Enteric coated granules for improved enzyme delivery in cystic fibrosis

...in stomach

Granules unaffected by stomach acid

Enzymes released in duodenum

Mimics the normal digestive process

creon®

pancreatin

A new release for cystic fibrosis patients

PRESCRIBING INFORMATION: Presentation: Brown/yellow capsules containing enteric coated granules of pancreatin equivalent to: 9,000 BP units of amylase, 8,000 BP units of lipase, 210 BP units of protease. Available in packs of 100. Basic NHS price £13.33. **Indication:** Pancreatic exocrine insufficiency. **Dosage and administration:** Adults and children: Initially one or two capsules with meals, then adjust according to response. The capsules should be swallowed whole, without chewing, with a little fluid, during the meal. **Contra-indications, Warnings, etc. Contra-indications:** Substitution with pancreatic enzymes is contra-indicated in the early stages of acute pancreatitis. **Warnings:** Use in pregnancy: There is inadequate evidence of safety in use during pregnancy. The product is of porcine origin. Rarely cases of hyper-uricosuria and hyper-uricaemia have been reported with high doses of pancreatin. Overdosage could precipitate meconium ileus equivalent. Perianal irritation could occur, and ,rarely, inflammation when large doses are used. **Product Licence Number** 5727/0001.

duphar Further information is available from:
Duphar Laboratories Ltd, Duphar House, Gaters Hill, West End, Southampton SO3 3JD. Tel: (0703) 472281

Epilim®
sodium valproate

In a wide range of epilepsies

Presentation 1. Epilim 200 Enteric Coated. A lilac-coloured enteric coated tablet containing 200mg sodium valproate. 2. Epilim 500 Enteric Coated. A lilac-coloured enteric coated tablet containing 500mg sodium valproate. 3. Epilim 100mg crushable tablets. A white scored tablet containing 100mg sodium valproate. 4. Epilim Syrup. A red, cherry-flavoured syrup containing 200mg sodium valproate per 5ml. 5. Epilim Liquid. A red, cherry-flavoured, sugar-free liquid containing 200mg sodium valproate per 5ml. **Indications** In the treatment of generalised, partial or other epilepsies. In women of child-bearing age Epilim should be used only in severe cases or in those resistant to other treatment. **Dosage and Administration** To be taken with or after food. Epilim may be given twice daily. Enteric coated tablets should be swallowed whole. **Monotherapy** *Adults:* Start at 600mg/daily increasing by 200mg at 3 day intervals until control is achieved. (Maximum dose 2,500mg per day). *Children over 20kg:* Initially 400mg/day with spaced increases until control is achieved. (Usually within the range 20-30mg/kg body weight per day). *Children under 20kg:* 20mg/kg of body weight per day: in severe cases may be increased up to 40mg/kg day. Increases above this only if plasma valproic acid levels, clinical chemistry and haematological parameters can be monitored. **Combined Therapy** It may be necessary to raise the dose when used with anticonvulsants which induce liver enzyme activity. Dosage of barbiturates should be reduced if sedation is observed. Optimum dosage is mainly determined by seizure control and routine measurement of plasma levels is unnecessary. **Contra-indications, Warnings; Contra-indication:** Active liver disease. **Side effects:** Liver dysfunction including hepatic failure resulting in fatalities has occurred in patients whose treatment included valproic acid or sodium valproate. The incidents mainly occurred during the first 6 months of therapy. Clinical symptoms are more helpful than laboratory investigations in the early stages of hepatic failure. The onset of an acute illness, especially within the first 6 months, which may include symptoms of vomiting, lethargy or weakness, drowsiness, anorexia, jaundice or loss of seizure control is an indication for immediate withdrawal of the drug. Evidence to date does not establish which investigation could predict this possible adverse effect: measurement of liver function should be performed in the first 6 months of therapy in those who seem most at risk. Hyperammonaemia without hepatic damage can occur, it is usually transient, but may occasionally present clinically. If so Epilim should be discontinued. Valproic acid inhibits platelet aggregation. Thrombocytopenia has been reported. Spontaneous bruising or bleeding is an indication for withdrawal of medication. Pancreatitis, tremor, weight gain, transient hair loss, increased alertness, aggressiveness, hyperactivity, amenorrhoea, stupor and oedema have been reported. **Drug Interactions** Epilim may potentiate monoamine oxidase inhibitors and other anti-depressants. Loss of efficacy of oral contraceptive agents does not appear to be a problem. **Women of Childbearing Age** Valproic acid and sodium valproate, like certain other anti-convulsants, have been shown to be teratogenic in animals. In women of childbearing age the benefits of these compounds should be weighed against the possible hazard suggested by these findings and their pregnancies should be carefully monitored. **Product Licence Numbers** Epilim 200 Enteric Coated 0623/0006. Epilim 500 Enteric Coated 0623/0005. Epilim 100mg crushable tablets 0623/0015. Epilim Syrup 0623/0004. Epilim Liquid 0623/0016. **NHS Cost** Epilim 200 Enteric Coated 100 tablets, £6.59. Epilim 500 Enteric Coated 100 tablets, £16.45. Epilim 100mg crushable tablets 100 tablets, £3.99. Epilim Syrup 200ml, £4.03. Epilim Liquid 200ml, £4.03. Further information is available from: Labaz: Sanofi UK Ltd., Floats Rd., Wythenshawe, Manchester M23 9NF. Tel: 061-945 4161.

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sodium valproate

helps to maintain the normality of life

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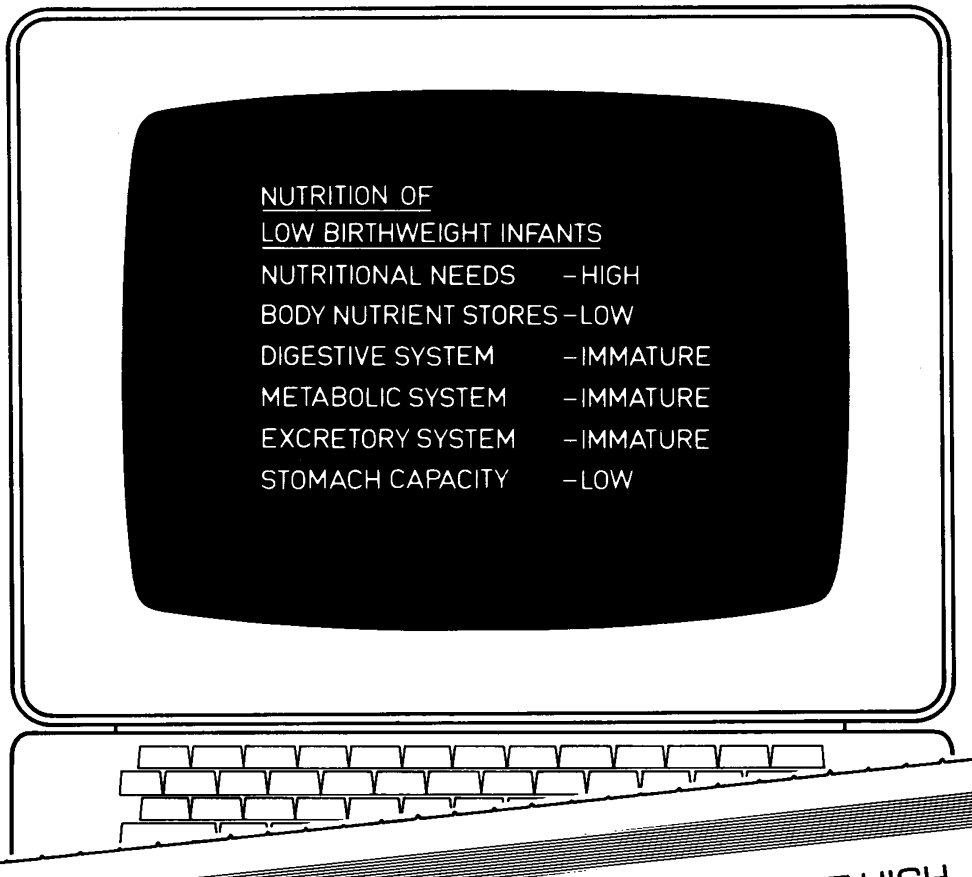

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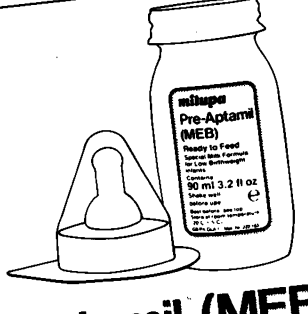

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1. Brooke, O. G., Wood, C., Barley, J. *Arch. Dis. Child* 1982, **57**, 898–904.

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Volume 144 Number 1 May 1985

Subscription information: Volume 144 (6 issues) will appear in 1985. Information about obtaining back volumes and microform editions available upon request.

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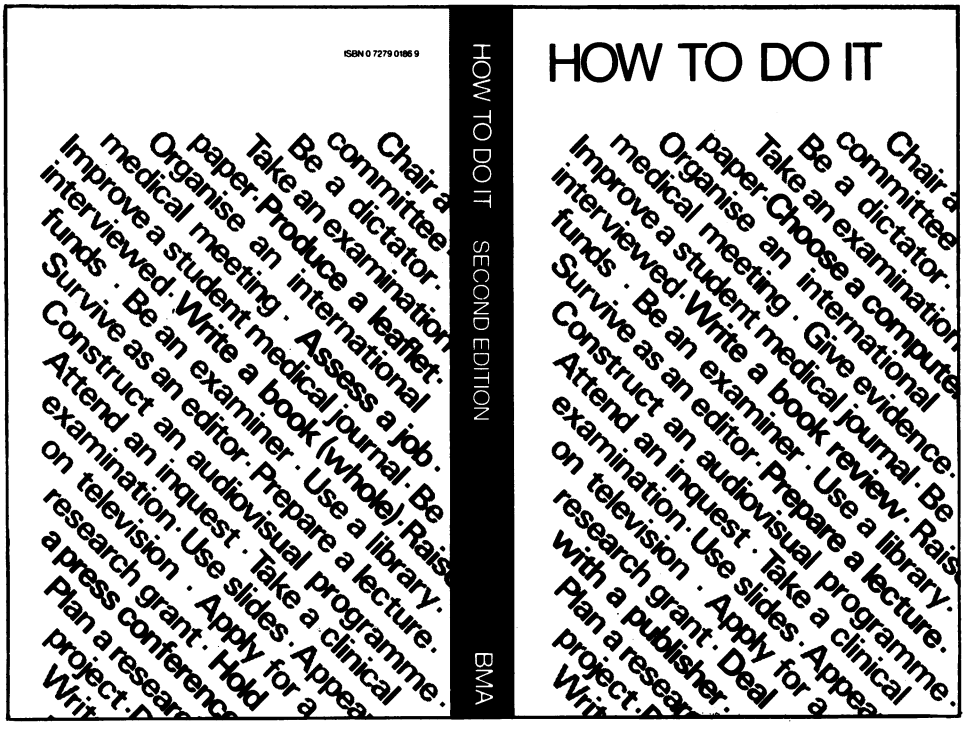

Published by British Medical Association, Tavistock Square, London WC1H 9JP, and
Printed in England by The Devonshire Press Ltd., Torquay.

Indications Epilepsy (generalised tonic-clonic and partial seizures).
Dosage in epilepsy Use a gradually increasing dosage scheme, adjusting to patient's needs. Adults: 100-200mg once or twice daily, increasing slowly up to 800-1,200mg daily; in some cases 1,600mg daily may be necessary. Children: up to 1 year old, 100-200mg daily; aged 1-5 years, 200-400mg daily; aged 5-10 years, 400-600mg daily; aged 10-15 years, 600-1,000mg daily. It may be helpful to monitor plasma drug levels: optimum therapeutic range is 3-10μg/ml (13-42μmols/l).
Side-effects Dizziness and diplopia (usually dose-dependent), less frequently dry mouth, nausea and vomiting. Generalised erythematous rash, disappearing on cessation of therapy. Isolated reports of oedema, hyponatraemia, exfoliative dermatitis, leucopenia, thrombocytopenia, agranulocytosis, aplastic anaemia, cholestatic jaundice and acute renal failure. Blood count should be checked in early stages of treatment.
Precautions Caution in patients taking oral anticoagulants or requiring oral contraception.
In pregnancy, potential benefits of Tegretol must be weighed against potential hazards. Do not administer with, or within two weeks of cessation of, MAOI therapy.
In rats treated with carbamazepine for two years, incidence of liver tumours increased (no evidence of significant bearing on the therapeutic use of the drug). Serum folic acid levels should be observed during anticonvulsant therapy.
Contra-indications Previous drug sensitivity to Tegretol. Do not administer to patients with atrioventricular conduction abnormalities unless paced.
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® denotes registered trademark. Full prescribing information is available on request from Geigy Pharmaceuticals, Horsham, West Sussex.

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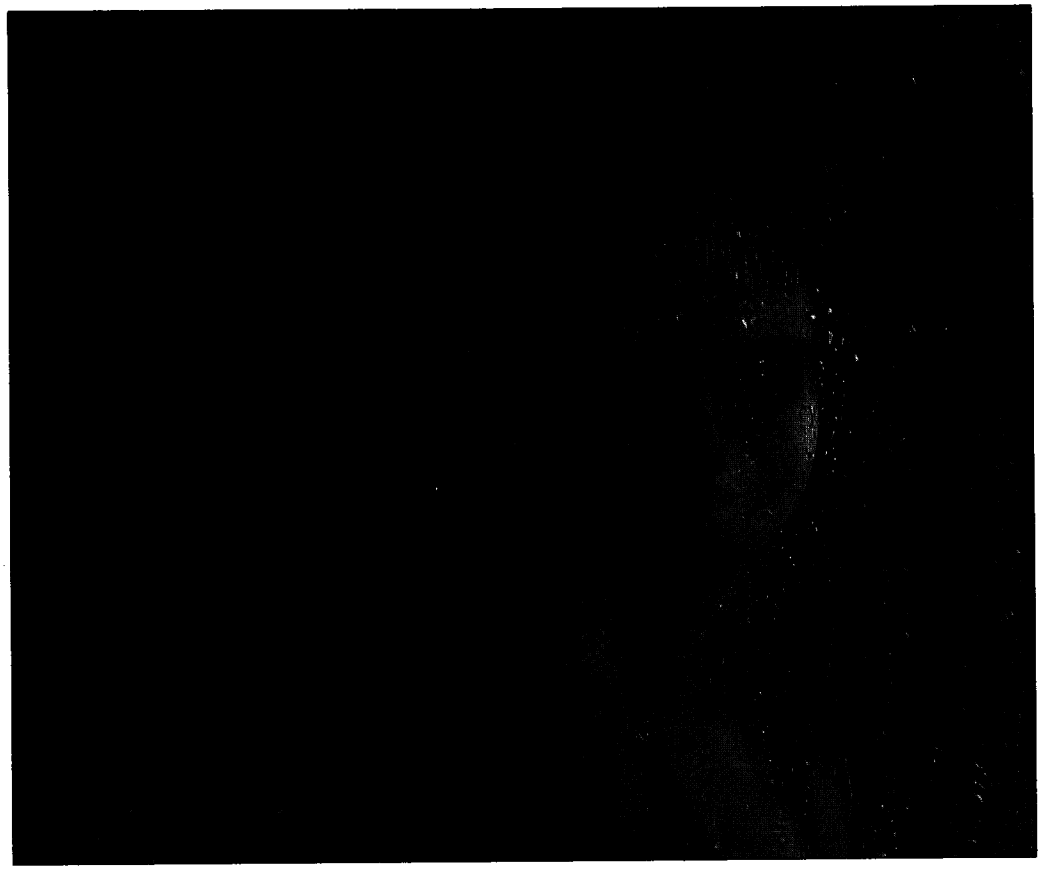

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