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The ECT Handbook

The Second Report of the Royal College of Psychiatrists' Special Committee on ECT

£14.99, 168pp., 1995, ISBN 0 902241 83 4

Available from good bookshops and from the Publications Department, Royal College of Psychiatrists, 17 Belgrave Square, London SW1X 8PG (Tel. +44(0)171 235 2351, extension 146)

Epilim Oral Prescribing Information

Presentation Epilim 200 Enteric Coated and Epilim 500 Enteric Coated: Enteric coated tablets containing 200mg, and 500mg Sodium Valproate Ph.Eur. respectively. Epilim Crushable Tablets containing 100mg Sodium Valproate Ph.Eur. Epilim Syrup and Epilim Liquid (sugar free) both containing 200mg Sodium Valproate Ph.Eur. per 5ml. Epilim Chrono 200, Epilim Chrono 300, and Epilim Chrono 500: Controlled release tablets containing a mixture of Sodium Valproate Ph.Eur. and Valproic Acid Fr.P. equivalent to 200mg, 300mg, and 500mg Sodium Valproate respectively. **Indications** Oral formulations of Epilim are indicated for all types of epilepsy. In women of child bearing age Epilim should be used only in severe cases or in those resistant to other treatment. **Dosage and administration** *Adults*; the dose should be titrated at three day intervals until seizure control is achieved. Initially 600mg a day increasing in steps of 200mg to a maximum dose of 2500mg per day. *Children over 20kg*; initially 400mg a day increasing in steps to a maximum dose of 35mg/kg/day. *Children under 20kg*; initially 20mg/kg/day - the dose may be increased in severe cases provided that plasma levels are monitored; above 40mg/kg/day chemistry and haematology should be monitored. Epilim Chrono may be given once or twice daily. All other formulations should be given twice daily. *Combination therapy*; levels of Epilim and co-administered anticonvulsants may be affected and optimum dosage is determined by seizure control. **Contraindications, Warnings, etc.** *Contraindications* Active liver disease, family history of severe liver disease, porphyria, hypersensitivity to valproate. *Side effects* Impaired hepatic function, particularly in children, occasionally leading to hepatic failure - treatment should be withdrawn in patients who suddenly develop symptoms compatible with hepatic disease such as nausea, anorexia, jaundice or malaise. Hyperammonaemia with or without hepatic dysfunction. Blood dyscrasia - impaired platelet function, thrombocytopenia, occasional leucopenia, pancytopenia and red cell hypoplasia. Occasionally increased appetite, weight gain, transient hair loss, behavioural disturbances, hearing loss, vasculitis, alterations to the menstrual cycle and pancreatitis. Symptoms of intoxication include ataxia, tremor, and stupor. *Drug interactions* Epilim has significant interactions with phenytoin, lamotrigine and other anticonvulsants. Epilim may potentiate the effects of neuroleptics, MAOIs and other antidepressants, anticoagulants and salicylates. Cimetidine and erythromycin may inhibit the metabolism of Epilim. Mefloquine may decrease serum valproate levels. Epilim has no effect on the efficacy of oral contraceptives. *Pregnancy* An increased incidence of congenital abnormalities has been demonstrated in offspring born to mothers with epilepsy both untreated and treated, including those treated with sodium valproate. Neural tube defects have been reported in about 1-2% of offspring of women who have received valproate during the first trimester of pregnancy. Pregnancies should be screened for neural tube defects by estimation of alpha-fetoprotein and ultrasound. Folate supplementation has been shown to reduce the incidence of neural tube defects in the offspring of high risk women. **Legal category** P.O.M. **Further information** Epilim is hygroscopic - tablets should not be removed from their foil until they are used. Epilim Chrono is recommended in cases where plasma valproate levels are being measured on account of its pharmacokinetics. The effective therapeutic range for valproate is 40-100mg/l (278-694 micromol/l). **Product Licence Numbers** Epilim 200 Enteric Coated 11723/0018, Epilim 500 Enteric Coated 11723/0020, Epilim 100mg Crushable Tablets 11723/0017, Epilim Syrup 11723/0025, Epilim Liquid 11723/0024, Epilim Chrono 200 11723/0078, Epilim Chrono 300 11723/0021, Epilim Chrono 500 11723/0079. **NHS Cost** Epilim 200 Enteric Coated 100 tablets £6.42, Epilim 500 Enteric Coated 100 tablets £16.04, Epilim 100mg Crushable Tablets 100 tablets £3.89, Epilim Syrup 300ml £5.89, Epilim Liquid 300ml £5.89, Epilim Chrono 200 100 tablets £7.70, Epilim Chrono 300 100 tablets £11.55, Epilim Chrono 500 100 tablets £19.25. **Address:** Sanofi Winthrop Ltd., One Onslow Street, Guildford, Surrey GU1 4YS. **Telephone:** (01483) 505515 **Fax:** (01483) 35432. Epilim, Epilim Chrono and the Chrono device are registered trade marks. **Date of preparation:** January 1997.

References:

1. Chadwick D., *J. Neurol. Neurosurg. Psychiatry* 1994; **57**: 264-277.
2. Gilham R.A., *Epilepsy Res.*, 1990; **7**: 219-225.

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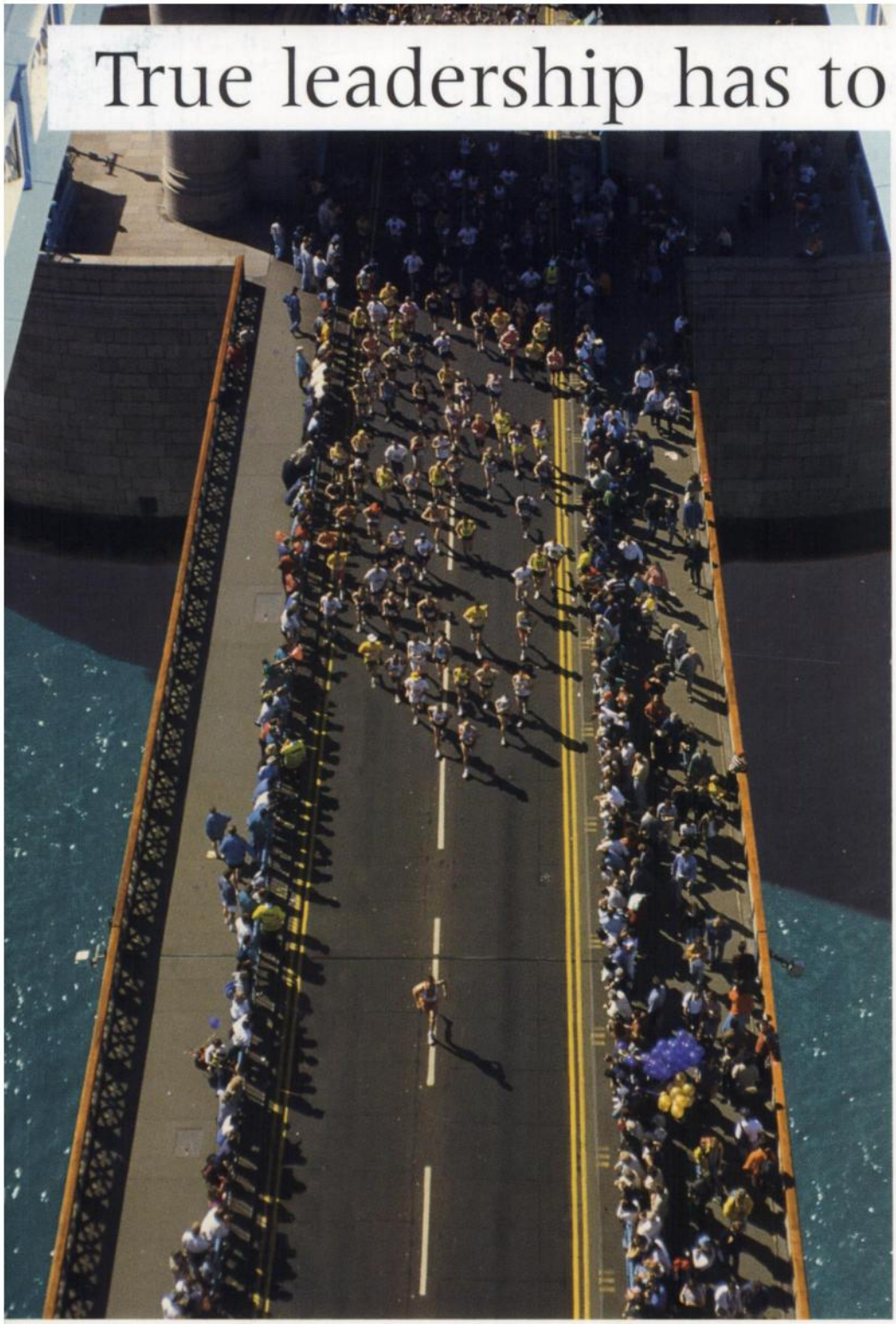

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'PROZAC' ABBREVIATED PRESCRIBING INFORMATION (FLUOXETINE HYDROCHLORIDE)
Presentation Capsules containing 20mg or 60mg fluoxetine, as the hydrochloride. Liquid containing 20mg fluoxetine, as the hydrochloride, per 5ml syrup. **USES Depression: TREATMENT OF THE SYMPTOMS OF DEPRESSIVE ILLNESS, WITH OR WITHOUT ASSOCIATED ANXIETY SYMPTOMS.** *Obsessive-compulsive disorder. Bulimia nervosa:* For the reduction of binge-eating and purging activity. **Dosage and Administration** (For full information, see data sheet.) For oral administration to adults only. *Depression, with or without associated anxiety symptoms - adults and the elderly:* A dose of 20mg/day is recommended. *Obsessive-compulsive disorder:* 20mg/day to 60mg/day. A dose of 20mg/day is recommended as the initial dose. *Bulimia - adults and the elderly:* A dose of 60mg/day is recommended. Because of the long elimination half-lives of the parent drug (1-3 days after acute administration; may be prolonged to 4-6 days after chronic administration) and its major metabolite (average 9.3 days), active drug substance will persist in the body for several weeks after dosing is stopped. The capsule and liquid dosage forms are bioequivalent. *Children:* Not recommended. *Patients with renal and/or hepatic dysfunction:* See 'Contra-indications' and 'Precautions' sections. **Contra-indications** Hypersensitivity to fluoxetine. Prozac should not be administered to patients with severe renal failure (GFR <10ml/min). *Usage in nursing mothers:* Prozac should not be prescribed to nursing mothers. *Monoamine oxidase inhibitors:* At least 14 days should elapse between discontinuation of an MAOI and initiation of treatment with Prozac. At least five weeks should elapse before discontinuation of Prozac and initiation of therapy with an MAOI. Serious, sometimes fatal reactions (including hyperthermia, rigidity, myoclonus, autonomic instability and mental status changes that include extreme agitation, progressing to delirium and coma) have been reported with concomitant use or when fluoxetine had been recently discontinued and an MAOI started. Some cases presented with features resembling neuroleptic malignant syndrome. **Warnings** *Rash and allergic reactions:* Angioneurotic oedema, urticaria and other allergic reactions have been reported. Upon appearance of rash, or of other allergic phenomena for which an alternative aetiology cannot be identified, Prozac should be discontinued. *Pregnancy:* Use of Prozac should be avoided unless there is no safer alternative. **Precautions** Prozac should be discontinued in any patient who develops seizures. Prozac should be avoided in patients with unstable epilepsy; patients with controlled epilepsy should be carefully monitored. There have been rare reports of prolonged seizures in patients on fluoxetine receiving ECT treatment. A lower dose of Prozac, eg, alternate day dosing, is recommended in patients with significant hepatic dysfunction or mild to moderate renal failure (GFR 10-50ml/min). Caution is advisable when Prozac is used in patients with acute cardiac disease. Prozac may cause weight loss which may be undesirable in underweight depressed patients. In diabetics, fluoxetine may alter glycaemic control. There have been reports of abnormal bleeding in several patients, but causal relationship to fluoxetine and clinical importance are unclear. *Drug interactions:* Increased (with fluoxetine) or decreased lithium levels have been reported. Lithium levels should be monitored. Because fluoxetine's metabolism involves the hepatic cytochrome P450IID6 isoenzyme system, concomitant therapy with other drugs also metabolised by this system, and which have a narrow therapeutic index (eg, carbamazepine, tricyclic antidepressants), should be initiated at or adjusted to the low end of their dose range. Greater than 2-fold increases of previously stable plasma levels of cyclic antidepressants have been observed when Prozac has been administered in combination. Agitation, restlessness and gastro-intestinal symptoms have been reported in a small number of patients receiving fluoxetine in combination with tryptophan. Patients on stable phenytoin doses have developed elevated plasma concentrations and clinical phenytoin toxicity after starting fluoxetine. *For further information, see data sheet.* **Adverse Effects** Asthenia, fever, nausea, diarrhoea, dry mouth, appetite loss, dyspepsia, vomiting, rarely abnormal LFTs, headache, nervousness, insomnia, drowsiness, anxiety, tremor, dizziness, fatigue, decreased libido, seizures, hypomania or mania, dyskinesia, movement disorders, neuroleptic malignant syndrome-like events, pharyngitis, dyspnoea, pulmonary events (including inflammatory processes and/or fibrosis), rash, urticaria, vasculitis, excessive sweating, arthralgia, myalgia, serum sickness, anaphylactoid reactions, hair loss, sexual dysfunction. The following have been reported in association with fluoxetine but no causal relationship has been established: aplastic anaemia, cerebral vascular accident, confusion, ecchymoses, eosinophilic pneumonia, gastro-intestinal haemorrhage, hyperprolactinaemia, immune-related haemolytic anaemia, pancreatitis, pancytopenia, suicidal ideation, thrombocytopenia, thrombocytopenic purpura, vaginal bleeding after drug withdrawal and violent behaviour. Hyponatraemia (including serum sodium below 110mmol/l) has been rarely reported. This appears to be reversible upon discontinuation. **Overdosage** On the evidence available, fluoxetine has a wide margin of safety in overdose. Since introduction, reports of death, attributed to overdosage of fluoxetine alone, have been extremely rare. One patient who reportedly took 3000mg of fluoxetine experienced 2 grand mal seizures that remitted spontaneously. **Legal Category** POM **Product Licence Numbers** 0006/0195 0006/0198 0006/0272 **Basic NHS Cost** £20.77per pack of 30 capsules (20mg). £67.85 per pack of 98 capsules (20mg). £62.31 per pack of 30 capsules (60mg). £19.39 per 70ml bottle. **Date of Preparation or L: Review** October 1996. **Full Prescribing Informati is Available From** Dista Products Limited, Dextra Co. Chapel Hill, Basingstoke, Hampshire, RG21 5SY. Telephon. Basingstoke (01256) 52011
'PROZAC' is a Dista trademark

References:1. Data on file, Dista Products Ltd. 2. Tignol J. *J Clin Psychopharm* 1993; **13** (6, suppl. 2): 18S-22S. 3. Bennie Mullin JM, Martindale JJ. *J Clin Psychiatry* 1995; **56**: 4. Prozac Data Sheet 24M.

Date of preparation: May 1997

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