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EVERYDAY PEOPLE TAKE LOSEC

NEW LOSEC® 10mg Capsules

(omeprazole-Astra)

LOSEC® CAPSULES (omeprazole) ABBREVIATED PRESCRIBING INFORMATION (refer to full data sheet before prescribing) **PRESENTATION:** LOSEC Capsules containing 10mg, 20mg or 40mg omeprazole as enteric coated granules with an aqueous based coating. **USES:** Oesophageal reflux disease. Duodenal and benign gastric ulcers (including NSAID-induced). Duodenal ulcer associated with *Helicobacter pylori*. Zollinger-Ellison syndrome. **DOSAGE & ADMINISTRATION: Adults (including the elderly):** The usual dose in oesophageal reflux disease and peptic ulcer is 20mg once daily, increasing to 40mg once daily in severe or refractory cases, if required. **Oesophageal reflux disease:** Healing: 20mg daily for 4 weeks. Continue for further 4-8 weeks if required. **Maintenance in acid reflux disease:** LOSEC 10mg daily. Increase to 20mg daily If symptoms return. **Duodenal ulcer (DU):** Healing: 20mg daily for 4 weeks. **DU maintenance:** LOSEC 10mg daily increasing to 20mg daily if symptoms return. **DU associated with *Helicobacter pylori*:** Usual dose is LOSEC 40mg daily with amoxycillin 1.5g daily (750mg b.d.) for 2 weeks. Up to 2g/day of amoxycillin has been used in clinical studies. **Benign Gastric Ulcer:** 20mg daily for 8 weeks. **Zollinger-Ellison Syndrome:** 60mg daily as long as clinically indicated. Individually adjust within range 20-120mg daily. If in excess of 80mg daily give in 2 equal divided doses. **Renal impairment:** No dose adjustment needed. **Hepatic impairment:** Adjust dose (maximum daily dose 20mg). **Children:** No experience of use. **CONTRA-INDICATIONS, WARNINGS, ETC:** No known contra-indications. In gastric ulcer, exclude malignancy before starting therapy. Avoid in pregnancy unless no safer alternative. Discontinue breast feeding if LOSEC is considered essential. **Side effects:** LOSEC is well tolerated. Adverse reactions are generally mild and reversible (relationship to LOSEC not established in many cases). They include diarrhoea, headaches, skin disorders and in isolated cases, angioedema, musculoskeletal disorders, fatigue, insomnia, dizziness, blurred vision, vertigo, paraesthesia, liver enzyme and haematological changes. LOSEC can delay the elimination of phenytoin and warfarin. **PHARMACEUTICAL PRECAUTIONS:** Use within three months of opening. Store below 30°C. Replace cap firmly after use. Dispense in original container. **LEGAL CATEGORY:** POM. **FURTHER INFORMATION:** ***Helicobacter pylori*** (Hp) is associated with acid peptic and ulcer disease, contributing to gastritis and ulcer recurrence. In patients known to be allergic to amoxycillin, clarithromycin may be a useful alternative in dual therapy. Omeprazole 40mg daily, amoxycillin 1500mg daily and metronidazole 1200mg daily for 14 days achieved an overall Hp eradication rate of 89% (96% in metronidazole-sensitive isolates). **PACKAGE QUANTITIES:** 10mg: bottles of 7 capsules £4.99, bottles of 28 capsules £19.95. 20mg: bottles of 7 capsules, £8.64, bottles of 28 capsules, £35.45; 40mg: bottles of 7 capsules £17.28, bottles of 14 capsules £35.45.

PRODUCT LICENCE NUMBERS:
PL 0017/0337- LOSEC Capsules 10mg.
PL 0017/0238 - LOSEC Capsules 20mg.
PL 0017/0320 - LOSEC Capsules 40mg.

Reference:

1. Hallerbäck B, *et al.* 9th Asian-Pacific Congress of Gastroenterology & 6th Asian-Pacific Congress of Digestive Endoscopy, Bangkok, Thailand. Nov 29-Dec 3 1992; 90: Abstract FP-88.

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olsalazine sodium

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Dipentum Presentation: Caramel coloured capsules containing 250 mg olsalazine sodium. **Uses:** Oral treatment of acute mild ulcerative colitis and the maintenance of remission. Olsalazine consists of two molecules of 5-amino-salicylic acid (5-ASA) joined through an azo-bond. The systemic absorption of olsalazine is minimal. 99% of an oral dose will reach the colon. Olsalazine is activated in the colon where it is converted into 5-ASA. The release of 5-ASA is neither pH nor time dependent.5-ASA acts topically on the colonic mucosa and local colonic concentrations of 5-ASA are more than 1000 times that found in the serum. **Dosage and Administration:** ***Acute Mild Disease:*** *Adults including the Elderly.* Commence on 1g daily in divided doses and, depending upon the patient response, titrate the dose upwards to a maximum of 3g daily over 1 week. A single dose should not exceed 1g. Olsalazine should be taken with food. **Remission:** *Adults including the Elderly.* Two capsules (0.5g) twice daily taken with food. **Contra-indications:** ***Warnings etc:*** *Contra-indications:* Hypersensivity to salicylates. there is no experience of use of olsalazine in patients with significant renal impairment. Olsalazine is contra-indicated in patients with significant renal impairment. **Pregnancy:** Reproduction studies performed in mice, rats and rabbits have revealed no evidence of impaired fertility, harm to the foetus or teratogenic effects due to olsalazine administration. However, the experience of use in pregnant women is limited. Dipentum should not be used during pregnancy unless the clinician considers that the potential benefit outweighs the possible risk to the foetus. **Lactation:** There are no data on the excretion of olsalazine in breast milk. **Adverse Reactions:** Watery diarrhoea has been recorded in 15% of patients treated. In half of these patients the diarrhoea was either transient or overcome by dose reduction. In patients who do not respond to dose reduction the drug should be stopped. As with sulphasalazine and mesalazine gastrointestinal side-effects are most common. The most frequently reported adverse reactions are diarrhoea, abdominal cramps, headache, nausea, dyspepsia, arthralgia and rash. **Treatment of Overdose:** There is no specific antidote to olsalazine. Treatment should be supportive. **Pharmaceutical Precautions:** Store at room temperature in a dry place. **Legal Category:** POM. **Package Quantities:** Containers of 100 capsules. **NHS Price:** 100 capsules £23.30. **Further Information:** Olsalazine has been used concomitantly with glucocorticosteroids. **Product Licence Number:** 0022/0134. **Product Licence Holder:** Pharmacia Ltd., Davy Avenue, Milton Keynes MK5 8PH. **Distributed by:** Pharmacia Ltd., Davy Avenue, Milton Keynes MK5 8PH.

References: 1. Bjarnason J., McPherson A.J. (1993) Inflammopharmacology; **2**: 277-287. 2. Raimundo A.H. *et al.* (1992) Gut; **33**(1): S63. 3. Data sheet. 4. Staerk Laursen L. *et al.* (1990) Gut; **31**(11): 1271-1276. 5. Courtney M.G. *et al.* (1992) Lancet; **339**: 1279-81. 6. Sandberg-Gertzen H. *et al.* (1988) Scand J Gastroenterol; **23**: Suppl. 148, 48-50.

*coated mesalazine (Eudragit S).
P/1918/494

Pharmacia

Pharmacia Ltd., Davy Avenue, Milton Keynes, MK5 8PH

PRESCRIBING INFORMATION:
Indications Duodenal ulcer, benign gastric ulcer, ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), prevention of NSAID-associated duodenal ulcer, oesophageal reflux disease, severe oesophagitis, long-term management of healed oesophagitis, chronic episodic dyspepsia. **Dosage** *Adults:* Duodenal ulceration and gastric ulceration: A single 300mg dose at bedtime or 150mg twice daily in the morning and evening for four weeks. In duodenal ulcers, 300mg twice daily produces higher healing rates at four weeks. Continued maintenance treatment of 150mg at bedtime is recommended for patients with a history of recurrent ulceration. Ulcers following non-steroidal anti-inflammatory drug therapy or associated with continued non-steroidal anti-inflammatory drugs: 150mg twice daily for up to eight weeks. Prevention of NSAID-associated duodenal ulcer: 150mg twice daily concomitantly with NSAID therapy. Chronic episodic dyspepsia: 150mg twice daily for six weeks, investigate early relapsers and non-responders. Oesophageal reflux disease: 300mg at bedtime or 150mg twice daily for up to eight weeks. Moderate to severe oesophagitis: 150mg four times daily for up to twelve weeks (see data sheet for full dosage instructions). Long-term treatment of healed oesophagitis: 150mg twice daily. *Children:* Oral dose for peptic ulcer: 2mg/kg to 4mg/kg, twice daily to a maximum of 300mg per day. **Contra-indications** Patients with known hypersensitivity to ranitidine. **Precautions** In patients in whom sodium restriction is indicated, care should be taken when administering sodium-containing Effervescent Tablets. Exclude the possibility of malignancy in gastric ulcer before instituting therapy, especially in middle-aged patients with new or recently changed dyspeptic symptoms. Regular supervision of patients taking NSAIDs concomitantly with Zantac is recommended, especially if elderly. Protects against NSAID-associated ulceration in duodenum and not in stomach. Reduce dosage in the presence of severe renal failure (see data sheet). Avoid in patients with history of porphyria. Effervescent Tablets contain aspartame, use with caution in patients with phenylketonuria. Like other drugs, use during pregnancy and lactation only if strictly necessary. **Side effects** Headache, dizziness, skin rash, occasional hepatitis, rarely arthralgia, myalgia. Rarely, reversible mental confusion states, usually in very ill or elderly patients. Rare cases of leucopenia and thrombocytopenia, usually reversible, agranulocytosis and pancytopenia. Hypersensitivity reactions, anaphylactic shock. Rare cases of breast symptoms in men. As with other H_2-receptor antagonists rare cases of bradycardia, A-V block and asystole (see data sheet). **Presentations** Zantac 150 Tablets each containing 150mg ranitidine HCl, (Product licence number 10949/0042, 60 tablets £27·89); Zantac 300 Tablets each containing 300mg ranitidine HCl (Product licence number 10949/0043, 30 tablets £27·43); Zantac Effervescent Tablets each containing 150mg ranitidine HCl and 14·3mEq sodium, (Product licence number 0004/0392, 60 tablets £27·89); Zantac Effervescent Tablets each containing 300mg ranitidine HCl and 20·8mEq sodium (Product licence number 0004/0393, 30 tablets £27·43), Zantac Syrup each 10ml dose containing 150mg ranitidine HCl (Product licence number 10949/0108, 300ml bottle £22·32). **Product licence holders** Glaxo Operations UK Limited, Greenford, Middlesex UB6 0HE. Glaxo Pharmaceuticals UK Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. POM Zantac is a Glaxo trade mark. Further information is available on request from: Glaxo Laboratories Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Telephone 081-990 9444. June 1994.

References
1. Hayllar J, Macpherson A, Bjarnason I. Drug Safety 1992; 7(2): 86-105. 2. Rodriguez LAG, Jick H. The Lancet 1994. Vol 343: 769-772. 3. Lancaster-Smith ML, Jaderberg ME, Jackson DA. Gut 1991; **32**: 252-255. 4. Robinson MG, Griffin JW, Bowers J *et al.* Dig Dis Sci 1989; **34**(3): 424-428. 5. Zantac Data Sheet.

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ZANTAC
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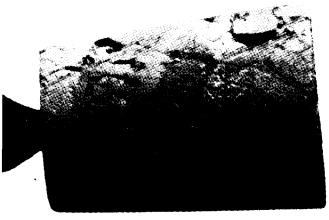
. TAKING THE UT OF NSAIDs.



NSAIDs claim around 3,000 lives a year in the UK alone.[1] Patients with a history of ulcer disease being at greatest risk of life-threatening complications.[2]

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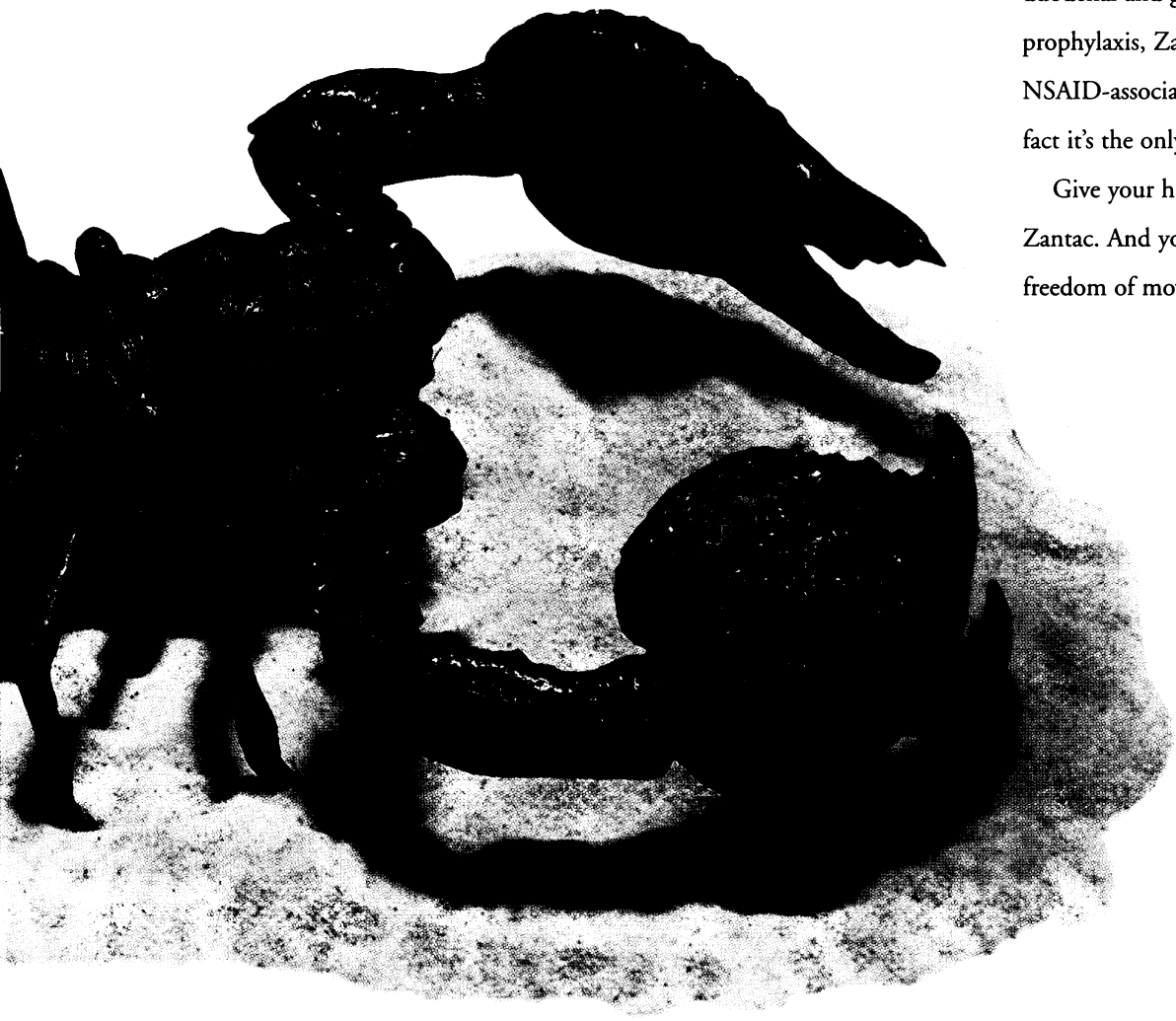

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Predfoam Prednisolone metasulphobenzoate sodium equivalent to 20mg prednisolone per metered dose. **Uses:** Treatment of proctitis and ulcerative colitis. **Dosage and administration:** Adults and elderly patients: One metered dose inserted rectally once or twice daily for two weeks, extending treatment for a further two weeks when a good response is obtained. Use should be discontinued at the discretion of the physician once the disease is stable and under control. Children: Not recommended. **Contra-indications, warnings etc.:** Contra-indications: Local conditions where infection might be masked or healing impaired e.g. peritonitis, fistulae, intestinal obstruction, perforation of the bowel. **Precautions:** The product should be used with extreme caution in the presence of severe ulcerative colitis. The possible occurrence of masking of local or systemic infection should be borne in mind when using this product. For rectal use only. **Side-effects:** The consequences of systemic absorption should be considered with extensive use over prolonged periods. As with all rectal corticosteroids, prolonged continuous use is undesirable. **Use in pregnancy and lactation:** There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may, therefore, be a very small risk of such effects in the human foetus. **Overdosage:** Overdosage by this route is unlikely. **Pharmaceutical Precautions:** Pressurised container. Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn even after use. Shake before use. **Legal Category:** POM. **Product Licence Number** 0108/0101. **Product Authorisation Number** 100/40/1. **Pack and NHS Price:** Box containing 1 fourteen dose canister, 14 disposable nozzles and plastic bags £7.06. Full prescribing information is available on request. **Date of Preparation:** November 1993.

References
1. Data on file, Pharmax. 2. K.W. Somerville, et al. (1985) BMJ, 291-866. 3. W.S.J. Rudden, et al. (1980) Gut, 885-889. 4. C. Rodrigues, et al. (1987) The Lancet, i, 1497. 5. Data on file, Pharmax.

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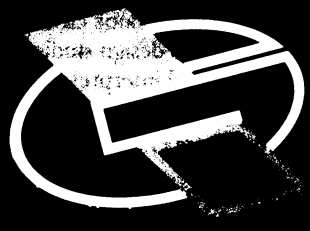

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GLYPRESSIN is a Trade Mark. **References:** 1. Soderlund C, et al. Scand J Gastroenterol 1990;25:677-680. 2. Burroughs AK. Drugs 1990;40(Suppl 2):1-15.

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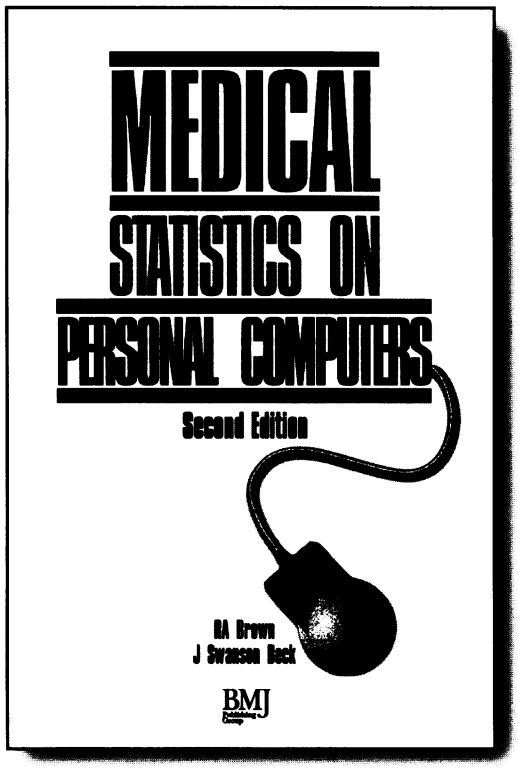

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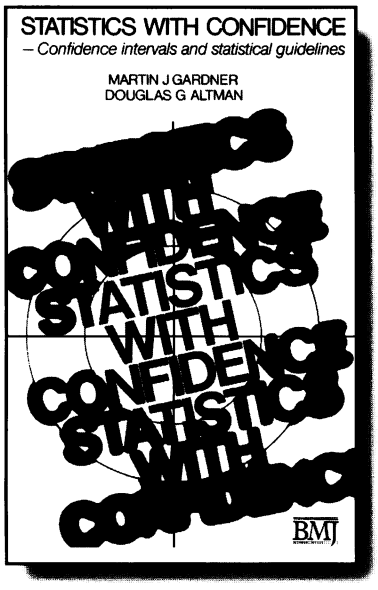

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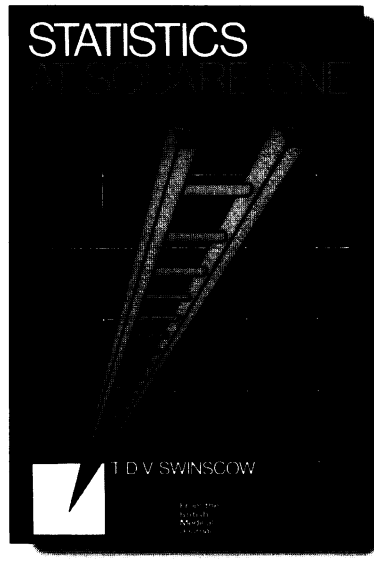

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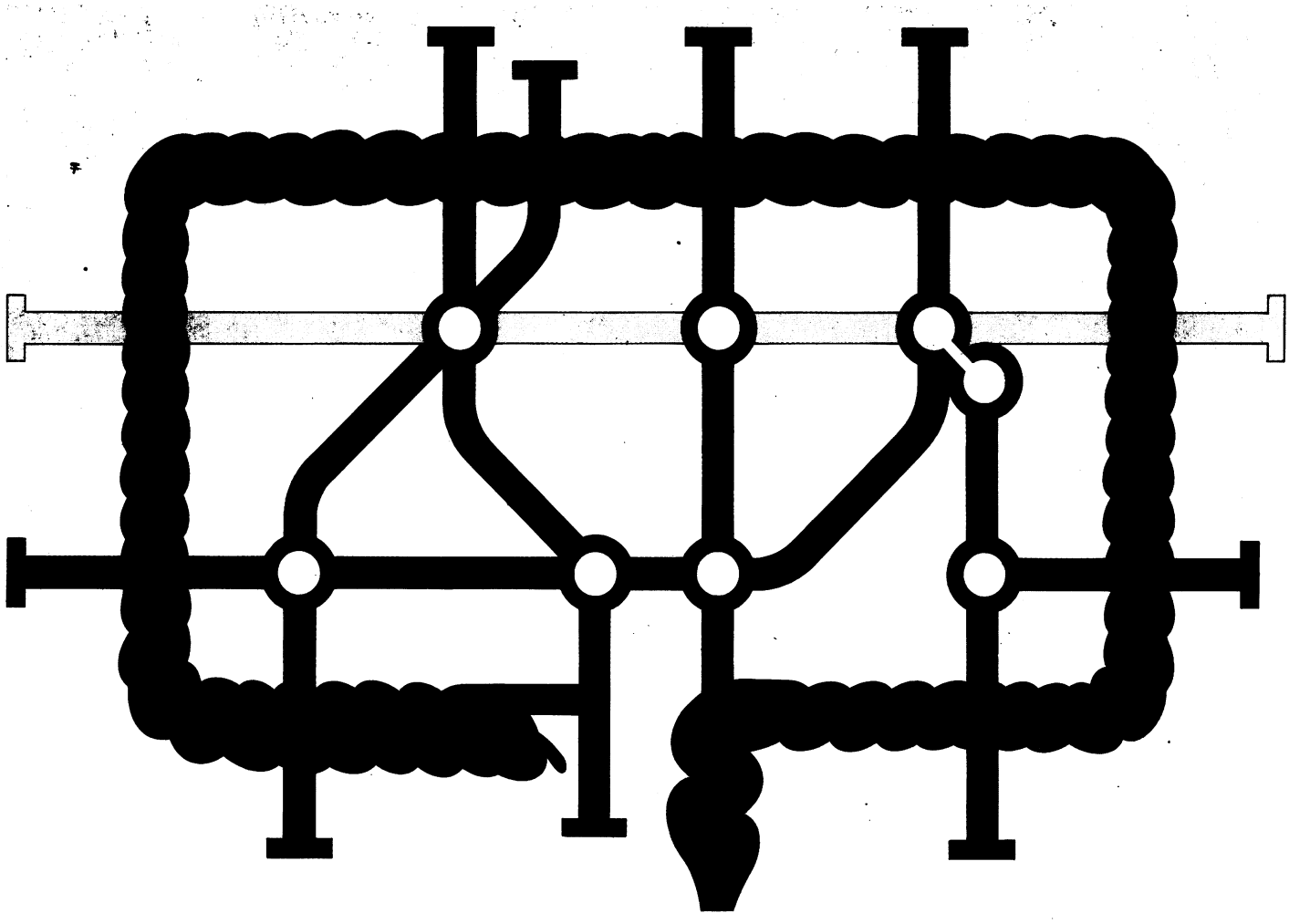

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