^{1,4,5}
- * cost-effective
- * simple regimen

References:

1. Roda, E *et al*. Hepatology 1982; 2, no6: 804-810.
2. Bachrach, WH, Holmann, AF. Digestive Diseases and Sciences 1982; 27, no8: 737-761.
3. Leuschner U. Bilanz der medikamentösen Gallestein Auflösung. Med Klin 1981; 76: 232-234.
4. Volpi C *et al*. Current Therapeutic Research 1979; 26: 225-229.
5. Dowling RH. Hospital Update 1979; 12 (Dec): 1081-1103.



Prescribing Information

Presentation White opaque hard gelatin capsules containing 250 mg ursodeoxycholic acid (UDCA).
Uses Dissolution of radiolucent gallstones measuring up to 15 mm diameter, as assessed on X-ray films, in patients whose gall bladders opacify on oral cholecystography. Ursofalk lowers biliary cholesterol secretion, reduces cholesterol saturation in bile, and facilitates transfer of cholesterol from gallstones to bile. **Dosage and Administration** The following dosage regime is recommended to provide a daily dosage of 8-12 mg UDCA/kg:

Body Weight (kg)	Dose of Ursofalk	
	Capsules daily (in 2 doses)	mg/kg/day
50-62	2	8.1-10
63-85	3	8.8-11.9
86-120	4	8.3-11.6

If doses are unequal the larger dose should be taken in late evening to counteract the rise in biliary cholesterol saturation which occurs in the early hours of the morning. The late evening dose may usefully be taken with food to help maintain bile flow overnight. The time required for dissolution of gallstones is likely to range from 6 to 24 months depending on stone size and composition. Follow up cholecystograms or ultrasound investigations may be useful at 6 month intervals until the gallstones have disappeared. Treatment should be continued until 2 successive cholecystograms and/or ultrasound investigations 4-12 weeks apart have failed to demonstrate gallstones. This is because these techniques do not permit reliable visualisation of stones less than 2 mm diameter. The likelihood of recurrence of gallstones after dissolution by bile acid treatment has been estimated as up to 50% at 5 years. The efficacy of Ursofalk in treating radio-opaque or partially radio-opaque gallstones has not yet been tested but these are generally thought to be less soluble than radiolucent

stones. Non-cholesterol stones may not be dissolved by bile acids. These account for 10-15% of radiolucent stones. Obese patients may require a higher dose of Ursofalk for gallstone dissolution, for example up to 15 mg/kg daily. **Contra-indications, Warnings etc.** Like other bile acids, Ursofalk is absorbed from the intestine, passed to the liver, conjugated and excreted into the bile. Little information is available on the effects and tolerance of Ursofalk in the presence of hepatic damage or inflammatory bowel disease. The following drugs bind bile acids in vitro and may therefore interfere with absorption of Ursofalk - cholestyramine, charcoal, colestipol and certain antacids e.g. aluminium hydroxide. As with all but essential drugs the use of Ursofalk in early pregnancy is contra-indicated. (In the rabbit, but not in the rat, embryotoxicity has been observed). A product of this class has been found to be carcinogenic in animals. The relevance of these findings to the clinical use of UDCA has not been established. **Overdosage** Doses of up to 4 g UDCA/day have been used therapeutically. The compound is almost entirely excreted in the stool as UDCA or bacterial metabolites. Serious toxicity from a gross overdose is not to be expected although some looseness of the bowels may occur. **Pharmaceutical Precautions** Store in a cool dry place. **Legal Category** POM. **Package Quantity** Ursofalk 250 mg capsules in packs of 60. **Further Information** Many patients report a reduction in severity and frequency of biliary colic during bile acid treatment. **Product Licence Number** 4408/0001 **Basic NHS cost:** £28.00 for pack of 60 capsules.

Thames Laboratories Ltd

The Old Blue School, 5 Lower Square, Isleworth, Middlesex TW7 6RL.

Gastrozepin is a selective antimuscarinic agent which provides balanced control of gastric secretion without markedly affecting other peripheral receptor sites. This gastro-selective action means that, in practice, Gastrozepin is a well-tolerated drug which heals peptic ulcers.

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- profoundly affect intragastric pH

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- reduce antacid intake
- heal peptic ulcers with one 50 mg tablet b.d.

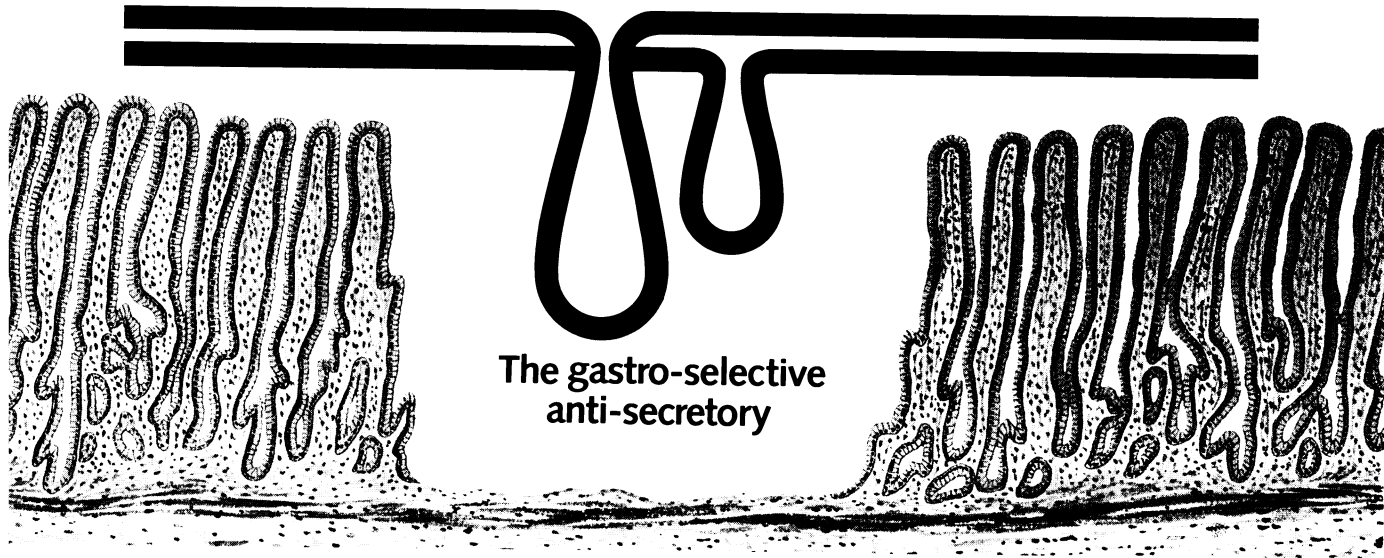
For the treatment of peptic ulcer

Twice daily


GASTRO SELECTIVE

Gastrozepin[®]


pirenzepine



The gastro-selective
anti-secretory

Prescribing Information; Presentation: White tablets each containing 50 mg of pirenzepine dihydrochloride scored on one face with "G" on one side of the score, and "50" on the other. The obverse is impressed with the symbol . **Uses:** Gastrozepin is indicated in the treatment of gastric and duodenal ulcers. **Dosage:** 50 mg at bedtime and in the morning before meals. In severe cases the total daily dose may be increased to 150 mg in divided doses. Continuous therapy may be recommended for up to three months. **Contra-indications, Warnings etc:** Interaction with sympathomimetics and monoamine oxidase inhibitors and Gastrozepin is a theoretical possibility. Gastrozepin is not recommended during pregnancy although in animal

experiments no teratogenic effects were noted. Breast milk concentration after therapeutic doses is unlikely to affect the infant. **Side effects:** occasionally transitory dry mouth and accommodation difficulty may occur. Treatment of overdosage: entirely symptomatic. There is no specific antidote. **Basic NHS price:** 50 mg tablets, 60 £20.50 **Product Licence No.:** 50 mg tablets, PL0034-0260

 Further information is available on request
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Nature Plays a Dual Role in the Management of Irritable Bowel Syndrome

1. With the natural goodness of high-fibre foods

The irritable colon is affected by the amount of fibre in the diet. It is known that diets rich in high-fibre foods tend to normalize the function of the colon, which can result in softer, bulkier stools and a decrease in patient discomfort. Thus, a high-fibre diet is often considered basic therapy in the management of IBS.



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Colpermin provides natural relief to help the irritable bowel regain normal function. It has a powerful antispasmodic effect that relieves abdominal pain.

It is a naturally occurring carminative that relieves flatulence and gaseous distension. Enteric-coated capsules deliver relief direct to the site of action in the distal small bowel.

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Presentation: Enteric-coated gelatine capsule. Each contains 0.2 ml standardised peppermint oil B.P. Ph. Eur. **Uses:** For the treatment of symptoms of discomfort and of abdominal colic and distension experienced by patients with irritable bowel syndrome. **Dosage and Administration:** One capsule three times a day, preferably before meals and taken with a small quantity of water. The capsules should not be taken immediately after food. The dose may be increased to two capsules, three times a day when discomfort is more severe. The capsules should be taken until symptoms

resolve, usually within one or two weeks. At times when symptoms are more persistent, the capsules can be continued for longer periods of between 2 to 3 months. There is no experience in the use of these capsules in children under the age of 15 years. **Contraindications, Warnings, etc. Precautions:** The capsule should not be broken or chewed. Patients who already suffer from heartburn, sometimes experience an exacerbation of these symptoms when taking the capsule. Treatment should be discontinued in these patients. **Adverse effects:** Heartburn, sensitivity

reactions to menthol which are rare, and include erythematous skin rash, headache, bradycardia, muscle tremor and ataxia. **Product Licence:** PL 0424/0009. **Basic NHS Cost:** £105.8 per 100. UK and Foreign Patents pending. Colpermin is a trade mark of Tillotts Laboratories. Further information is available from Tillotts Laboratories, Henlow Trading Estate, Henlow, Beds.

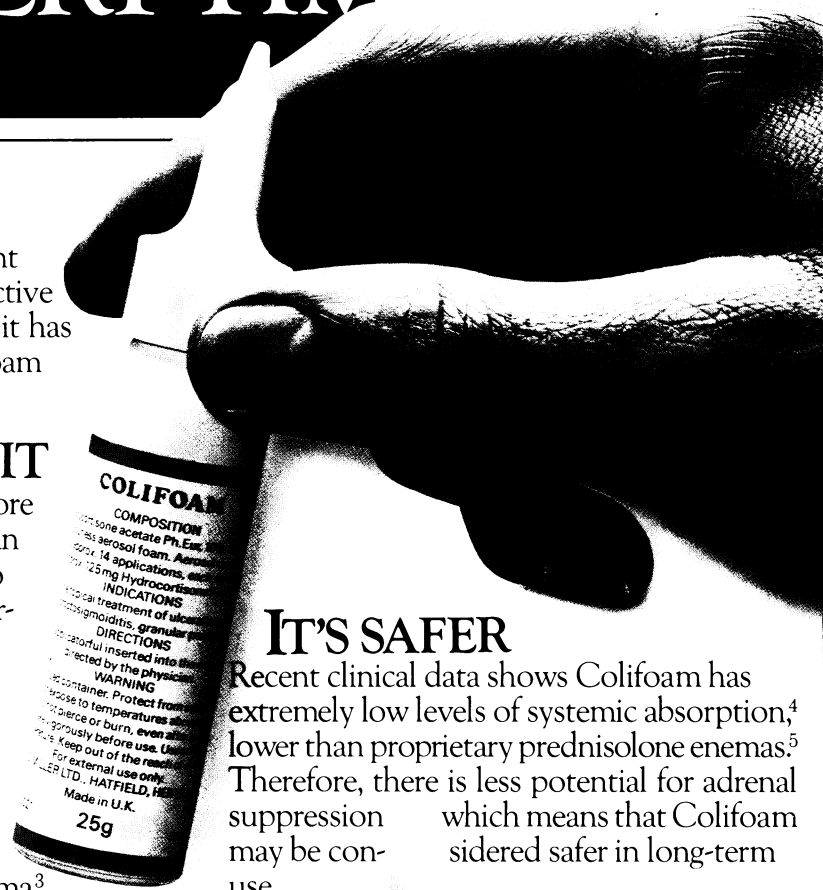
European Patent No. 0015334. UK Patent No. 2006011

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IT WORKS In the treatment of ulcerative colitis, Colifoam is as effective as steroid enemas. At the same time it has been shown that patients find the foam easier to retain.^{1,2}

PATIENTS PREFER IT Colifoam is far more comfortable, more convenient and more acceptable than enemas. Patients also find it easier to administer and that it causes less interference in their daily lives.

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COLIFOAM

hydrocortisone acetate foam

IN DISTAL INFLAMMATORY BOWEL DISEASE. A BETTER CHOICE EVERY TIME.

Presentation White odourless aerosol foam containing hydrocortisone acetate PhEur 1%. **Uses** Anti-inflammatory, corticosteroid therapy for the topical treatment of 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 every pack). Satisfactory response usually occurs within five to seven days. **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 above 50°C. Do not puncture or burn even after use. Do not refrigerate. Shake vigorously before use. Keep out of reach of children. For external use only. **Legal category POM. Package quantities** Aerosol canister, containing 25g (approx. 14 applications). **Basic NHS cost** 2.5g plus applicator, 17.42. **Further Information** One applicatorful of Colifoam provides a dose of approximately 12.5mg 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. **References** 1. Ruddell WSI, et al. *Gut* 1982; 21: 885-889. 2. O'Donoghue D. *Modern Medicine*, December 1981, 45. 3. Source: Mims. 4. Bar: WH, Kline B, Bengtson L, Zaas A. *Medical College of Virginia/Virginia Commonwealth University, FDA bioavailability submission document* October 1981. 5. Lee DAH, et al. *Gut* 1982; 21: 215-218. Further information is available on request. Stafford-Miller Ltd., Professional Relations Division, Hatfield, Herts. AL10 0NZ.

Gastro-technology

Tagamet

cimetidine

acid controlled

Prescribing Information. Presentations 'Tagamet' Tablets, PL 0002/0092, each containing 400 mg cimetidine. 56, £16.61. 'Tagamet' Tablets, PL 0002/0063, each containing 200 mg cimetidine. 500, £74.15. 'Tagamet' Syrup, PL 0002/0073, containing 200 mg cimetidine per 5 ml. 500 ml, £20.45. **Indications** Duodenal ulcer, benign gastric ulcer, recurrent and stomal ulceration, oesophageal reflux disease. Other conditions where reduction of gastric acid is beneficial: persistent dyspeptic symptoms, particularly meal-related; prophylaxis of stress-induced gastrointestinal haemorrhage and of acid aspiration (Mendelson's) syndrome; malabsorption and fluid loss in short bowel syndrome. Zollinger-Ellison syndrome. **Dosage Adults. Oral.** Usual dosage, 400 mg b.d. with breakfast and at bedtime, or, in duodenal ulcer, 800 mg once a day at bedtime. Alternatively 200 mg t.d.s. with meals and 400 mg at bedtime (1.0 g/day) or, if inadequate, 400 mg q.d.s. with meals and at bedtime (1.6 g/day). Treat for at least 4 weeks (6 weeks in benign gastric ulcer). To prevent relapse of peptic ulcer, 400 mg at bedtime or 400 mg morning and at bedtime. **Oesophageal reflux disease,** 400 mg t.d.s. with meals and 400 mg at bedtime (1.6 g/day) for 4 to 8 weeks. **Prophylaxis of stress-induced gastrointestinal haemorrhage,** up to 2.4 g a day, divided, to maintain intragastric pH above 4. **Prophylaxis of acid aspiration syndrome,** 400 mg 90-120 mins before induction of general anaesthesia; up to this dose repeated (parenterally if appropriate) as required if operation is prolonged. 400 mg at start of labour then 200 mg 2-hourly as necessary, suggested maximum 1.6 g. Do not use 'Tagamet' syrup. **Zollinger-Ellison syndrome,** 1.6 g or more a day, divided. **N.B.** Usual maximum 2.4 g/day. **For full dosage instructions see Data Sheet.** **Cautions** Impaired renal function: reduce dosage (see Data Sheet). Potentiation of oral anticoagulants, phenytoin and theophylline (see Data Sheet). Prolonged treatment: observe patients periodically. Potential delay in diagnosis of gastric cancer (see Data Sheet). Care in patients with compromised bone marrow (see Data Sheet). Avoid during pregnancy and lactation. **Adverse reactions** Diarrhoea, dizziness, rash, tiredness. Rarely, mild gynaecomastia, reversible liver damage, confusional states (usually in the elderly or very ill), interstitial nephritis, acute pancreatitis. **Legal category** POM. 11.5.84.

Smith Kline & French Laboratories Limited, Welwyn Garden City, Hertfordshire AL7 1EY. ©1984 Smith Kline & French Laboratories Limited. 'Tagamet' is a trade mark.

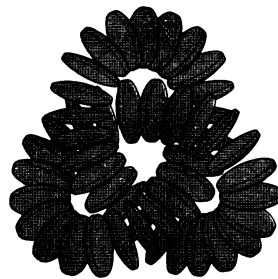
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SALAZOPYRIN[®] EN

sulphasalazine

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"Patients in whom sulfasalazine induces dyspeptic symptoms alone can be given EN Salazopyrin (entero-soluble) instead, and no more than 5% of these patients will be so troubled by dyspepsia that the treatment has to be discontinued."
Nielsen, O.H., Scand. J. Gastroenterol., 1982, 17, 389



Get them into the
SALAZOPYRIN habit
DAY AFTER DAY AFTER YEAR
500mg q.i.d. in ulcerative colitis

PRESCRIBING INFORMATION

Dosage and Administration Plain or EN Tabs: In acute/moderate attacks 2-4 tablets 4 times a day. In severe attacks give steroids also. Gradually reduce dose after 2-3 weeks to 3-4 tabs/day given indefinitely. Suppositories: Two morning and night reducing dose after 3 weeks with improvement. Enema: One to be given at bedtime. Preparation contains adult dose.

Children: Reduce adult dose on basis of bodyweight.
Contra-indications: Sensitivity to salicylates and sulphonamides. Infants under 7 years. Enema: Sensitivity to parabens.

Adverse Reactions Side effects common to salicylates or sulphonamides may occur. Most commonly these are nausea, loss of appetite and raised temperature which may be relieved on reduction of dose; use of EN tablets, enema or suppositories. If serious reactions occur the drug should be discontinued. **Rare Adverse Reactions** Haematological: haemolytic anaemia, agranulocytosis, aplastic anaemia. Hypersensitivity: eg rash, fever. Gastrointestinal: eg stomatitis, impaired folate uptake. C.N.S.: eg peripheral neuropathy. Fertility: eg reversible oligospermia. Renal: eg proteinuria, crystalluria. Also: Stevens-Johnson syndrome and lung complications: eg fibrosing colitis.

Precautions Care in porphyria, allergic renal or hepatic disease. Glucose 6-PD deficiency. Blood checks initially and periodically.

Pregnancy and Lactation While the ingestion of drugs in these situations may be undesirable, the severe exacerbations of the disease which can occur commends the continuance of therapy. Long clinical usage and experimental studies have failed to reveal teratogenic or other hazards. The amounts of drug present in the milk should not present a risk to a healthy infant.

Packages and Prices Plain Tablets (0.5g) 100 & 500; EN 70 for 100; EN Tablets (0.5g) 100 & 500; EN 70 for 100; Suppositories (0.5g) 10 & 50; £2.80 for 10; Enemas (3.0g) 7; £12.10 for 7.
Product Licence Numbers Plain Tablets 0009/5006; EN Tablets 0009/5007; Suppositories 0009/5008; Enema 0009/5009.



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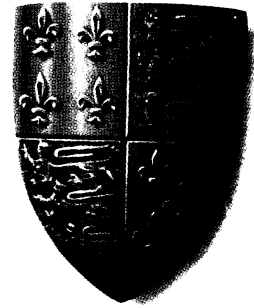
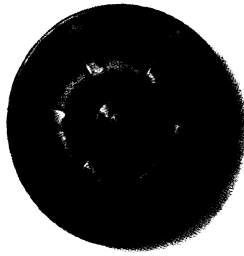
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Renaissance

Mediaeval Crusades



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Bodily defence still relies on shields

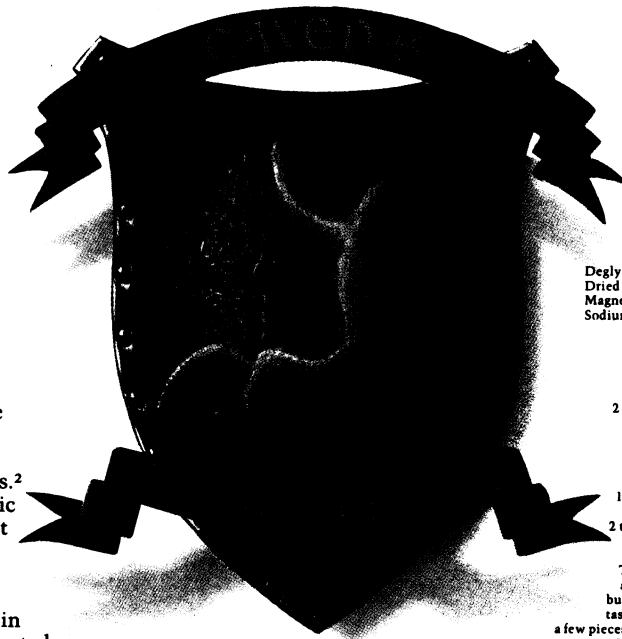
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An 88% healing rate in 12 weeks⁷ has been reported. Studies also confirm that CAVED-S offers comparable efficacy to cimetidine in healing gastric ulcers⁷ and comparable efficacy to ranitidine in healing duodenal ulcers.⁶

REFERENCES:

1. Van Marle J, Aarsen PN, Lind A, et al: Deglycyrrhizinised liquorice (DGL) and the renewal of rat stomach epithelium. *Eur J Pharmacol* 72:219-225, 1981. 2. Cooke WM, Baron JH: Metabolic studies of deglycyrrhizinised liquorice in two patients with gastric ulcer. *Digestion* 4:264-268, 1971. 3. Rees WDW, Rhodes J, Wright JE, et al: Effect of deglycyrrhizinised liquorice on gastric mucosal damage by aspirin. *Scand J Gastroenterol* 14:605-607, 1979. 4. Morgan RJ, Nelson LM, Russell RI, et al: The effect of deglycyrrhizinised liquorice on the occurrence of aspirin and aspirin plus bile acid-induced gastric lesions, and aspirin absorption in rats, abstracted.



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"The Mucosal Shield" for peptic ulcers



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PRESCRIBING INFORMATION

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Deglycyrrhizinised Liquorice 380 mg
Dried Aluminum hydroxide gel 100 mg
Magnesium carbonate 200 mg
Sodium bicarbonate 100 mg

Indications:
For the treatment of peptic ulcer and other allied conditions.

Dosage and Administration:

Adult dose for gastric ulcer:
2 tablets 3 times a day between meals.

Adult dose for duodenal ulcer:
Increase to 2 tablets 6 times a day between meals when necessary.

Prophylactic dose:

Gastric ulcer:
1 tablet 3 times a day, between meals.

Duodenal ulcer:
2 tablets 3 times a day, between meals.

Children's dosage 10-14 years:
half adult dose.

The tablets should be lightly chewed and swallowed with a drink of water, but in exceptional cases of objection to taste, the tablets should be broken into a few pieces and then swallowed with a drink of water. No additional antacids are necessary.

Contra-indications, warnings, etc:

Rare cases of mild diarrhoea can occur. No other side-effects have been reported.

Caved-S should be used with caution in pregnancy.

Basic NHS Price:

60's—£2.83

240's—£10.12

600's—£22.76

PL0424/5000.



Gastroenterology 82:1134, 1982. 5. Morris TJ, Calcraft BJ, Rhodes J, et al: Effect of a deglycyrrhizinised liquorice compound in the gastric mucosal barrier of the dog. *Digestion* 11:355-363, 1974. 6. McAdam WAP, Morgan AC, Pacao C, et al: A comparison between ranitidine and Caved-S in duodenal ulcer treatment, abstracted. Proceedings, World Congress of Gastroenterology, Stockholm, June 1982. 7. Morgan AC, McAdam WAP, Pacao C: Comparison between cimetidine and Caved-S in the treatment of gastric ulceration, and subsequent maintenance therapy. *Gut* 23:545-551, 1982.

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Prescribing Information Presentation: Blue/grey opaque hard gelatin capsules each containing 60 mg Alverine Citrate USNF XIII. **Uses:** Selective smooth muscle spasmolytic. **Dosage and administration:** Adults 1 or 2 capsules one to three times daily, orally. No specific dosage recommendations can be made for children. **Contra-indications, warnings, etc.:** Nil. **Pharmaceutical precautions:** Store in a cool dry place. **Legal category:** P. **Package quantities:** 100 capsules. **Basic NHS cost:** £6.98. **Further information:** Alverine citrate is a synthetic, non-narcotic, non-habit forming spasmolytic of a low order of toxicity in comparison with other anti-spasmodics. It is related to (but more than twice as active as) papaverine, and has a specific effect on the smooth muscle of the intestine and uterus, but not on those of the respiratory or cardiovascular system. **Product licence number:** 0322/5014. **References:** 1. Trotman, I.F. (awaiting publication). 2. Evangelista, I (1966) West. Med. 3, 49.

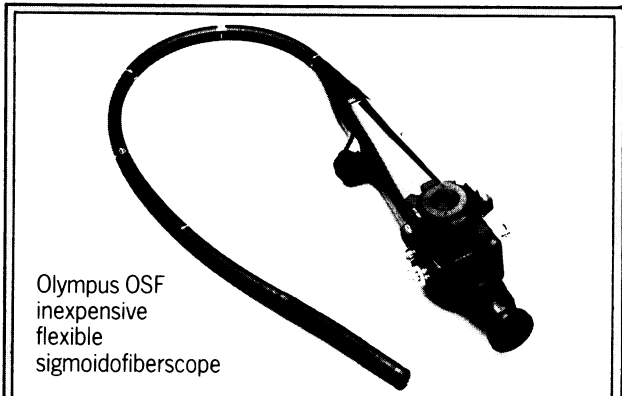
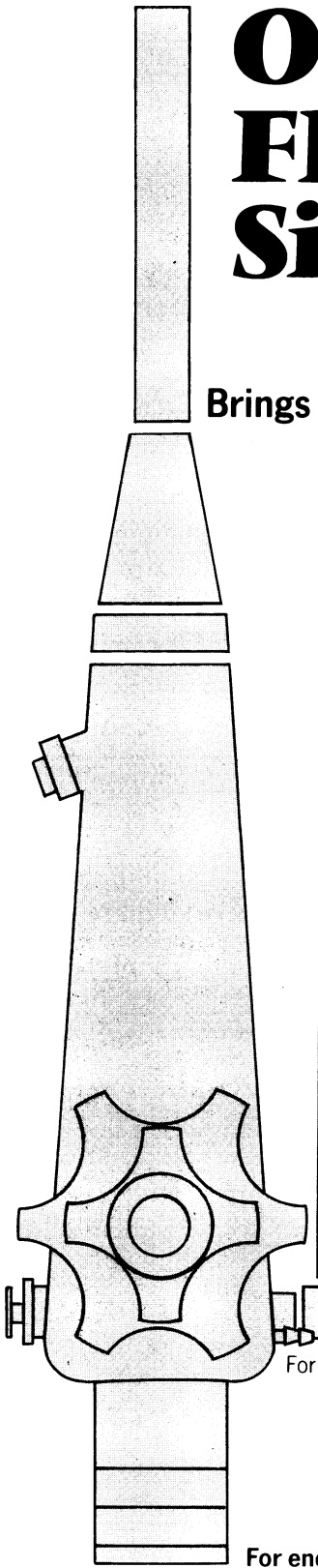


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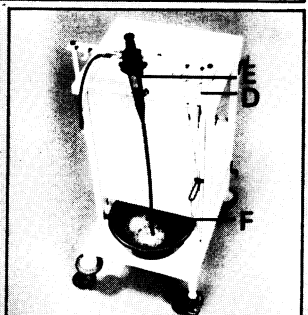
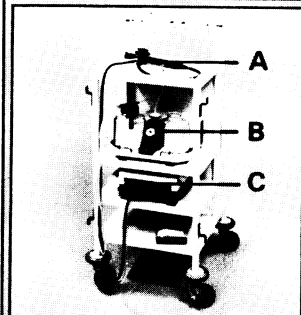
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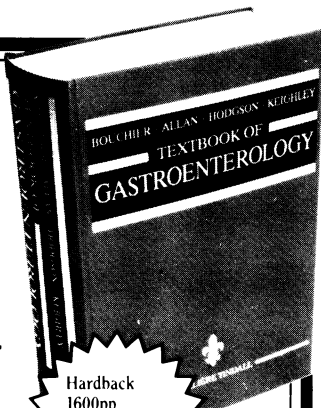
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