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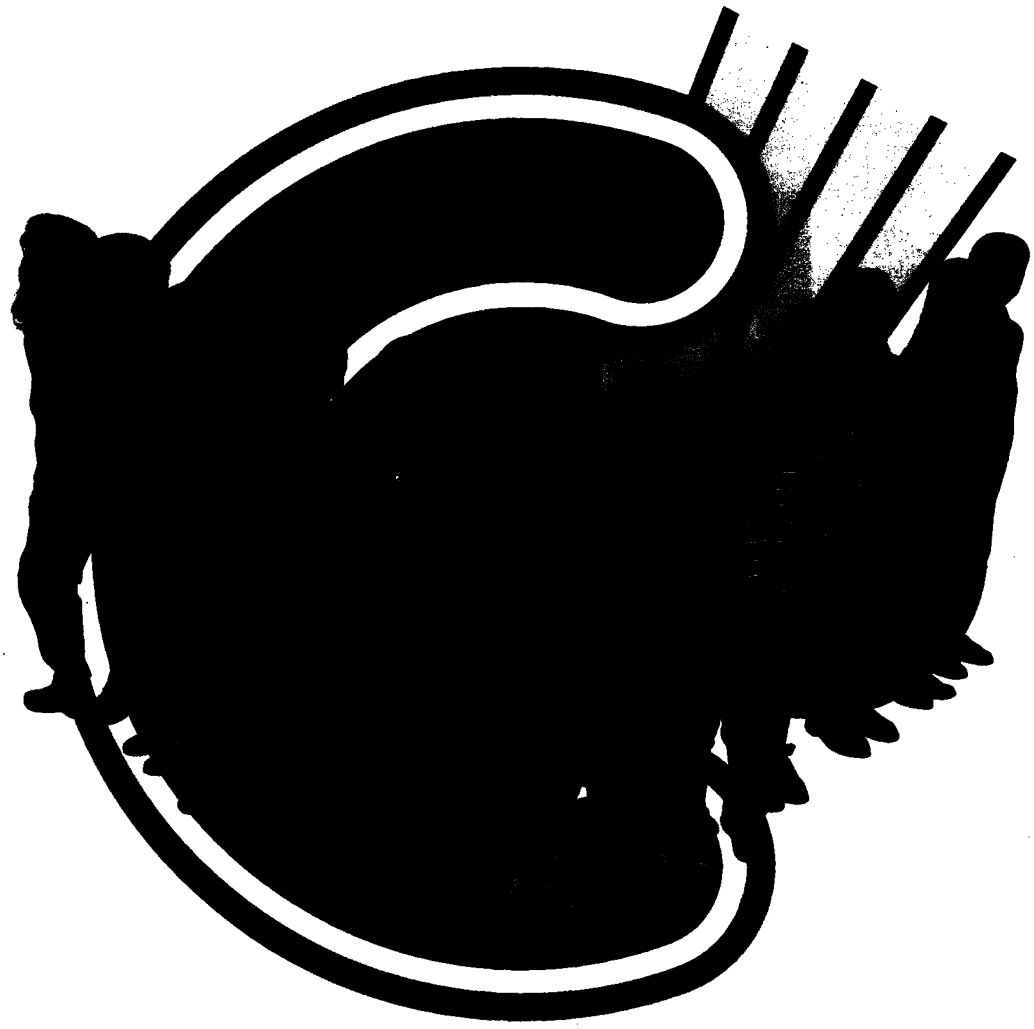

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PRESCRIBING INFORMATION

Presentation 1. Creon - brown/yellow capsules containing enteric coated granules of pancreatin, equivalent to: 8,000 PhEur units of lipase; 9,000 PhEur units of amylase and 450 PhEur units (total) of protease (210 BP units). Available in packs of 100. Basic NHS price of £13.33. PL 5727/0001. 2. Creon sachets - unit dose sachets containing enteric coated granules of pancreatin, equivalent to: 20,000 PhEur units of lipase, 22,500 PhEur units of amylase and 1,125 PhEur units (total) of protease. Available in packs of 40. Basic NHS price of £13.33. PL 5727/0007.

Indication Pancreatic exocrine insufficiency.

Dosage and Administration: Adults and children: 1. Creon - initially one or two capsules with meals, then adjust according to response. 2. Creon sachets - initially the contents of one sachet with meals, then adjust according to response. (Note that two sachets of Creon granules are equivalent to five capsules of Creon.) The contents of each sachet can be taken from a spoon or tipped directly onto the tongue, and then washed down with a drink of water or other fluid. The granules contained in Creon capsules or sachets can also be sprinkled on soft food, which should then be swallowed without chewing. If the granules are mixed with food, it is important that they are taken immediately, otherwise dissolution of the enteric coating may result.

Contra-indications, Warnings etc. Contra-indications: substitution with pancreatic enzymes is contra-indicated in the early states of acute pancreatitis. Use in pregnancy: there is inadequate evidence of safety in use during pregnancy. **Warnings:** The product is of porcine origin. Rarely cases of hyper-uricosuria and hyper-uricaemia have been reported with very high doses of pancreatin. Perianal irritation, and rarely, inflammation, could occur when large doses are used.

Legal Classification: P

Name and Address of Licence Holder: Kali Chemie Pharma GmbH, Postfach 220, D-30173, Hannover 1, Germany.

Further information available from: Duphar Laboratories Limited, Gaters Hill, West End, Southampton SO18 3JD. Tel: 0703 472281.

Date of preparation August 1994

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ABBREVIATED PRESCRIBING INFORMATION FOR DIFLUCAN* (fluconazole) (UK) Presentation: Capsules containing 50mg, 150mg or 200mg fluconazole; intravenous infusion containing fluconazole 2mg/ml in 0.9% sodium chloride solution; Powder for Oral Suspension available as two dosage strengths containing either fluconazole 50mg/5ml or 200mg/5ml on reconstitution with 24ml water. **Indications and dosage: Adults:** Systemic candidiasis: 400mg on the first day followed by 200-400mg once daily. Cryptococcosis, including meningitis: 400mg on the first day followed by 200-400mg once daily. Maintenance therapy to prevent relapse of cryptococcal meningitis in patients with AIDS: 100-200mg daily. Oropharyngeal candidiasis: 50-100mg once daily for 7-14 days or longer in immunocompromised patients. Other mucosal candidal infections: 50-100mg once daily for 14-30 days. Prevention of fungal infections in neutropenic patients following cytotoxic chemotherapy or radiotherapy: 50-400mg once daily based on patient's risk for developing fungal infection. For patients at high risk of systemic infection, eg patients who are anticipated to have profound or prolonged neutropenia such as during bone marrow transplantation, the recommended dose is 400mg daily. Start dosage several days before anticipated onset of neutropenia and continue for seven days after neutrophil count rises above 1000 cells per mm^3. Dermal fungal infections: 50mg once daily for up to 6 weeks (usually 2-4 weeks - see data sheet). Vaginal candidiasis: Single 150mg dose. Use in the elderly - as above except for those renally impaired - see data sheet. **Children: Over 4 weeks old:** Mucosal candidiasis: 3mg/kg daily. A loading dose of 6mg/kg may be used on the first day. Systemic candidiasis and cryptococcal infection: 6-12mg/kg daily depending on severity of disease. Prevention of fungal infections in neutropenic patients following cytotoxic chemotherapy or radiotherapy: 3-12mg/kg daily depending on the extent and duration of the neutropenia. **Children below 4 weeks of age:** First two weeks of life: The same mg/kg dosing as above but administered every 72 hours. During weeks 2-4 of life same mg/kg dose should be given every 48 hours. Doses of less than 10mg fluconazole should only be administered in hospital. A suitable measuring device should be used for administration of the suspension. **Administration:** DIFLUCAN may be administered either orally or by intravenous infusion at a rate of approximately 5-10ml/min. The dosages for the two routes are equivalent. **Contra-indications:** Hypersensitivity to fluconazole or related azoles, pregnancy and women of childbearing potential unless adequate contraception is employed. **Warnings:** Lactation: Not recommended. Renal impairment: Dosage reduction in both adults and children may be necessary, see data sheet. **Drug interactions:** Anticoagulants, cyclosporin, oral sulphonylureas, phenytoin, rifampicin and theophylline. **Side-effects:** Nausea, abdominal discomfort, diarrhoea, flatulence and rarely anaphylaxis. **Legal Category:** POM. **Basic NHS Cost and Package Quantities:** DIFLUCAN capsules in calendar packs containing 7x50mg (£16.61, PL 57/0289), 7x200mg (£66.42, PL 57/0317) or 1x150mg (£7.12, PL 57/0290); Powder for Oral Suspension, 35ml bottle of 50mg/5ml (£16.61, PL 57/0343), 35ml bottle of 200mg/5ml (£66.42, PL 57/0344); Intravenous Infusion: 25ml (50mg) bottle (£7.32, PL 57/0315); 100ml (200mg) bottle (£29.28, PL 57/0315). Hospital prices are available on request. † DIFLUCAN is well tolerated with few adverse effects: Marchisio P *et al.* (1994) Eur J Clin Microbiol Infect Dis **13:** 338-340. Fasano C *et al.* (1994) Eur J Clin Microbiol Infect Dis **13:** 344-347. Further information on request.

* Trade Mark. **Pfizer Limited,** Sandwich, Kent.
51336 March 1995.

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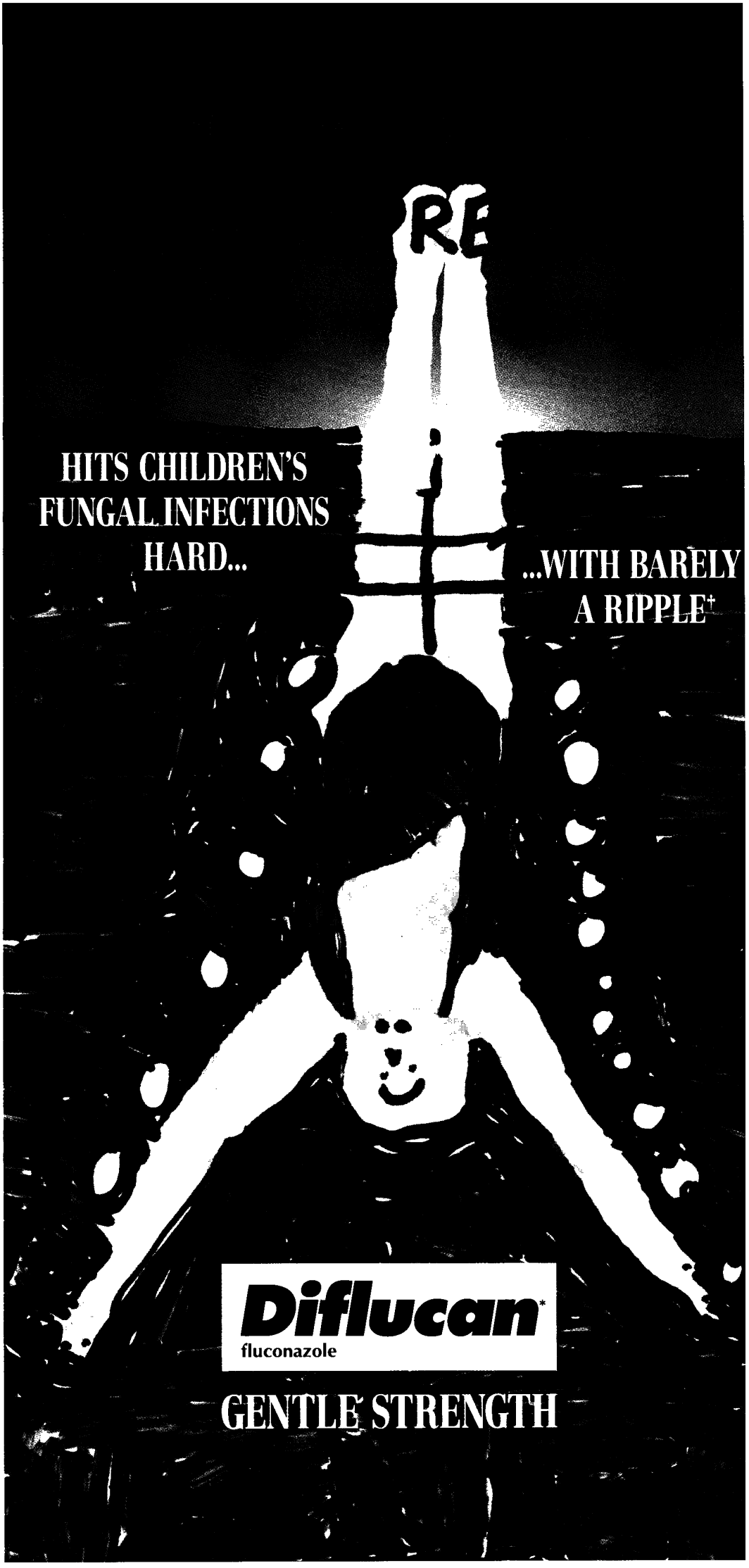

DECISIVE ACTION

[illegible] Fortum/Saline Infusion Kit - [illegible] 2g ceftazidime [illegible] [illegible] (See Data Sheet for details.) 1g to [illegible] per day and by the i.p. route [illegible] per 2L dialysis fluid. Most [illegible] 2g i.v. b.i.d.; severe infections, [illegible] per day. Cystic fibrosis - up [illegible] per day in three divided doses. [illegible] should be reduced when [illegible] filtration <50ml/min. An [illegible] 1g loading dose may be given with [illegible] renal insufficiency. *Elderly:* [illegible] dosage should not normally exceed [illegible] *Neonates/Infants/Children:* (See Data Sheet for details.) Up to two months: 25 [illegible] 60mg/kg/day as two divided doses. Over two months: 30 to 100mg/kg/day as two or three divided doses. Cystic fibrosis, meningitis, immunocompromised: up to 150mg/kg/day (max 6g daily) in three divided doses. Sensitivity results are recommended before commencing meningitis monotherapy. The Infusion Kit, in the dosage presented, may not be appropriate for use in children. **Contra-indication** Known hypersensitivity to cephalosporins. **Precautions** Previous anaphylactic reaction to penicillin. Administer with caution in early pregnancy, infancy and with concurrent nephrotoxic drug treatment. Fortum is excreted in human milk in low concentrations. Slight interference with copper reduction methods may occur. Fortum and aminoglycosides should not be mixed in the same giving set or syringe. Prolonged use may cause overgrowth of non-susceptible organisms (e.g. Candida, Enterococci) which may require interruption of treatment or other measures. **Side effects** Adverse reactions occur infrequently; pain and/or inflammation (i.m.) and phlebitis and/or thrombophlebitis (i.v.), rashes, fever, pruritus, anaphylaxis, GI disturbances, headache, dizziness, paraesthesia and bad taste. Transient changes in laboratory values may occur: eosinophilia, positive Coombs' test, thrombocytosis, leucopenia, neutropenia, thrombocytopenia and slight rises in hepatic enzymes. **Basic NHS cost** Packs of vials for injection (5 x 250mg, 5 x 500mg, 5 x 1g, 5 x 2g), and an infusion pack (5 x 2g); £9·90 per gram. Fortum/Saline Infusion Kit; £20·82. **Product licence numbers** Fortum for Injection: 250mg: 0004/0304; 500mg: 0004/0292; 1g: 0004/0293; 2g: 0004/0294. Sodium Chloride Intravenous Infusion: 3460/0015. **Product licence holder** Fortum for Injection: Glaxo Operat[illegible] UK Limited, Greenford, Middles[illegible] UB6 0HE. Sodium Chloride Intravenous Infusion: Galen Research Ltd, Craigavon, Northern Ireland BT63 5UA. POM

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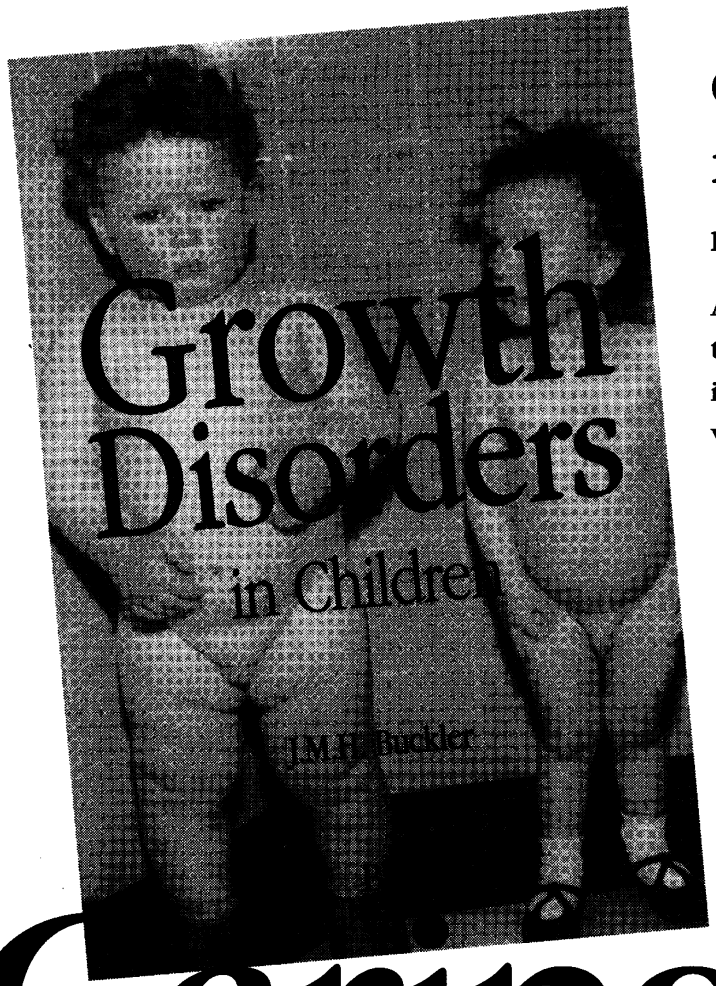

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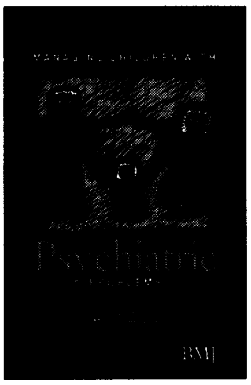

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Lamictal

PRESCRIBING INFORMATION

Presentation: Pale yellow tablets containing 25 mg, 50 mg, 100 mg and 200 mg lamotrigine, and white dispersible/chewable tablets containing 5 mg, 25 mg and 100 mg lamotrigine.

Uses: In monotherapy trials, efficacy has been demonstrated in partial epilepsy with or without secondarily generalised tonic-clonic seizures and in primary generalised tonic-clonic seizures.

Dosage and administration: *Dosage in monotherapy: Adults and Children over 12 years:* The initial Lamictal dose in monotherapy is 25 mg once a day for two weeks, followed by 50 mg once a day for two weeks. Thereafter, the usual maintenance dose to achieve optimal response is 100-200 mg/day given once a day or as two divided doses. Some patients have required 500 mg/day of Lamictal to achieve the desired response. The recommended initial dose should not be exceeded (see Data Sheet). *Children aged less than 12 years and the Elderly:* Insufficient information available in these patients and consequently not recommended.

Dosage as add-on therapy: Adults and children over 2 years: See Data Sheet.

Contra-indications: Hypersensitivity to lamotrigine. Significant hepatic impairment.

Precautions: Close monitoring of patients who acutely develop any combination of unexplained rash, fever, flu-like symptoms, drowsiness or worsening seizure control is recommended, especially within the first month of starting treatment. Pregnancy and lactation. Renal failure. Avoid abrupt withdrawal.

Interactions: Antiepileptic drugs which alter drug metabolising enzymes in the liver (e.g. phenytoin, carbamazepine, phenobarbitone, primidone, sodium valproate) alter the metabolism of Lamictal.

Side and adverse effects: During monotherapy trials: headache, tiredness, rash, nausea, dizziness, drowsiness, and insomnia. In use as add-on therapy, severe skin reactions including angioedema, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported. Rarely hepatic dysfunction, lymphadenopathy, leucopenia and thrombocytopenia have been reported in conjunction with skin rash and all patients who develop rash should be promptly evaluated. (See Data Sheet).

Legal category: POM.

Basic NHS costs: £14.97 for Starter Pack of 42 x 25 mg tablets (PL3/0272), £99.56 for Calendar Pack of 56 x 200 mg tablets (PL3/0297), £58.57 for pack of 56 x 100 mg tablets (PL3/0274).

Date of preparation: March 1995.

BQGT 91-13, 93-18, 94-09.

Lamictal is a Trade mark.

Further information is available on request.

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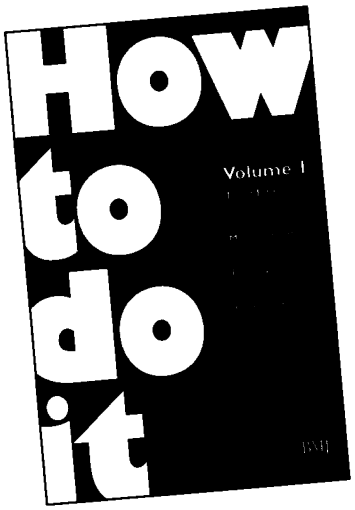

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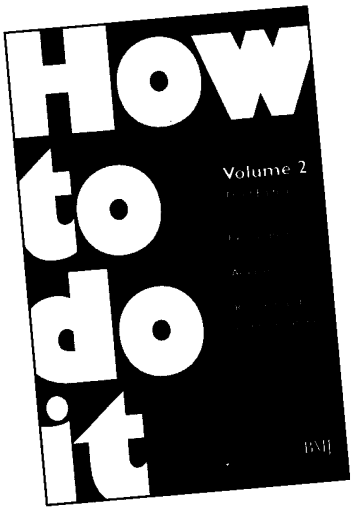

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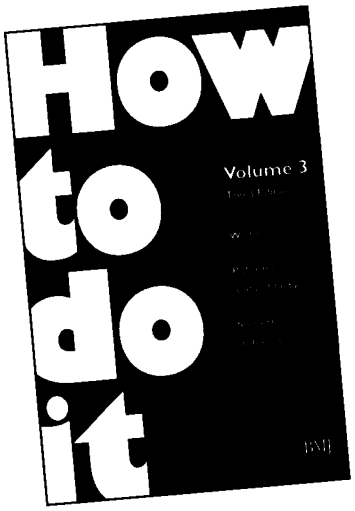

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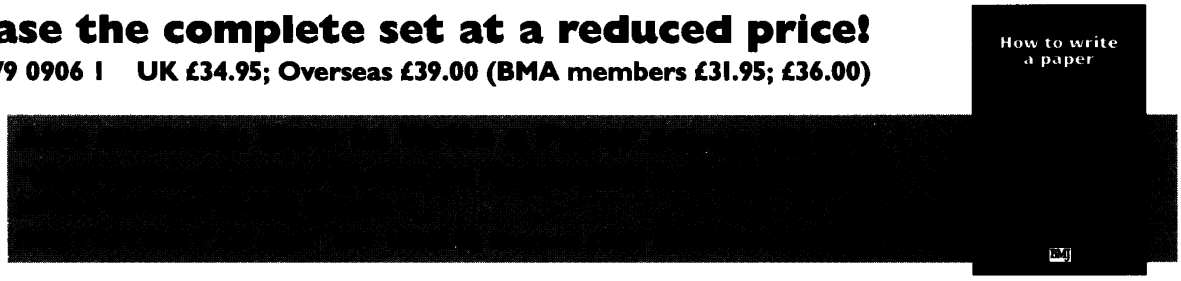

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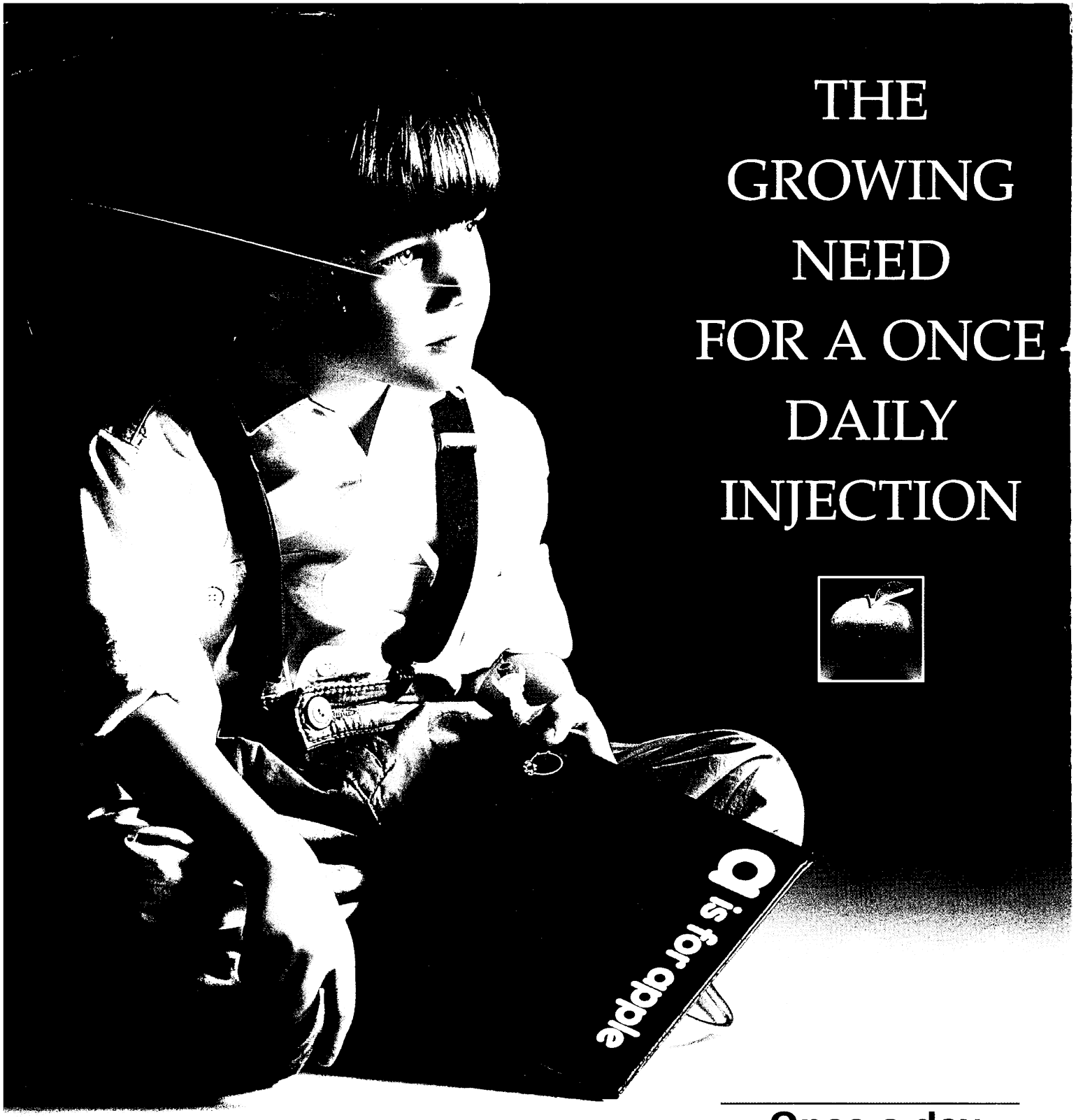

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References
1. Kissling M, Ruch W, Fernex M. Medipress (1988) 4(2): 17.
2. Estimated current cash annual sales worldwide - Datamon File, Roche Products Ltd.

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