

# Management for Psychiatrists

Second Edition

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### 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, 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Impaired hepatic function, particularly in children, occasionally leading to hepatic failure - treatment should be withdrawn in patients who suddenly develop symptoms compatible with hepatic disease such as nausea, anorexia, jaundice or malaise.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 and red cell hypoplasia. Occasionally increased appetite, weight gain, transient hair loss, behavioural disturbances, 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 may inhibit the metabolism of Epilim. 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% 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:** May 1996.

### 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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in mind. The potential of LUSTRAL to interact with e.g. warfarin, diazepam, tolbutamide and cimetidine has not been fully assessed. With warfarin prothrombin time should be monitored when LUSTRAL is initiated or stopped. **Side-effects:** Dry mouth, nausea, diarrhoea/loose stools ejaculatory delay, tremor, increased sweating, dyspepsia, dizziness insomnia and somnolence. Asymptomatic elevations in serum transaminases have been reported infrequently (approx. 0.8%) in association with LUSTRAL. These usually occurred within the first 9 weeks treatment and resolved on cessation of therapy. Malaise and rash have been reported. Seizures (see precautions, warnings). There have been isolated reports of movement disorders and rare cases of hyponatraemia. **Legal category:** POM. **Basic NHS cost:** 50mg tablet (PL 57/0308) Calendar pack of 28, £26.51; 100mg tablet (PL 57/0309) Calendar pack of 28, £39.77. Further information on request. Invicta™ Pharmaceuticals or Richborough™ Pharmaceuticals Divisions of Pfizer Limited, Sandwich, Kent.

