CONCLUSIVE EVIDENCE IN CROHN'S TREATMENT

Prescribing Information
Dosage and Administration
Plain or EN Tablets: In acute moderate attacks 2-4 tablets 4 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.
Enema: One enema should be given daily preferably at bed time. This preparation contains an adult dose of Salazopyrin. Patient instructions are enclosed in each box.
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.
Enema only: 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 or use of EN tablets or suppositories. If serious reactions occur the drug should be discontinued. Rarely the following adverse reactions have been reported.
Haematological e.g. Heinz body anaemia, haemolytic anaemia, leucopenia, agranulocytosis and aplastic anaemia.
Hypersensitivity e.g. Rash, fever.
Gastrointestinal e.g. Impaired folate uptake, stomatitis.
CNS e.g. Headache, peripheral neuropathy.
Renal e.g. Proteinuria, crystalluria. Also, Stevens-Johnson syndrome and lung complications e.g. 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.
Pregnancy
The benefit to risk ratio must be carefully evaluated when the drug is given during pregnancy.
Packages & Prices
Plain Tablets: 100 & 500
£5.05 for 100 tablets
EN Tablets: 100 & 500
£6.55 for 100 tablets
Suppositories: 10 & 50
£2.05 for 10 suppositories
Enemas: 7 £9.80 for 7 enemas
Product Licence Numbers
Plain Tablets 0009/5006
EN Tablets 0009/5007
Suppositories 0009/5008
Enema 0009/0023
References
1. Gastroenterology (1979) 77, 847-849
2. Gastroenterology (1979) 77, 870-882

Pharmacia

Salazopyrin (reg'd) sulphasalazine is a product of Pharmacia (Great Britain) Ltd, Prince Regent Road, Hounslow, Middlesex TW3 1NE.
Tel: 01-572 7321
Further information is available on request from the Company.

The use of Salazopyrin in Ulcerative colitis is well established, and for a number of years more positive links for its use in treating active Crohn's disease have emerged.

Recently in the U.S.A. a National Cooperative Crohn's Disease Study (NCCDS) looked at 569 patients from 14 Centres over a period of approximately 5 years. Prednisone, azathioprine and sulphasalazine (Salazopyrin) were selected as the agents most meriting clinical trial.

All three were studied for both suppressive and prophylactic efficacy and toxicity.[1,2]

In terms of efficacy[1] the results of the drug trials showed that *"sulphasalazine was significantly superior to placebo in the treatment of active Crohn's disease."* Sulphasalazine proved significantly superior in *"patients with colon involvement, whether or not the small bowel was involved."*

Patients with recent onset of disease who had not received any treatment prior to the study *"... did not respond well to any of the drugs except sulphasalazine..."*

Adverse reactions and relative toxicity of the three drugs were also mentioned and evaluated.[2]

"Sulphasalazine was the least toxic of the three drugs used..." while *"prednisone and azathioprine showed an approximately equal incidence of toxic reactions."*

On balance it was concluded that:-

"Sulphasalazine proved to be the safest effective suppressive drug for Crohn's disease."

Proven efficacy and acceptability in Crohn's Disease

SALAZOPYRIN

sulphasalazine

Ease the spasm. Ease the mind.

LIBRAXIN

clidinium bromide and chlordiazepoxide

Clidinium bromide to calm the gut. Chlordiazepoxide to calm the mind.

Indications For the control of hypersecretion, hypermotility and emotional factors associated with gastro-intestinal disorders, such as nervous dyspepsia, peptic ulcer, cardiospasm, pylorospasm, nervous or irritable colon.

Dosage 1 or 2 tablets three or four times daily. In elderly patients, it is recommended that the initial dose be 1 tablet twice daily.

Contra-indications Because of its anticholinergic effects, Libraxin should not be given to patients suffering from glaucoma or prostatic enlargement.

Precautions Patients should avoid alcohol while under treatment with Libraxin, since the individual response cannot be foreseen. Patients' reactions (driving ability, operation of machinery, etc.) may be modified to a varying extent, depending on dosage and individual susceptibility. The established medical principle of prescribing medicaments in early pregnancy only when absolutely indicated should be observed.

Side-effects Side-effects are infrequent and are controlled by reduction of dosage. They include drowsiness, muscle weakness, dryness of the mouth, blurring of vision, constipation and hesitancy of micturition.

Presentation Libraxin tablets containing 5mg chlordiazepoxide and 2.5mg clidinium bromide in packings of 100 and 500.

Basic NHS Cost 1 tablet 3 times daily 7.4p/day ex 500 pack.

Licence Number 0031/5024

Licence Holder Roche Products Limited, PO Box 8 Welwyn Garden City, Hertfordshire AL7 3AY
Libraxin is a trade mark

ROCHE

J486041/580

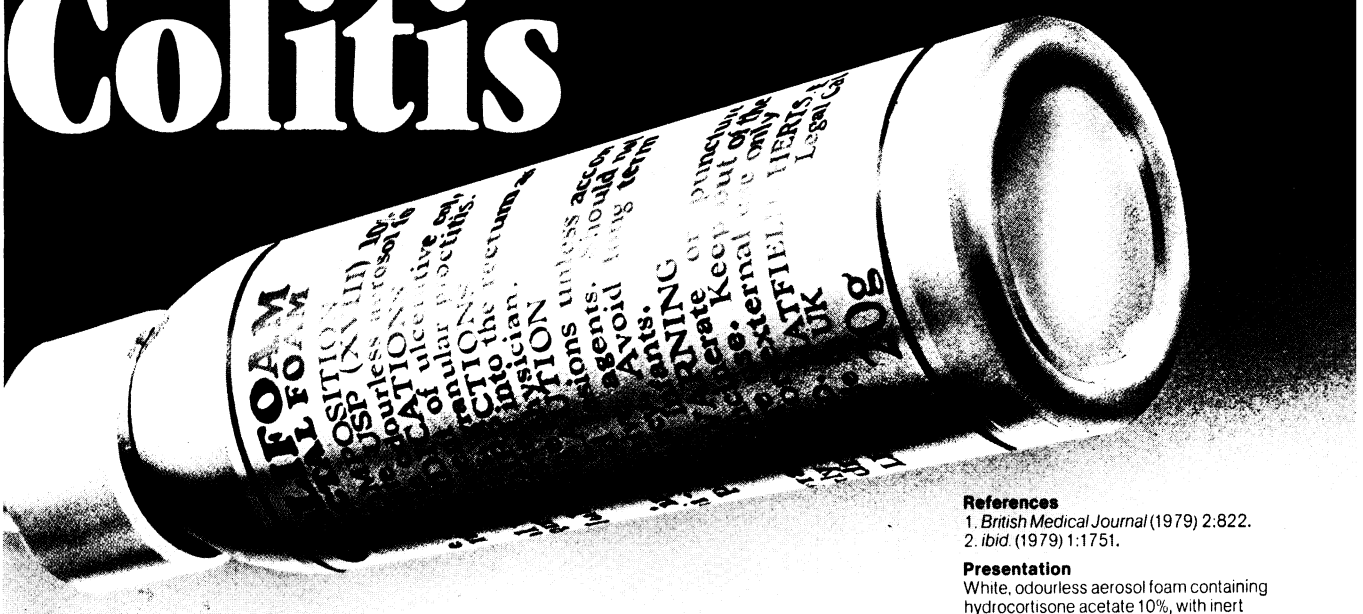
Unique i
Ulcerative

Colifoam is a unique therapy for ulcerative colitis, being a topical anti-inflammatory with exceptional benefits over the rectal enema in terms of simplicity and convenience.

Gamma photography studies[1-3] have shown that a single dose of Colifoam remains in contact with the rectal mucosa for several hours. In one of these studies[1] the foam was seen to reach the sigmoid colon in most patients. The second study,[2] using a different protocol which included healthy subjects, did not confirm this finding but the authors concluded:

"Unquestionably, however, the foam is more comfortable and easier to retain

n Colitis



than a retention enema, and since the patient need not be immobilised, the foam obviously has a place in outpatient practice for patients with proctitis and distal ulcerative colitis."

Colifoam: hydrocortisone acetate foam supplied in a metered dose dispenser, delivering approximately 5 ml. of Colifoam rectal foam containing 10% hydrocortisone acetate.

Colifoam

hydrocortisone acetate foam

comfort and convenience in ulcerative colitis

References
1. *British Medical Journal* (1979) 2:822.
2. *ibid.* (1979) 1:1751.

Presentation
White, odourless aerosol foam containing hydrocortisone acetate 10%, with inert propellants.

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 in each pack). One applicatorful of Colifoam provides a dose of approximately 90-110mg of hydrocortisone, similar to that used in a retention enema for the treatment of ulcerative colitis, sigmoiditis and proctitis. Satisfactory response usually occurs within five to seven days.

Contra-indications and Warnings etc.
Local contra-indications to the use of intrarectal steroids include obstruction, abscess, perforation, peritonitis, fresh intestinal anastomoses and extensive fistulas. 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 diseases because of their predisposition to perforation of the bowel wall. Safety during pregnancy has not been fully established.

Pharmaceutical Precautions
Do not refrigerate, incinerate or puncture the aerosol can. Shake vigorously before use. Keep out of reach of children.

Package Quantities
Aerosol canister containing 20g (14 applications) plus a plastic applicator and illustrated leaflet.

Basic NHS Cost
£6.90.

Product Licence No.
0036/0021

Further information is available on request from:
Stafford-Miller Limited,
Professional Relations Division, Hatfield, Herts. AL10 0NZ.

In dyspepsia, antacids only cloud the issue.

Maxolon
metoclopramide

clears it.

Maxolon protects the gastric mucosa from over-long exposure to gastric acid[1] by promoting normal peristalsis and gastric emptying.[2,3] This action contrasts with that of antacids.

By restoring the stomach's normal control, symptoms described by the patient as fullness, pain, heartburn and discomfort can be effectively treated and their recurrence prevented.[4]

To the patient, Maxolon is the simple and convenient therapy to replace his repetitive antacid prescriptions.

Prescribing Information

Indications
Dyspepsia, heartburn and flatulence associated with the following conditions e.g., Reflux oesophagitis, Gastritis, Hiatus hernia, Peptic ulcer.

Adult Dosage (oral)
Adults 10mg
1 tablet or 10ml syrup 3 times a day.
Young adults (15-20 years) 5-10mg
½-1 tablet or 5-10ml syrup 3 times a day commencing at the lower dosage.

Note: Total daily dosage of Maxolon, especially for children and young adults should not normally exceed 0.5mg/kg body-weight.

Side-effects and Precautions
There are no absolute contra-indications to the use of Maxolon.

Various extra-pyramidal reactions to Maxolon, usually of the dystonic type, have been reported. The incidence of these reactions in children and young adults may be increased if daily dosages higher than 0.5mg/kg body-weight are administered. The majority of reactions occur within 36 hours of starting treatment and the effects usually disappear within 24 hours of withdrawal of the drug. Should treatment of a reaction be required, an anticholinergic anti-Parkinsonian drug e.g. benapryzine, or a benzodiazepine may be used. Since extra-pyramidal symptoms may occur with both Maxolon and phenothiazines, care should be exercised in the event of both drugs being prescribed concurrently.

Raised serum prolactin levels have been observed during metoclopramide therapy: this effect is similar to that noted with many other compounds.

Maxolon's action on the gastro-intestinal tract is antagonised by anticholinergics. Although animal tests in several mammalian species have shown no teratogenic effects, treatment with Maxolon is not advised during the first trimester of pregnancy.

Following operations such as pyloroplasty or gut anastomosis Maxolon therapy should be withheld for three or four days as vigorous muscular contractions may not help healing.

Availability and NHS Prices
Tablets 10mg (£5.84 per 100).
Syrup 5mg/5ml (£2.42 for 200ml).

A paediatric liquid presentation and ampoules for injection are also available.

Average daily cost of Maxolon tablets (ex. 500 pack) 17p. Prices correct at January 1979. Further information is available on request to the company.

Maxolon (metoclopramide) is a product of
Beecham Research Laboratories,
Brentford, England.
A branch of Beecham Group Limited.

1. Gut. (1969), *10*, 678-680. **2.** Postgrad. med. J., (1973), *49*, (Suppl.), 29 **3.** Gut. (1974), *15*, 462-467 **4.** Brit. med. J., (1971), *2*, 25

PL 0038/0095 0098 5040 5041 BRL 4023

Intravenous Valium Roche

the preferred sedative for gastro-intestinal endoscopy

Vast would be an apt description of the experience with intravenous Valium Roche in gastro-intestinal endoscopy – an experience which covers the range of procedures and patients of all age groups.* Endoscopy without premedication is for many patients an unpleasant experience.[1] Intravenous Valium Roche sedation improves patient acceptance without impairing their ability to co-operate. Keeping medication to a minimum is particularly important for out-patients[2] and avoidance of analgesics leads to faster recovery times.[3] In certain circumstances where prolonged intubation is required or pain from an operative procedure likely, the addition of a narcotic analgesic such as pethidine may be desirable.[4] Neuroleptanalgesia has also been used to good effect with intravenous Valium Roche.[5] The amnesic effect of intravenous Valium Roche undoubtedly contributes to the excellent acceptance by patients and their willingness to undergo repeat procedures.[6] The shortness of the amnesic effect is a boon for the operator too when treating out-patients.

Age is no barrier to intravenous Valium Roche sedation for gastro-intestinal endoscopy.* Whether the patient is six weeks or 103-years-old favourable results have been obtained.[7] This is true also for many poor-risk patients including those with liver disease in whom intravenous Valium Roche has been extensively used.[8-10] The dosage must, of course, be adjusted to the patient's needs and the necessary precautions observed.

**Annotated bibliography of references available on request.*

Indications
Intravenous sedative cover before and during unpleasant surgical and medical procedures.

Dosage
0·2mg/kg body weight. The usual adult dose is 10–20mg but more may be needed on occasions. In elderly patients half the usual adult dose.

Administration
With the patient in the supine position the injection should be given slowly (0·5ml Valium Roche ampoule solution per half minute) into a large vein of the antecubital fossa until the patient becomes drowsy, his speech becomes slurred and there is ptosis. He should still be able to respond to requests. Provided these conditions for administration are adhered to the rare possibility of hypotension or apnoea occurring will be greatly diminished. A second person should be present and resuscitation facilities should be available.

Precautions and side-effects
Patients should not be allowed to leave the surgery until one hour at least has elapsed from the time of injection and should always be accompanied by a responsible adult with a warning not to drive or operate machinery for the rest of the day and to avoid alcohol. In patients with organic cerebral changes or with cardiorespiratory insufficiency, injections of Valium Roche should not be employed unless in an emergency or in hospital if indicated and then should be given slowly and in reduced dosage. The possibility of intensified sedative effects and severe respiratory and cardiovascular depression should be considered if central depressant drugs are given, particularly by parenteral route, in conjunction with Valium Roche for injection. Valium Roche should not be given in early pregnancy unless absolutely indicated. Intravenous injection may be associated with local reactions including thrombophlebitis.

Presentation
Ampoules containing 10mg diazepam in 2ml and 20mg in 4ml in packings of 10.

Product Licence Numbers
0031/0068 (ampoules 10mg)
0031/5128 (ampoules 20mg)

Basic NHS Cost
Ampoules 10mg x 10 £2·22
20mg x 10 £3·28

References
1. Brit med J. 1976;2:20
2. Brit J Hosp Med. 1976;16:7
3. Scand J Gastroent. 1979;14:747
4. Scand J Gastroent. 1978;13:33
5. Gut 1976;17:655
6. Brit J Hosp Med. 1971;6(Suppl.):52
7. Amer J Gastroent. 1976;66:523
8. Amer J med Sci. 1974;267:151
9. Gut 1976;17:975
10. Advanced Medicine. 1978;No.14:p19

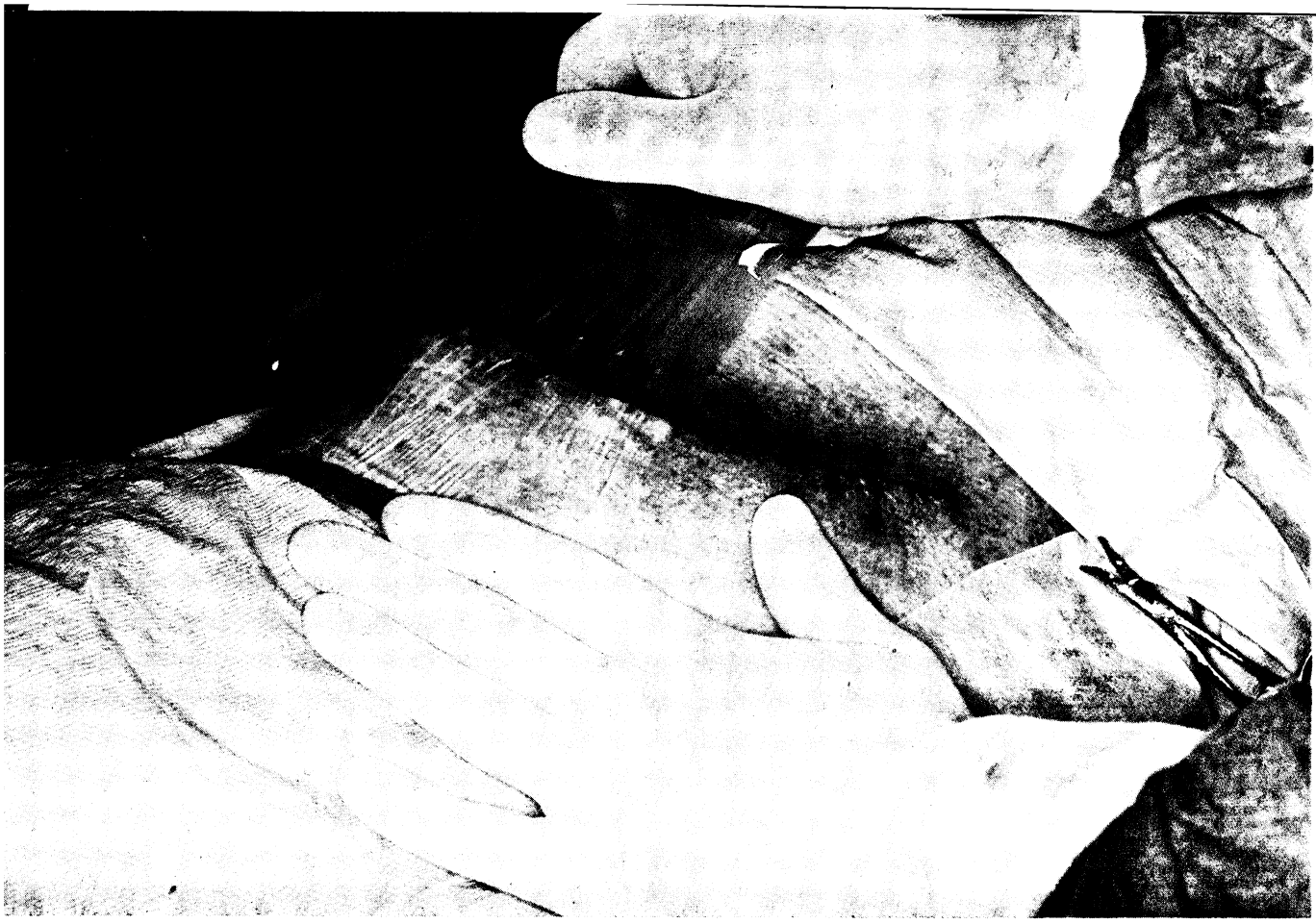
Intravenous Valium Roche

diazepam

where experience counts

ROCHE

Roche Products Limited
PO Box 8, Welwyn Garden City,
Hertfordshire AL7 3AY



NEW OP-SITE SKIN CLOSURE. AN OUTSTANDINGLY SIMPLE, NON-INVASIVE TECHNIQUE.

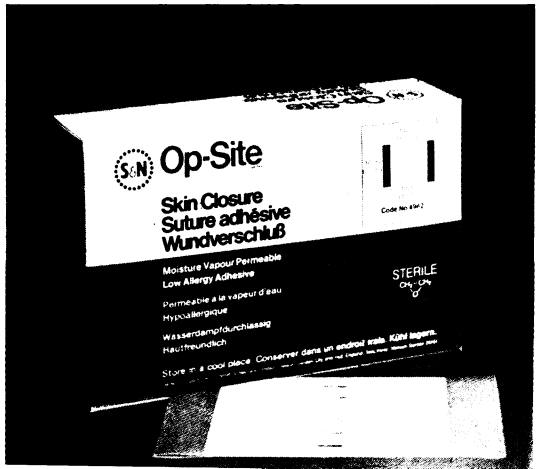
Op-Site Skin Closures represent a major new advance in surgical wound closure and have been designed to produce significant advantages over existing methods.

Being a sutureless technique, they produce no localised tension or ischaemia at the wound edge. They eliminate foreign body reactions and the risk of infection at the puncture site.

Produced from a transparent, adhesive, polyurethane membrane, Op-Site Skin Closures are easy to apply, strong and conform readily to body contours. The fenestrations along their length allow for correct appositioning of the wound.

Op-Site Skin Closures are comfortable and can stay in place for up to 14 days. This, together with with the non-invasive technique employed, greatly enhances the final cosmetic effect.

Removal is painless – relieving patients, particularly children, of the anxiety normally associated with suture removal.



In clinical trials, 94 out of 100 patients were satisfactorily treated[1]. They were infection free and enjoyed a *superior* cosmetic effect.

Contact Smith & Nephew Medical now for more details.

Smith & Nephew Medical

WELWYN GARDEN CITY, HERTFORDSHIRE
TELEPHONE (07073) 25151

1. S Westaby Bsc., MB, BS., FRCS. Evaluation of a new product for Sutureless Skin Closure. March 1980. Annals of the Royal College of Surgeons.

"...the major cause of sepsis after surgery of the gastrointestinal tract or female genital tract".

Br.Med.J. **i**, 318, 1976

METRONIDAZOLE

INJECTION

proves decisive in anaerobic infections

Only with recent improvements in bacterial culturing techniques has the pathogenic role of anaerobes in post-surgical infections been fully recognized.[1-3] Now 'Flagyl' Injection offers you a decisive means of treating these infections – which are often life-threatening and often resistant to established antimicrobials. The response to 'Flagyl' Injection is rapid and dependable,[2] as it is consistently bactericidal to pathogenic anaerobes at tissue concentrations easily achieved in treatment. Bacterial resistance is not a problem,[2,4] and 'Flagyl' is highly acceptable – as eighteen years of use in other indications has established.

Dosage: Treatment: adults and children over 12 years: 100 ml by intravenous infusion eight-hourly, administered 5 ml per minute. Oral medication with 400 mg three times daily should be substituted as soon as this becomes feasible. Treatment for seven days should be satisfactory in most cases. 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. Prevention: 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 course. 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. Precautions: pregnancy; lactation; clinical and biological surveillance if recommended duration of treatment exceeded; dosage may be halved for patients with renal failure; avoid alcohol; if 'Flagyl' is to be given to patients receiving oral anticoagulants the dosages of the latter should be recalibrated. Side effects and adverse reactions: occasionally an unpleasant taste, furred tongue, nausea, vomiting (very rarely), gastro-intestinal disturbance. Drowsiness, dizziness, headache, ataxia, skin rashes, pruritus, inco-ordination of movement, darkening of the urine very rarely. During intensive and/or prolonged therapy, peripheral neuropathy has been reported. A moderate leucopenia has been reported but the white cell count has always returned to normal before or after treatment has been completed. Transient epileptiform seizures in a few patients undergoing intensive, high-dosage metronidazole radiosensitization therapy.

'Flagyl' metronidazole

Tablets 200 mg	PL 0012/5256
400 mg	PL 0012/0084
Suppositories 500 mg	PL 0012/0113
1 gram	PL 0012/0114
Injection 0.5% w/v	PL 0012/0107

Basic NHS (as at May 1979)

Injection for i.v. infusion Bottle of 100 ml £6.40.

References 1. Willis, A.T. (1977) Scottish Medical Journal, **22**, 155. 2. Willis, A.T. et al. (1977) British Medical Journal, **i**, 607. 3. Finegold, S.M. Anaerobic Bacteria in Human Disease, Academic Press Inc. New York, 1977. 4. Willis, A.T. et al (1975) Journal of Antimicrobial Chemotherapy, **1**, 393, 1975.

Further information is available on request.

'Flagyl' is a trade mark.

May & Baker Ltd., Dagenham, Essex RM10 7XS.

TRADE MARK

INJECTION

the complete anaerobicide

M&B May & Baker

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