

TON MAINTA

It is well recognised that duodenal ulceration is peculiarly susceptible to relapse and that such relapse occurs at a frequency irrespective of type, or use, of pharmacological agents that may have promoted initial remission. Generally speaking, it is more difficult to maintain remission than it is to induce it. In fact. it has been estimated that 75-80% of duodenal ulcer patients will have at least one relapse within five years of the initial episode! with some patients relapsing several times in one

Thus great interest has centred on the long-term usage of 'Tagamet' as a means of extending remission times. Trials have now been published2-4 that emphasise how "Tagamet' - the only drug proven to reduce the frequency of relapse - can be of use in such an application.

'Tagamet' 90.5% of patients remained in remission



Overall results from clinical trials² have shown that over 90% of the 379 'Tagamet'treated patients remained in remission

compared with 50.1% of the 411 placebo-treated patients.

The mean duration of treatment in the "Tagamet' group was approximately 6.3 months at a dosage of 400 mg nocte or 400 mg bd.

Symptomatic relief, reduction in gastric acid output, were maintained and ulcer recurrence significantly reduced²⁻⁴ Equally important, extensive monitoring for haematological, clinical and biochemical effects revealed no factors in these trials which are likely to limit the general use of 'Tagamet' for longer term treatment at the recommended dosage? Furthermore, over 21/2 million patients have now been treated with 'Tagamet'; reports of adverse reactions received by SK&F follow a generally similar pattern to that reported in clinical trials.

Thus the patient may be usefully maintained in remission with the concomitant advantages of general well-being and ability to conduct an active working life. In fact in one study3 there was a significant difference in the number of working days lost between the 'Tagamet' and placebo groups.

'Tagamet' 2.8 days per patient/year

placebo 49.3 days per patient/year

A synopsis of how 'Tagamet' can be successfully applied to long-term ulcer management is available on request.

Prescribing Information Presentations

Presentations
Tagamet' Tablets PL0002/0063 each containing
200mg cimetidine 100. £14.29.500. £70.00.
Tagamet' Syrup PL0002/0063 containing 200mg
cimetidine per 5ml syrup 200ml. £6.29

Indication
Duodenal ulcer

Dosage
Adults 200mg tds with meals and 400mg at bedtime (10g/day) for at least 4 weeks (for full instructions see Data Sheet)

To prevent relapse, 400mg at bedtime or 400mg morning and evening for at least 6 months

Cautions

Impaired renal function: reduce dosage (see Data Sheet). Prolonged treatment: observe patients periodically. Avoid during pregnancy and lactation.

Adverse Reactions

Diarrhoea, dizziness or rash, usually mild and transient tiredness Rarely mild gynaecomastia or evidence of reversible liver damage.

- References
 1 The Natural History of Duodenal Ulcer
 Disease (1976) Surg Clin N Amer. 56, 1235
 2 Cimetidine Treatment in the Management of
 Chronic Duodenal Ulcer Disease. (1978)
- Chronic Duorenal Urier Disease, (1878)
 Topics in Gastroenterology, (In Presses, 1878)
 3. Maintenance Treatment of Recurrent Peptic
 Ulcer by Cimetidine (1978) Lancet, i, 403.
 4. Prophylactic Effect of Cimetidine in
 Duodenal Ulcer Disease. (1978) Brit. med. J.
 i, 1095.



Full prescribing information is available from



Smith Kline & French Laboratories Limited Welwyn Garden City, Hertfordshire AL7 1EY Telephone: Welwyn Garden 25111

agamet' is a trade mark Smith Kline & French Laboratories Limited 1978

INTRALIPID* 10% INTRALIPID* 20%

Presentation

A milky-white oil in water emuls or Intralipid contains fractionated sova pears oil 10% or 20% emulsified with fractionated egg legithin at nH 7 It also contains

Indications: Intralipid fat emuisions are indicated in conditions of severe depletion requiring also a high energy intake to compensate for excessive loss of calories following trauma, infection, fever, burns, etc

Dosage and Administration

500ml, daily in conjunction with intravenous amino acids are administered by slow intravenous infusion

Infant dosage: Intralipid IO^a - or 2O^as: I5-20ml, per kg. body weight in 24 hours

Contra-indications

Intralipid is contra-indicated in pathalogica hyperlipaemia and severe liver damas-

Pharmaceutical Precautions

No drugs should be added to Intralipid prior to or during infusion

Package Quantities

£2.75, £6.50

Intralipid 10% Product Licence, 003 Intralipid 10% Product Licence, 2022, 2023 Intralipid 20% Product Licence, 2022, 2028

VAMIN* GLUCOSE

Clear, straw-coloured solutions for intravenous use containing all essential amino acids, and a balanced mixture of non-essential amino-acids in each 1,000ml. (pH 5.2) Carbohydrate, as glucose (100g-1), has been added as an energy source. Electrolytes are present, but these may need supplementing according to patient needs. Nitrogen per litre: 9.4g, corresponding to about 60g, of first-class protein. Caloric content per litre: 650 Kcal., of which 410 Kca

Vamin Glucose is indicated in conditions of protein depletion where oral or intragastric feeding is impossible or impracticable

Dosage and Administration

are provided by glucose

Depending on the individual protein require ment, 0.5-2.0 litres intravenously per day.

Infant dosage: 30-40ml, per kg. body weight in 24 hours.

Contra-indications, Warnings, etc.

Irreversible liver damage and seve uraemia when dialysis facilities are not available. Care should be taken when administering this solution to diabetic

Side effects: As with all hypertonic infusion solutions, thrombophlebitis may occur when peripheral veins are used.

Package Quantities

Bottles of 100ml, 500ml, and 1,000ml

NHS price:

£2.50, £6.75, £12.50

Product Licence 0022 10030

*Additives contain electrolytes, trace elements. fat soluble vitamins and water soluble vitamins for adults and children







When you start to think about IV feeding...

......make sure its complete and balanced, like a normal healthy diet. Intralipid and Vamin provide all the calories, all the essential fatty acids and all the nitrogen required for anabolism and recovery.

In addition there is now a range of additives specially tailored to meet the other nutritional requirements - vitamins, electrolytes and trace elements.



NOW AVAILABLE - ADDITIVES*



the only nutritionally-complete recovery builders.

NEW

for positive healing and relief of symptoms of oesophageal ulcers, erosions and oesophagitis

PYROGASTRONE

PROTECTS against gastric and bile reflux

RELIEVES symptoms of reflux oesophagitis

HEALS by local actions of carbenoxolone

Chewable Pyrogastrone tablets form a viscous alginate-antacid foam which soothes the mucosa, protects it from reflux, exerts a buffering effect against regurgitated acid and alkali, and helps to localise the action of low-dose carbenoxolone, the healing component.



In a recent study¹ Pyrogastrone was shown to give significantly better relief of symptoms of oesophagitis and healing of oesophageal ulcers than an alginate-antacid control containing no carbenoxolone*.

Each chewable, strawberry flavoured tablet contains carbenoxolone sodium B.P. 20mg, magnesium trisilicate B.P. 60 mg and dried aluminium hydroxide gel B.P. 240mg in a base containing alginic acid B.P.C. 600mg and sodium bicarbonate B.P. 210mg.

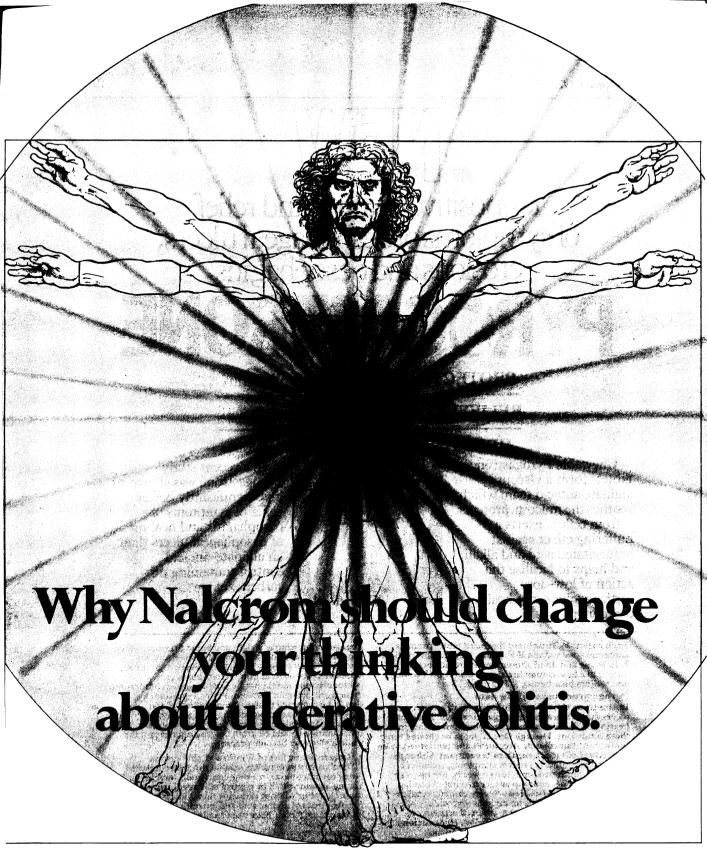
Pvrogastrone prescribing data

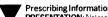
Indications Oesophageal inflammation, erosions and ulcers due to hiatus hernia or gastric reflux. Relief of heartburn, flatulence and other symptoms arising from these conditions. Dosage One tablet to be chewed three times daily immediately after meals and two tablets to be chewed at bedtime. Length of treatment Although Pyrogastrone quickly relieves symptoms, treatment should be continued for at least 6 weeks, but up to 12 weeks may be necessary to ensure maximum healing effect. Contra-indications Severe cardiac, renal or hepatic failure. Patients on digitalis glycosides (unless serum electrolyte levels are monitored regularly to detect development of hypokalaemia). Precautions Special care should be exercised with patients predisposed to sodium and water retention, potassium loss and hypertension (e.g. the elderly and those with cardiac, renal or hepatic disease) since the carbenoxolone content of Pyrogastrone can induce similar changes.

Regular monitoring of weight and blood pressure, which should indicate the development of such effects, is advisable for all patients. A thiazide diuretic should be administered if oedema or hypertension occurs (spironolactone should not be used because it hinders the therapeutic action of carbenoxolone). Potassium loss should be corrected by the administration of oral supplements. No teratogenic hazard is anticipated from the use of Pyrogastrone during pregnancy but careful consideration should be given before prescribing it for women who may become pregnant.

I. Data from the files of Winthrop Laboratories. *The Pyrogastrone tablets used in this trial contained 20mg carbenoxolone in a base containing antacids and 200mg alginic acid. The control tablets contained the same base, but without carbenoxolone. Since this trial, the quantities of alginic acid and antacids in Pyrogastrone tablets have been trebled.

Pyrogastrone is made under licence from Biorex Laboratories Ltd., Brit. Pat. Nos. 843133 and 1390683. Pyrogastrone is a registered trade mark. Full information is available on request from Winthrop Laboratories, Surbiton-upon-Thames, Surrey.





Prescribing Information
PRESENTATION: Nalcrom is a presentation of sodium cromoglycate for oral use. It is
presented in clear/clear hard gelatine capsules printed Fisons 101 in black. Each capsule
contains 100 mg sodium cromoglycate as a white powder.
USES: As an adjuvant in the treatment of ulcerative colitis, procitiis and proctocolitis.

Sodium cromoglycate is considered to exert a stabilising effect upon mast cells capable of releasing mediators, thus preventing the local inflammatory reaction in the gastrointestinal tract.

DOSAGE AND ADMINISTRATION: Dosage Adults: Two capsules four times daily. Children: From 2–14 years; one capsule four times daily. Naicrom should not be used for children under two years. Maintenance dosage To prevent relapses dosage should be maintained indefinitely at two capsules four times daily in adults and one capsule four times daily in children.

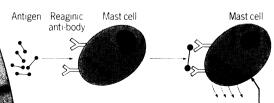
 $\label{eq:Administration} \begin{tabular}{ll} Administration The capsules may be swallowed whole or alternatively the powder contents may be dissolved in 20–30ml of water and swallowed. \end{tabular}$

Nalcrom offers a completely new approach to the management of ulcerative colitis.

And it could mean freedom from side effects often associated with the limited number of treatments now available.

Nalcrom is sodium cromoglycate.

Sodium cromoglycate is the unique drug which is used successfully in the treatment of allergic diseases, such as asthma and rhinitis.



Sodium cromoglycate prevents the degranulation of mast cells caused by the Interaction of antigens and reaginic antibodies.

t is a potent inhibitor of mast cell ulation. It prevents the release of indao matory agents into sub-mucosal tissue in the lung, nose and other organs. So it stops symptoms before they even start. And over ten years of clinical use proved it to be a very effective drug with remarkably few serious side-effects.

Now it offers hope as a new treatment for ulcerative colitis.

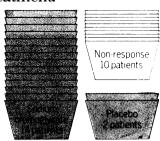




On left mast cell undergoing gross degranulation. On right mast cell stabilised after treatment with sodium cromoglycate. Photomicrographs prepared by: $R\&D\,Laboratories, Fisons\,Ltd., Pharmaceutical\,Division.$

Why an anti-allergy drug?

Ulcerative colitis in its natural history and histological appearance has many features such as macrophages, mast cells and eosinophils that suggest that an allergic or immunological process may be involved. Sodium cromoglycate may have a clinically beneficial effect in these processes. So a double blind cross-over trial was carried out with 26 patients suffering from chronic proctitis¹. The 14 responders to sodium cromoglycate had a high local eosinophil count which in most cases fell in the course of treatment.



In a double-blind crossover trial of 26 patients, 14 responded to sodium cromoglycate, 10 didn't respond and 2 responded to placebo.

Another study of 12 patients with ulcerative colitis treated with sodium cromoglycate showed a significant improvement in sigmoidoscopic appearance. And again, rectal biopsies showed a significant reduction in eosinophil counts^{2,3}.

How to find out more about Nalcrom.

Specialist representatives are available at this stage to discuss Nalcrom with hospital doctors. Simply fill in and post the coupon or write to: Fisons Limited, Pharmaceutical Division,

Loughborough, Leicestershire. Nalcrom[®]
(Sodium Cromoglycate B.P.)

G/N/10

References 1. Heatley, R.V. et al, 1975, "Gut," 16, 559 2. Mani, V. et al, 1976, "Lancet." 1, 439 3. Mani, V. et al, 1977, "Gastro-enterology," 72, 1093

| Please arrange for a specialist representative to call. | | |
|--|---------|-----------------------------|
| Name | Address | |
| | | ®JL FIGALIC |
| Further information is available on request from Fisons Limited, | | ZA FISONS |
| Pharmaceutical Division Loughborough Leicestershire | | Leaders in Allergy Research |

CONTRA-INDICATIONS, WARNINGS, ETC: Contra-indications There are no specific contra-indications. The safety of Nalcrom during pregnancy has not yet been established. Side-effects Nausea has been reported in a few cases.

Overdosage As Nalcrom is absorbed only to a very limited extent, no action other than medical observation should be necessary

medical observation should be necessary.

PHARMACEUTICAL PRECAUTIONS: Store in a dry place. Reclose the container tightly after use

LEGAL CATEGORY: P.O.M.

PACKAGE QUANTITIES: Containers of 100 capsules.

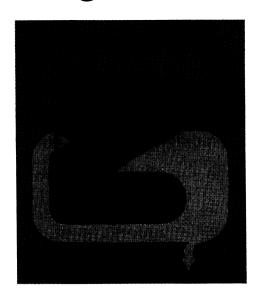
FURTHER INFORMATION: 1. Nalcrom may be used in conjunction with steroid therapy and sulphasalazine in the treatment of acute relapses of proctocolitis and in maintaining remissions.

2. If steroid therapy is to be reduced or withdrawn this should be done cautiously.

3. Nalcrom may be used in patients with a history of hypersensitivity to or intolerance of sulphasalazine.

4. Dosages of 2000mg daily have been used in some cases of proctocolitis. **PRODUCT LICENCE NUMBER:** PL 0113/0073.

When bile acids are requested Sterognost-3α® A Sterognost-3α®



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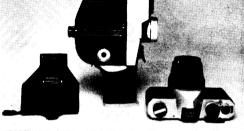
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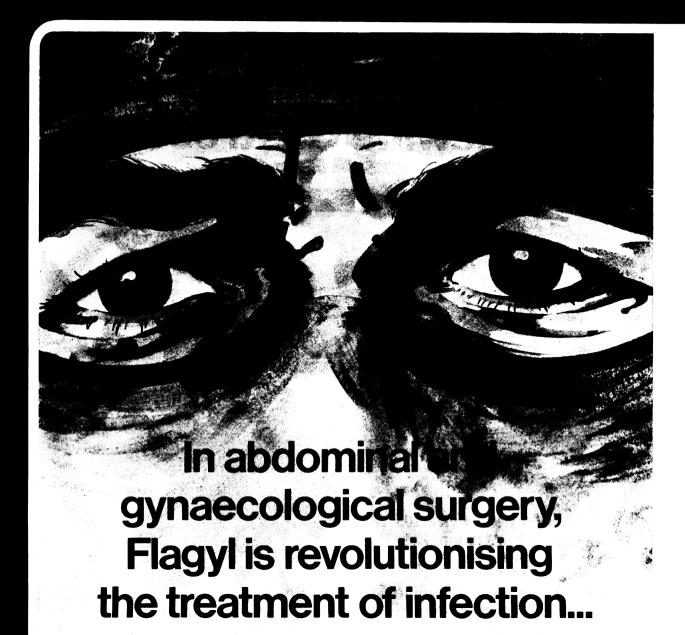
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and now

Flagyl Injection

for i.v. infusion



Flagyl Injection

cause - specific. effect ... decisive in most infections following abdominal or gynaecological surgery

Most of these infections are caused by anaerobes In both the colon and the female genital tract, the importance of non-sporing obligate anaerobes - commonly occurring organisms of the normal bacterial flora – as the major pathogens in post-surgical infection is now increasingly recognized. 1-8

'Flagyl' is specifically, intensely bactericidal to anaerobes . . .

The only available antimicrobial with selective activity against obligate anaerobes, 2,5,9 'Flagyl' is consistently bactericidal to these organisms - at readily obtained serum, tissue and body fluid concentrations.^{1,7,10}

... and thus uncompromisingly, spectacularly effective against most of the infections

"In all our infected patients the clinical and microbiological response to metronidazole was dramatic. Within 12-24 hours the temperature and pulserate had usually returned to normal, the patient looked and felt better . . . There was a strikingly rapid disappearance of anaerobic bacteria from pathological discharges, which ceased to be purulent and offensive and quickly subsided."2

'Flagyl' doesn't have the drawbacks of previous treatments

'Flagyl' is favourably distinguished from previously preferred antimicrobial treatments by reliable anaerobicidal activity,11 low toxicity4,7 and a specificity of action incapable of inducing resistance in aerobic pathogens.^{2,4,5,12}

'Flagyl' injection: especially for the seriously ill

a conveniently given, rapidly effective new dosage form for anaerobic sepsis following major surgery, 7 quickly achieving, and satisfactorily maintaining, high blood levels.7,13

"... safe, easy to administer, and well tolerated by patients . . . "7

- bacteriologically compatible in the body with other antimicrobials12
- now in oral, rectal and i.v. presentations
- 17 years' well tolerated use in other indications

'Flagyl'* injection prescribing information N.B. Metronidazole is inactive against aerobic and facultatively anaerobic bacteria.

Injection (for intravenous infusion) 0.5 per cent w/v in 100 ml bottles (500 mg metronidazole per 100 ml).

1) Treatment of infections in which anaerobic bacteria have been identified or are suspected as pathogens, particularly Bacteroides fragilis and other species of bacteroides and including other species for which metronidazole is bactericidal, such as fusobacteria, eubacteria, clostridia and anaerobic cocci.

'Flagyl' has been used successfully in : senticaemia hacteraemia brain abscess necrotising pneumonia osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis, peritonitis and post-operative wound infection, from which one or more of these anaerobes have been isolated

2) Prevention of post-operative infections due to anaerobic bacteria, particularly species of bacteroides and anaerobic streptococci.

Dosage and administration

In patients with severe anaerobic infection for whom oral medication is not possible or is contra-indicated; it is particularly useful in emergencies

- and is indicated in patients needing surgery who: have or are believed to have anaerobic sepsis such as septicaemia, peritonitis, subphrenic or pelvic abscesses.
- at operation show signs of established or impending anaerobic sepsis
- undergo operations in which contamination occurs with anaerobes from the gastro-intestinal or female genital tracts or the oropharynx.
 In infants and other patients maintained on intravenous fluids, 'Flagyl' injection may be diluted with appropriate volumes of normal saline. dextrose-saline, dextrose 5 per cent w/v or potassium chloride injections (20 mmol and 40 mmol).

Adults and children over 12 years: 100 ml by intravenous infusion eight-hourly. The injection should be infused intravenously at the rate of 5 ml per minute but may be administered alone or concurrently (but separately) with other bacteriologically appropriate anti-bacterial agents in parenteral dosage forms. Oral medication with 400 mg three times daily should be substituted as soon as this becomes feasible. Treatment for seven days should be satisfactory for most patients but, depending upon clinical and bacteriological assessments, the physician might decide to prolong treatment e.g. for the eradication of infection from sites which cannot be drained or are liable to endogenous re-contamination by anaerobic pathogens from the gut, gropharynx or

Children under 12 years: As for adults but the single intravenous dose is based on 1.5 ml (7.5 mg metronidazole) per kg bodyweight and the oral dose on 7.5 mg per kg bodyweight.

Adults and children over 12 years: 100 ml by intravenous infusion immediately before, during or after operation, followed by the same dose eight-hourly until oral medication (200 to 400 mg three times daily) can be given to complete a seven-day

Children under 12 years: As for adults but the single intravenous dose is based on 1.5 ml (7.5 mg metronidazole) per kg bodyweight and the oral dose on 3.7 to 7.5 mg per kg bodyweight.

Contra-indications, warnings, etc.
There are no absolute contra-indications for the use of 'Flagyl' injection for anaerobic antibacterial

therapy. Precautions:

The recommended dosages, frequencies of administration and durations of medication have been found effective and well tolerated in nearly all cases. However, regular clinical and biological surveillance are advised if administration of 'Flagyl' for more than 10 days is considered to be necessary. Clinicians who contemplate continuous therapy, for the relief of chronic conditions, for periods longer than those recommended are advised to consider the possible therapeutic benefit against the risk of peripheral neuropathy.

Such evidence as is available suggests that nationts with various degrees of renal impairment handle metronidazole like patients with normal renal metroniciazole like patients with normal renal function. Daily dosage may, however, be halved for patients with renal failure, if the clinician so wishes, as such dosage has been found effective.

Patients should be advised not to take alcoholic drinks during metronidazole therapy.

Metronidazole enhances the activity of warfarin and

if 'Flagyl' is to be given to patients receiving this or other oral anticoagulants the dosage of the latter should be recalibrated.

Pregnant women tolerate metronidazole well and no adverse effect on their offspring has been reported. As with all medicines 'Flagvi' should not be given during pregnancy or during lactation unless the physician considers it essential.

Side effects and adverse reactions: No serious adverse reactions have been encountered with the recommended regimes. There have been occasional reports of an unpleasant taste in the arely) and gastro-intestinal disturbance Drowsiness, dizziness, headache, ataxia, skin rashes, pruritus, inco-ordination of movement and darkening of the urine (due to a metronidazole metabolite) have been reported but very rarely. During intensive and/or prolonged metronidazole therapy, a few instances of peripheral neuropathy have been reported but in most cases the reaction disappeared after treatment was stopped or when dosage was reduced. A moderate leucopenia has been reported in some patients but the white cell count has always returned to normal before or after treatment has been completed. Transient epileptiform seizures have been reported in a few patients undergoing intensive, high-dosage metronidazole radiosensitisation therapy.

Pharmaceutical precautions THIS PRODUCT SHOULD BE PROTECTED FROM LIGHT.

Further information

Treatment of overdosage:

There is no specific treatment for gross overdosage of 'Flagyl'. Uneventful recovery has followed attempts at suicide with quantities of 30 and 60 x 200 mg tablets. Other established indications for 'Flagyl' include urogenital trichomoniasis giardiasis, all forms of amoebiasis, acute ulcerative gingivitis and acute dental infections. 'Flagyl' is also available as tablets and, in some territories, as suppositories

References

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- Hyg., **213**, 258, 1970 10 J. Infect. Dis., **131**, 417, 1975
- J. Infect. Dis., 131, 417, 1975 Antimicrob. Ag. Chemother., 10, 736, 1976 J. Antimicrob. Chemother., 1, 387, 1975 Selkon, J. B., Hale, J. H. Ingham, H. R., Chemotherapy, Vol. 1, p. 277, Plenum Pub. Corp., New York, 1973

Further information is available on request *'Flagyl' is a trade mark of May & Baker Ltd Dagenham Essex RM10 7XS for its preparations of metronidazole.

May & Baker Ltd Dagenham Essex RM10 7XS



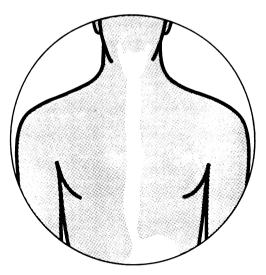
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June 1978

Injection

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German

Foreword: K. Heinkel, Stuttgart 1977. ISBN 3-85698-0001-8 SFr./DM 285.-

French

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Gut October 1978 XI

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This publication will regroup in each of its numbers clinical articles published up to the present in the Archives françaises des Maladies de l'appareil digestif with biological articles published in Biologie et Gastro-entérologie.

Articles in French or in English with summaries in both languages.

Some recently pubished articles:

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XIV Gut October 1978

PHARMACIA. THE MANUFACTURERS OF SALAZOPYRIN. WISH TO DRAW AND SURGEONS T **SOME IMPORTAN** NEW INFORMATION

Crohn's **Disease**

Various clinical trials and publications 1,2,3,4,5 have now demonstrated that the benefits of Salazopyrin may be successfully extended to the management of active Crohn's Disease.

Ulcerative Colitis

Recent work has stressed that the ideal maintenance dose in ulcerative colitis is 2g per day,6 and that such maintenance should be extended indefinitely to minimise the risk of relapse? Cessation of therapy increases relapse risk four-fold regardless of time^{7,8} since the acute. attack, or whether placebo⁷ or high fibre diet[®] are substituted.

Salazopyrin

36 years of therapeutic management.

Prescribing Information

Dosage and Administration

Plain or EN Tablets: In acute moderate attacks 2-4 tablets A times a day in severe attacks steroids should also be given. After 2-3 weeks the dose may gradually be reduced to the maintenance level of 3-4 tablets daily which should be given indefinitely.

Suppositories: Two inserted morning and night, the dose being gradually reduced after 3 weeks as improvement occurs.

Children: Reduce the adult dose on the basis of body weight.

Contra-Indications Warnings etc.

Contra-Indications: Contra-indicated in sensitivity to salicylates and sulphonamides. Infants under 2 years

Adverse Peaction: Side effects common to saliculates or Adverse Reaction: 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 or suppositories. If serious reactions occur the drug should be discontinued. 1. Scand, J. Gastri. Rarely the following adverse reactions have been reported. 2. Scand, J. Castri.

Haematological: eg Heinz body anaemia, haemolytic anaemia leucopenia, agranulocytosis and aplastic anaemia. Hypersensitivity: eg Rash, fever.

Gastrointestinal: eq. Impaired folate uptake, stomatitis, C.N.S.: eg. Headache, peripheral neuropathy. Renal: eq. Proteinuria crystalluria.

Also, Stevens-Johnson syndrome and lung complications. eg. Fibrosing alveolitis.

Precautions

Care in cases of porphyria, allergic, renal or hepatic disease, glucose 6-PD deficiency. Blood checks should be made initially and periodically.

PregnancyThe benefit to risk ratio must be carefully evaluated when the drug is given during pregnancy.

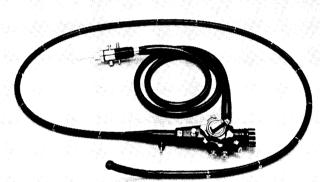
- Scand, J. Gastroenterol (1974) **9,** 549. Scand, J. Gastroenterol (1978) **13,** 161. Brit med J. (1975) **2,** 297.
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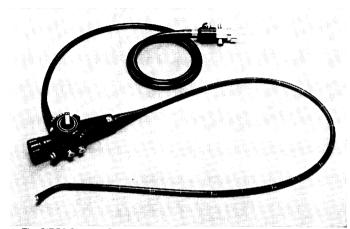
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