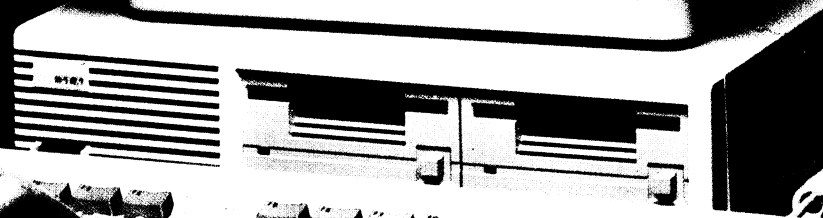
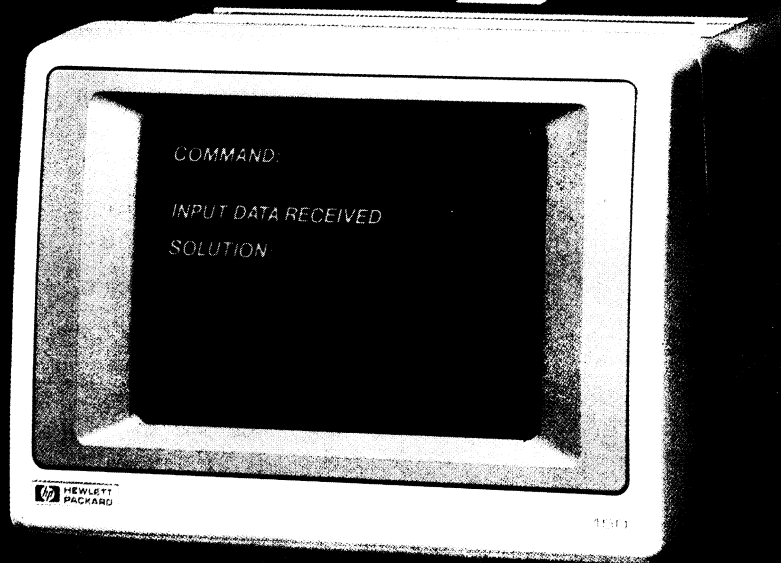


# In peptic ulcer therapy the search ends here

## INPUT DATA

- Effective ulcer healing
- Prolonged ulcer free period
- Rapid symptomatic relief
- Non-systemic mode of action
- Minimal incidence of side-effects and drug interactions



sucralfate

## Prescribing Information

**Presentation:** Antepsin Tablets 1 gram are white, oblong, biconvex, uncoated tablets scored and engraved 1239 on one side and Ayerst on the other. Each tablet contains 1 gram sucralphate, a basic aluminium salt of sucrose octasulphate. **Uses:** For the treatment of duodenal ulcer, gastric ulcer and chronic gastritis. **Dosage and Administration:** For oral administration. Adults - Usual dose 1 gram 4 times a day to be taken one hour before meals and at bedtime. Maximum daily dose 8 grams. Four to six weeks treatment is usually needed for ulcer healing but up to twelve weeks may be necessary in resistant cases. Antacids may be used as required for relief of pain, but should not be taken half an hour before or after Antepsin. Elderly - There are no special dosage requirements for elderly patients but as with all medicines the lowest effective dose should be used. Children - Safety and effectiveness in children have not been established. **Contra-Indications, Precautions, Warnings, etc.** **Contra-indications:** There are no known contra-indications. **Precautions:** 1. The product should only

be used with caution in patients with renal dysfunction. 2. Although animal reproductive studies show no evidence of foetal malformations, safety in pregnant women has not been established and Antepsin should be used during pregnancy only if clearly needed. 3. It is not known whether this drug is excreted in human milk. Caution should be exercised when Antepsin is administered to a nursing woman. **Drug Interactions:** Concomitant administration of Antepsin may reduce the bio-availability of certain drugs as has been observed in animal studies with tetracycline, phenytoin and cimetidine, and in human studies with digoxin. Administration of Antepsin with any of these drugs should be separated by two hours. Since Antepsin may hinder warfarin absorption, caution should be exercised when these two drugs are used together. **Side Effects:** A low incidence of mild side effects, e.g. constipation, has been reported. **Overdosage:** There is no experience in humans with overdosage. Acute oral toxicity studies in animals, however, using doses up to 12g/kg body weight, could not find a lethal dose. Risks associated with

overdosage should, therefore, be minimal. **Pharmaceutical Precautions:** No special requirements for storage are necessary. **Legal Category:** POM. **Package Quantities:** Antepsin 1 gram - Securifainers of 100. **Product Licence Numbers:** PL No. 0607/0045. PA No. 149/4/2. **Basic N.H.S. Price:** Average daily cost 50p.

\*ANTEPSIN is a registered trade mark  
Further information is available on request to the Company  
Date of preparation January 1985



Ayerst Laboratories Ltd.  
South Way, Andover, Hampshire SP10 5LT  
Telephone: Andover (0264) 58711  
Distributors in Ireland: Ayerst Laboratories Ltd.  
765 South Circular Road, Islandbridge, Dublin 8

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.

#### Gastrozepin DOES NOT . . .

- rely on acid reduction alone
- rely on pepsin reduction alone
- rely on mucosal protection alone
- profoundly affect intragastric pH

#### Gastrozepin DOES . . .

- relieve daytime pain
- relieve night-time pain
- reduce antacid intake
- heal peptic ulcers with one 50 mg tablet b.d.

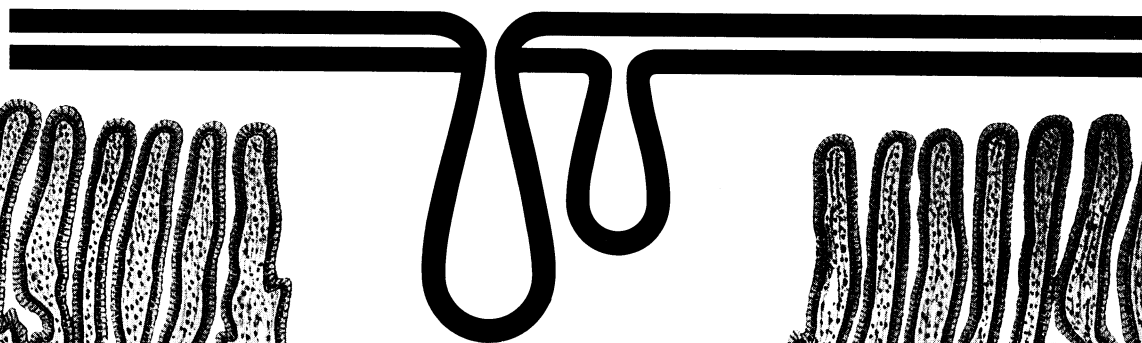
# For the treatment of peptic ulcer

Twice daily


GASTRO SELECTIVE

# Gastrozepin<sup>®</sup>


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, PL0014/0260.

 Further information is available on request  
The Boots Company PLC Nottingham

Gastrozepin<sup>®</sup> Trade Mark

# Concept and Evolution through Pilkington...



## ...UGI-3 Flexible Endoscope

Designed and built in Britain the UGI-3 Flexible Endoscope is the product of intense research and development. The result is an exceptional instrument with many advantageous characteristics more fully appreciable when in operation.

**\*Comfort and Ease of Use.** The latest developments in durable and lightweight materials have been applied throughout all stages of construction achieving a flexible, well-balanced instrument.

**\*Unique Bending Section.**

**\*Bright Imaging.** This allows clear visual examination and precise diagnosis.

**\*Compatible.** Suitable for most Cold Light Sources

produced by recognised manufacturers by using a simple adaptor and via its 2.8mm biopsy channel the UGI-3 will accept almost all makes of biopsy forceps, cleaning or cytology brushes and washing tubes.

**\*After Sales Service – Guaranteed.** †A replacement endoscope will be made available to you within 48 hours of notification should your instrument not perform to your complete satisfaction.

† Available to UK customers only



Typical photographs obtained through a UGI-3 using a 35mm SLR Camera and no-lens coupling.

You can obtain further information on the Pilkington UGI-3 Flexible Endoscopes by contacting the Medical Sales Division at the address below:



# PILKINGTON

◀ Medical Systems ▶

The Focus of Medical Technology.

A MAJOR NEW UK TRIAL  
COLIFOAM v PREDNISOLONE ENEMA

IMPORTANT  
NEW EVIDENCE



THE FINAL VERDICT

**PROVEN: Equal efficacy. PROVEN: Superior quality of life.**

Although much has been published on the comparative efficacy and patient acceptance of COLIFOAM, the literature has until now lacked a comparison against prednisolone enemas.

That study has now  
The verdict? COLI-  
FOAM is equal in efficacy  
to prednisolone enemas in  
the treatment of distal  
inflammatory bowel disease,  
but causes significantly less



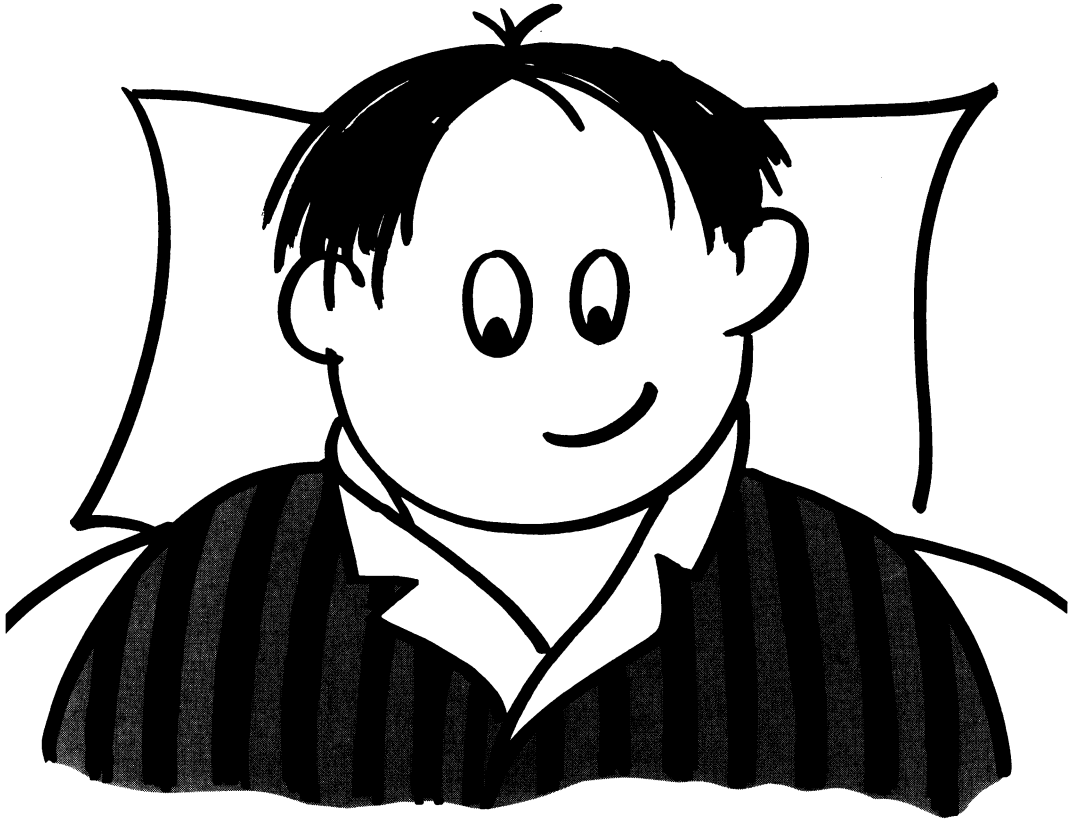
interference in patients' daily lives<sup>(1)</sup>.  
Analysis of the disturbance in social, sexual,  
occupational and routine outdoor activities all revealed  
statistically significant differences in favour of COLIFOAM.  
COLIFOAM is also easier to retain than  
steroid enemas<sup>(1,2,3)</sup>. Retro-  
grade spread has been shown  
to increase with the extent of  
disease<sup>(4)</sup> and COLIFOAM  
can reach well into the  
descending colon<sup>(5)</sup>.

**COLIFOAM**  
10% Hydrocortisone acetate foam

**In distal inflammatory bowel disease. A better choice every time.**

**References** (1) Somerville KW et al. British Medical Journal 1985;291:866. (2) Ruddell WSJ et al. Gut 1980; 21:885-889. (3) Gaucher P and Champignuelle B. Revue Française de Gastroenterologie 1983;193:35-39. (4) Farthing MGJ et al. British Medical Journal 1979; 2:822-824. (5) Rhodes JM. Journal of Clinical & Hospital Pharmacy 1983;8:219-232. **Prescribing Information. Presentation** White odourless aerosol foam containing hydrocortisone acetate PhEur 10%. **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 pierce 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) plus a plastic applicator and illustrated leaflet. **Basic NHS cost** 25g plus applicator, £7.25. **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. Further information is available on request. **Stafford-Miller Ltd.**, Professional Relations Division, Hatfield, Herts. AL10 0NZ.

# EASY EXAMINATIONS WITH NUBAIN\* ANALGESIA



- strong, effective non-MDA analgesic, suitable for use during endoscopy or colonoscopy and radiological and gynaecological investigations
- "ceiling" effect to respiratory depression reduces risks associated with opioid use<sup>1</sup>
- minimal effect on cardiac haemodynamics when used during catheterization<sup>2</sup>
- allows more accurate diagnosis of bile duct and gut obstructions due to minimal interference with function<sup>3</sup> and motility<sup>4</sup>



**NUBAIN\***  
nalbuphine hydrochloride

Effective, comfortable  
analgesia during clinical  
investigations

#### Prescribing Information

**Presentation:** Nubain\* Injection, 20mg of nalbuphine hydrochloride in 2ml ampoules.  
**Uses:** For the relief of moderate to severe pain.

**Dosage and Administration:** 10-20mg for a 70kg individual, adjusted according to the severity of pain, physical status of the patient and concomitant medications. Nubain is not recommended for children.

**Contra-indications:** Hypersensitivity to Nubain.

**Precautions and Warnings:** Use with care in known and potential opioid abusers.

Also care in active patients who may drive or operate machinery. Caution in patients with impaired respiration. Safety for use in myocardial infarction is not yet established. Caution and dose reduction in patients with impaired renal or hepatic function.

Safe use not established in pregnancy and in conditions of raised intracranial pressure. Abrupt discontinuation of chronic therapy may produce withdrawal symptoms.

**Side Effects:** The most frequent reaction is sedation. Also sweating, nausea, vomiting, dizziness, dry mouth, vertigo and headache and other opioid effects may occur.

**Product Licence No.:** 4524/0003. **NHS Price:** £11.60 per box of 10 x 2ml ampoules.

**References:** 1. Julien RM. Effects of nalbuphine on normal and oxymorphone - depressed ventilatory responses to carbon dioxide challenge. *Anaesthesiology* 1982; 57: No 3A. 2. Fahmy NR, Sunder N, Soter NA. A comparison of histamine releasing properties and hemodynamic effects of morphine and nalbuphine in humans. *Anesth Analg* 1984;63:175. 3. Vatahsky E, Haskel Y. The effect of nalbuphine (Nubain®) compared to morphine and fentanyl on common bile duct pressure. *Curr Ther Res* 1985;37:1:95-102. 4. Shah M, Rosen M, Vickers MD. Effect of premedication and diazepam, morphine or nalbuphine on gastrointestinal motility after surgery. *Br J Anaesth*. 1984;56: 1235-8. Further information is available on request from Du Pont (UK) Limited, Pharmaceuticals, Wedgwood Way, Stevenage, Hertfordshire SG1 4QN. Telephone: (0438) 734549.

Nubain\* is a registered trade mark of E.I. du Pont de Nemours and Co. Inc.

Du Pont Pharmaceuticals 

# HEALING POWER WHEN IT'S NEEDED MOST IN DUODENAL ULCER



Acid attack at night is now known to be one of the most important factors in the formation of duodenal ulcers.

'Tagamet' 800 mg at bedtime effectively controls this damaging nocturnal acid without disturbing the patient's normal daytime gastric physiology.

One 'Tagamet' 800 mg tablet at bedtime for four weeks is the recommended healing regimen for all duodenal ulcer patients.

And the results are impressive. . .  
'Tagamet' 800 mg completely healed 79 per cent

of duodenal ulcers in four weeks and 96 per cent in eight weeks<sup>1</sup> whilst providing prompt and effective relief from both daytime and night-time pain.

With 'Tagamet' 800 you can offer your patients healing power precisely when it's needed.

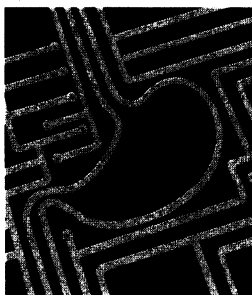
## **TAGAMET** **CIMETIDINE 800**

### One tablet at bedtime for four weeks

**Reference** 1. Lambert R. In: 'Tagamet'. New Dimensions. A Symposium Proceedings. XII Int Cong Gastroenterol, Lisbon, 1984;15-23.

**Prescribing Information. Presentations** 'Tagamet' Tablets, each containing 800 mg cimetidine (PL 0002/0128: 28 tablets, £15.78) or 400 mg cimetidine (PL 0002/0092: 56 tablets, £16.61). 'Tagamet' Syrup, containing 200 mg cimetidine per 5 ml (PL 0002/0073: 500 ml, £19.20).

**Indication** Duodenal ulcer. **Dosage Usual dosage: Adults.** Duodenal ulcer, 800 mg once a day at bedtime, or 400 mg b.d. with breakfast and at bedtime. To prevent relapse, 400 mg at bedtime or 400 mg morning and at bedtime. **Elderly:** As above unless markedly impaired renal function. **N.B. 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. Gynaecomastia, occasional reversible liver damage, confusional states (usually in the elderly or very ill). Very rarely interstitial nephritis, acute pancreatitis, thrombocytopenia, headache, myalgia, arthralgia; very rare reports of alopecia, reversible impotence but no causal relationship established at usual therapeutic doses. **Legal category** POM. 4.3.85. Smith Kline & French Laboratories Limited, Welwyn Garden City, Hertfordshire AL7 1EY. © 1985 Smith Kline & French Laboratories Limited. 'Tagamet' is a trade mark.

**SK&F** 

**NEW**

ANNOUNCING

**ASACOL™**  
**(MESALAZINE)**

**“This preparation is an  
important advance in the  
management of colitis since it  
may be given to patients unable  
to take sulphasalazine. . . .”<sup>1</sup>**

For full prescribing information see overleaf



**NEW**

# ASACOL™

(MESALAZINE)

**For the maintenance of remission in patients with ulcerative colitis who cannot tolerate sulphasalazine.**

Asacol delivers only 5-amino salicylic acid and is effective in maintaining clinical remission in patients with ulcerative colitis<sup>1</sup>.

Asacol provides efficacy comparable to sulphasalazine, but with considerably less side effects<sup>3</sup>.

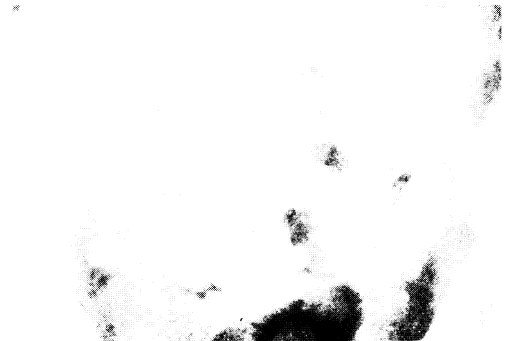
Asacol tablets have a patented acrylic-based resin coating that enables them to remain intact until all the active ingredient is released in the colon<sup>2</sup>.

Asacol is specifically recommended for ulcerative colitis patients who have difficulty tolerating sulphasalazine.

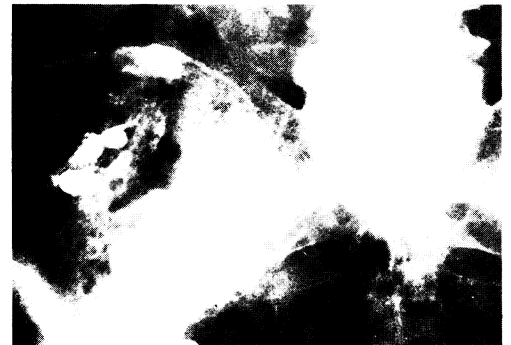
Mesalazine is the British approved name for 5-amino salicylic acid.

**References:**

1. Dew MJ, Hughes P, Harries AD, et al. Maintenance of remission in ulcerative colitis with oral preparation of 5-aminosalicylic acid. *Br Med J* 285;1012-1014, 1982.
2. Dew MJ, Hughes PJ, Lee MG, et al. An oral preparation to release drugs in the human colon. *Br J Clin Pharmacol* 14:405-408, 1982.
3. Dew MJ, Harries AD, Evans BK, Rhodes J, et al. Treatment of ulcerative colitis with oral 5-aminosalicylic acid in patients unable to take sulphasalazine. *The Lancet* October 1, 1983 p.801.



Radiograph taken five hours after convalescent patients ingested Asacol in capsule form containing barium, showing them to be intact in the terminal ileum.<sup>2</sup>



Radiograph of the same patient after eight hours, showing broken capsules in the ascending colon.

**ABBREVIATED PRESCRIBING INFORMATION**

**PRESENTATION**

Red tablets containing 400mg of mesalazine (5 amino salicylic acid) coated for release in the terminal ileum and colon.

**USES**

For the maintenance of remission of ulcerative colitis in patients who cannot tolerate sulphasalazine.

**DOSEAGE AND ADMINISTRATION**

*Adults:* 3 to 6 tablets daily in divided doses  
There is no dose recommendation for children.

**CONTRA-INDICATIONS, WARNINGS, ETC.**

**Contra-indications**

Contra indications: a history of sensitivity to salicylates. Children under 2 years of age

**Precautions**

Renal disorder. Mesalazine is excreted rapidly by the kidney mainly as its metabolite, N acetyl 5 amino salicylic acid. In rats large doses of mesalazine injected intravenously

produce tubular and glomerular toxicity. Although no renal toxicity has been reported in patients taking Asacol, it is not recommended in patients with renal impairment and caution should be exercised in patients with a raised blood urea or proteinuria.

Asacol should not be given with lactulose or similar preparations which lower stool pH and may prevent release of mesalazine.

**Adverse Reactions**

Adverse reactions occur in a small proportion of patients who previously could not tolerate sulphasalazine. The side effects are predominantly gastrointestinal (nausea, diarrhoea and abdominal pain) and headache. Asacol may be associated with the exacerbation of the symptoms of colitis in those patients who have previously had such problems with sulphasalazine.

Other side effects observed with sulphasalazine such as depression of bone marrow and of sperm count and function, have not been reported with Asacol.

**LEGAL CATEGORY: POM**

PL: 0424 / 0032

Basic NHS Price: £21.85 / 100 tablets

U.K. Patent No. 8322387



Henlow Trading Estate, Henlow, Beds. SG16 6DS.



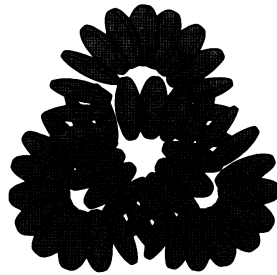
# SALAZOPYRIN<sup>®</sup> EN

sulphasalazine

# HAS TOLERABILITY ALL WRAPPED UP

"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 indelimitely. 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 2 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 alveolitis.

**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. £6.70 for 100. EN Tablets (0.5g) 100 & 500. £8.70 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.

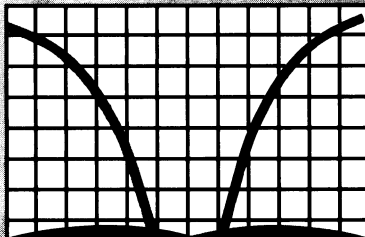
 **Pharmacia**

Further information is available on request  
Pharmacia Limited, Pharmacia House  
Midsummer Boulevard, Milton Keynes MK9 3HP  
Telephone Milton Keynes (0908) 661101

# DE-NOL REBALANCES THE ULCER EQUATION

- Local cytoprotective action.
- As effective as the H<sub>2</sub> antagonists.
- Lower relapse rates than H<sub>2</sub> antagonists.
- Heals 85% of H<sub>2</sub> antagonist failures.
- Favours lower relapse rates in smokers.

Key factor  
Mucosal  
Defence



Key factor  
Acid Secretion

The inescapable equation of ulcer aetiology Acid Attack v. Mucosal Defence remains the basis for our understanding of peptic ulcer. With an ulcer the acid side of the equation gains the upper hand, although it is now clear that this is more often a result of poor mucosal resistance than excessive acid secretion. An agent which enhances the mucosal defence mechanism should be the treatment of choice. The approach to ulcer therapy should thus be based on the truism:

**NO MUCOSAL BREAKDOWN,  
NO ULCER.**

## De-Nol

### Prescribing Information De-Noltab and De-Nol

**Presentation:** De-Noltab is presented as flat round pink tablets, each tablet containing 120mg tri-potassium di-citrate bismuthate (calculated as Bi<sub>2</sub>O<sub>3</sub>). De-Nol is presented as a clear red liquid in a 560ml bottle containing 120mg tri-potassium di-citrate bismuthate (calculated as Bi<sub>2</sub>O<sub>3</sub>) in each 5ml. **Uses:** Ulcer healing agent. For the treatment of gastric and duodenal ulcers. **Dosage and administration:** By oral administration. Each tablet is to be crushed in the mouth and swallowed with a draught of water. Each dose of the liquid presentation is to be diluted with 15ml of water. **ADULTS:** One tablet or 5ml dose four times a day on an empty stomach, half an hour before each of the three main meals and two hours after the last meal of the day. The treatment course should be taken for the full 28 day period and it is important that a dose is not missed. If necessary, one further course of therapy may be given. Maintenance therapy with De-Noltab/De-Nol is not indicated. **CHILDREN:** As for adults. **Contra-indications, Warnings, etc:** De-Noltab and De-Nol should not be administered to patients with renal disorders, and on theoretical grounds the products are contra-indicated in pregnancy. **SPECIAL PRECAUTIONS:** De-Noltab and De-Nol may inhibit the efficacy of orally administered tetracyclines. **SIDE EFFECTS:** Blackening of the stool usually occurs. Darkening of the tongue, nausea and vomiting have been reported. **OVERDOSAGE:** No reports of overdosage have been received; gastric lavage and, if necessary, supportive therapy would be indicated. **Pharmaceutical precautions:** Normal pharmaceutical storage and handling are indicated. **Legal category:** P. **Package quantities:** DE-NOLTAB: Foil treatment packs of 112 tablets. DE-NOL: Treatment packs of 560ml. **Basic N.H.S. Price:** De-Noltab £15.84. De-Nol £10.31. **GMS Price (Ire):** De-Noltab IR£20.99. De-Nol IR£13.66. **Further information:** Some patients with an associated gastritis may experience an initial discomfort whilst taking De-Nol liquid. Milk should not be drunk by itself during the course of treatment as this can prevent the medicine from working properly. Small quantities of milk on a breakfast cereal or in tea or coffee taken with meals are permissible. Antacids should not be taken for half an hour before or half an hour after taking a dose of De-Noltab/De-Nol as these can interfere with the action of the drug. **Product Licence Numbers:** De-Noltab: 0166/0102. De-Nol: 0166/5024. **Product Authorisation Numbers:** De-Noltab: 62/22/1. De-Nol: 62/23/1.

# MATERIAL BENEFITS-NOW AND FOR THE FUTURE.

Many major hospitals are putting the absorbable suture of the future into their operating rooms. They have created a new standard for absorbable sutures. PDS (Polydioxanone) is the standard for absorbable sutures. A major reason for this is that PDS sutures are made from a synthetic absorbable material. PDS sutures are made from a synthetic absorbable material. PDS sutures are made from a synthetic absorbable material.

**SYNTHETIC ABSORBABLES FROM ETHICON**  
The future of surgical sutures

**ETHICON**  
(Ethicon 910)

**PDS**  
(Polydioxanone)

**ETHICON\***  
a **Johnson & Johnson** company

ETHICON Ltd., P.O. Box 408, Bankhead Avenue, Edinburgh EH11 4HE,  
Scotland.  
\*Trademark © ETHICON Ltd 1985.



## TECHNICAL DATA

### DATA SHEET

## PDS\* (Polydioxanone) Sterilised Absorbable Synthetic Monofilament Suture

#### Presentation

PDS (Polydioxanone) Monofilament Synthetic Absorbable Suture is prepared from the polyester poly (p-dioxanone). The empirical molecular formula of the polymer is  $(C_8H_{12}O_4)_n$ . PDS (Polydioxanone) sutures are coloured by adding D & C blue No 6 (gauge 0.2 metric and 0.3 metric) D&C violet No 2 (gauge 0.4 metric to 5 metric) during polymerisation. These sutures may also be manufactured undyed (clear).

PDS (Polydioxanone) sutures are relatively inert, non-antigenic, non-pyrogenic and elicit only a mild tissue reaction during absorption.

#### Action

Two important characteristics describe the in vivo behaviour of absorbable sutures. The first of these is tensile strength retention and the second absorption rate or loss of mass.

Data obtained from implantation studies in rats show that, at two weeks post implantation, approximately 70% of the suture strength is retained whilst at four weeks the strength retention is approximately 50%. At eight weeks approximately 14% of the original strength remains. *This indicates a significantly longer period of wound support than previously available with an absorbable suture.*

The absorption or loss of mass is minimal until about the 90th post implantation day and is essentially complete within six months.

#### Uses

PDS (Polydioxanone) monofilament sutures are intended for use where an absorbable suture or ligature is indicated. They may have particular application where longer wound support is required. See strength retention data above.

#### Dosage and Administration

By implantation.

#### Contra-indications, Warnings, etc.

These sutures, being absorbable, should not be used where extended approximation of tissues under stress is required.

As with all monofilament synthetic sutures, care should be taken to ensure proper knot security.

Conjunctival, cuticular and vaginal mucosal sutures could cause localised irritation if left in place for longer than 10 days and should be removed as indicated. Superficial placement of subcuticular sutures may also be associated with erythema and reaction during the course of absorption.

The safety and effectiveness of PDS (Polydioxanone) sutures in neural and cardiovascular tissue have not yet been established. The use of this material in the renal tract is currently under investigation.

#### Pharmaceutical Precautions

Do not re-sterilise.

#### Legal Category P

Pharmacy medicine sold to surgeons and hospitals through surgical dealers.

#### Packaging

The gauge range available will be 0.3 metric (9/0) to 5 metric (2). Various lengths of material attached to non traumatic stainless steel needles are packaged in sealed aluminium foil sachets.

The primary pack is sealed within a peel-apart secondary pouch and contained in a film-wrapped drawer style carton.

#### Further Information

No suture related adverse reactions were reported during clinical trials, although a number of minor reactions were classified as being of unknown cause.

Product Licence Nos PL 0508/0011 (dyed); PL 0508/0012 (clear).

Br Pat No 1 540 053.

*Date of preparation of Data Sheet—September 1982.  
Revised 1/1985.*

### DATA SHEET

## Coated VICRYL\* (Polyglactin 910) Sterilised Absorbable Synthetic Braided Suture

#### Presentation

The basic VICRYL (Polyglactin 910) Suture is prepared from a copolymer of glycolide and lactide. The substances are derived respectively from glycolic and lactic acids. The empirical formula of the copolymer is  $(C_2H_2O_2)_m(C_3H_4O_2)_n$ .

Coated VICRYL (Polyglactin 910) Sutures are obtained by coating the braided suture material with a mixture composed of a copolymer of glycolide and lactide and an equal amount of calcium stearate. This coating does not affect the biological properties of the suture.

Coated VICRYL (Polyglactin 910) Sutures are coloured by adding D & C Violet No 2 during polymerisation of the lactide and glycolide. Suture may also be manufactured in the undyed form.

These sutures are relatively inert, nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption.

#### Action

Two important characteristics describe the in vivo behaviour of absorbable sutures. The first of these is tensile strength retention and the second, absorption rate.

Subcutaneous tissue implantation studies of Coated VICRYL Suture in rats show at two weeks post-implantation approximately 55% of its original tensile strength remains, while at three weeks approximately 20% of its original strength is retained.

Intramuscular implantation studies in rats show that the absorption of these sutures is minimal until about the 40th post-implantation day. Absorption is essentially complete between the 60th and 90th days.

#### Uses

Coated VICRYL synthetic absorbable sutures are intended for use where an absorbable suture or ligature is indicated.

#### Dosage and Administration

By implantation.

#### Contra-indications, Warnings, etc.

These sutures, being absorbable, should not be used where extended approximation of tissue under stress is required.

Sutures placed in skin and conjunctiva may cause localised irritation if left in place for longer than 10 days and should be removed as indicated.

The safety and effectiveness of Coated VICRYL (Polyglactin 910) Sutures in neural tissue and in cardio-vascular tissue have not been established.

#### Pharmaceutical Precautions

Do not re-sterilise.

#### Legal Category P

Pharmacy medicine sold to surgeons and hospitals through surgical dealers.

#### Package Quantities

Various lengths of material packaged in sealed aluminium foil sachets. This primary pack is contained in a peel-apart secondary pack. The unit of sales is 12 packs contained in a film wrapped drawer style carton.

#### Further Information

No suture related adverse reactions were reported during clinical trials, although a number of minor reactions were classified as being of unknown cause.

Product Licence No PL 0508/0009  
Br. Pat. No. 1583390

*Date of preparation of Data Sheet - April 1981.  
Revised 1/1985.*

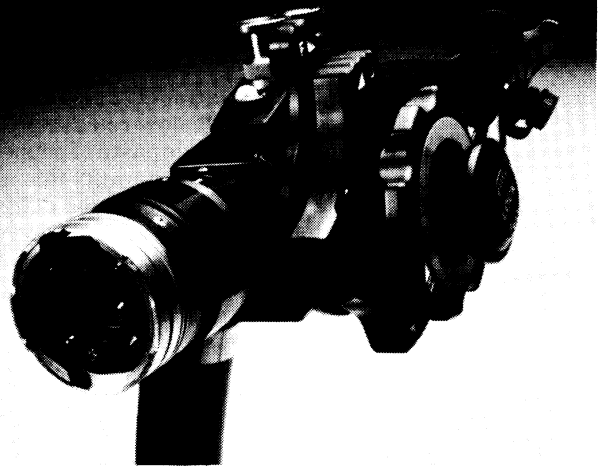
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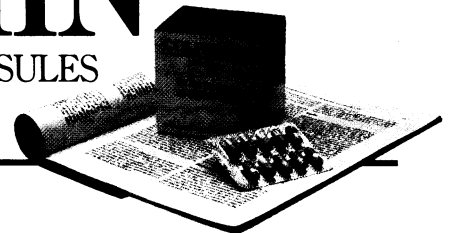
- A delayed-release preparation, Colpermin reaches the colon in an unmetabolised state, allowing it to effectively reduce colonic motility.<sup>2</sup>

- Recent ultrasound studies show a consistent inhibitory effect of topical peppermint oil on colon motility and symptomatic improvement of irritable bowel patients given peppermint oil.<sup>3</sup>

#### References:

1. Rees WDW, Evans BK, Rhodes J: Treating irritable bowel syndrome with peppermint oil. *Br Med J* 2:835-836, 1979.
2. Somerville KW, Richmond CR, Bell GD: Delayed release peppermint oil capsules (Colpermin) for the spastic colon syndrome: A pharmacokinetic study. Proceedings of the British Pharmacological Society, Cambridge, April 1983. *Br J Clin Pharmacol*, to be published.
3. Taylor BA, Duthie HL, Oliveira RB, et al: Ultrasound used to measure the response of colonic motility to essential oils. Proceedings of *The International Motility Symposium Aix-en-Provence, France, September 1983*, to be published.

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#### PRESCRIBING INFORMATION

**Presentation:** Enteric-coated gelatin 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:** £10.58 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.** 00153334. **UK Patent No.** 2006011.

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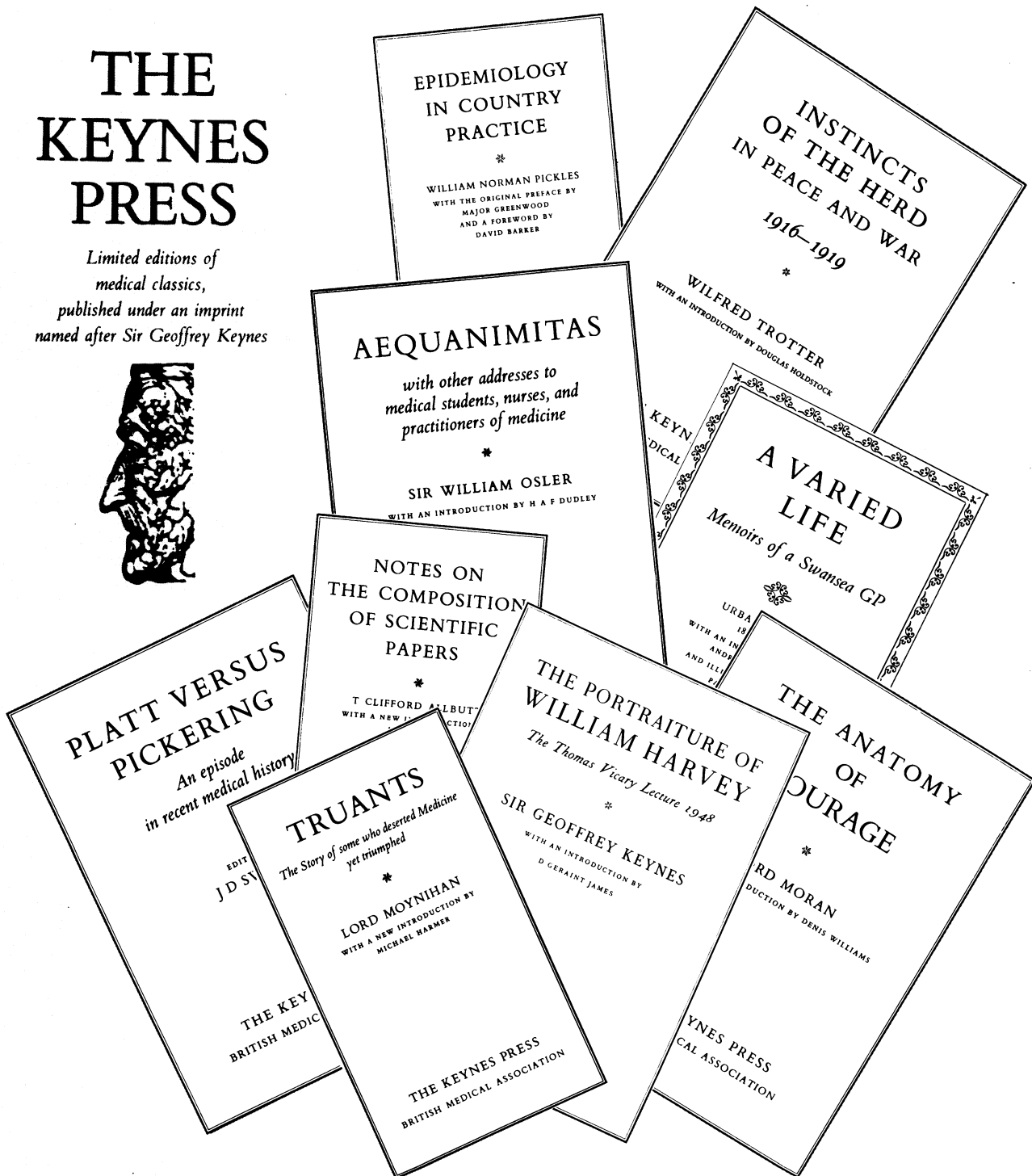


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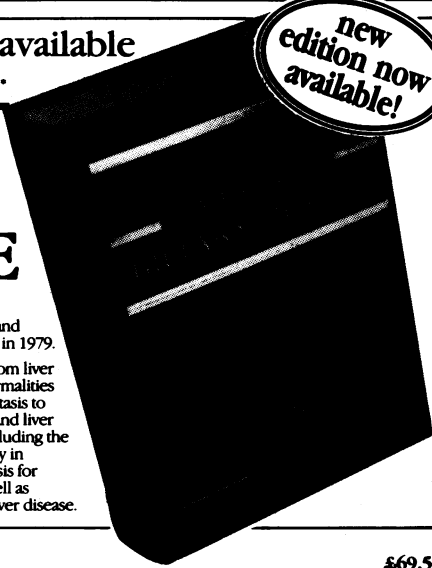
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