

In a wide range of epilepsies

Presentation 1. Epilim® Enteric Coated: A white coloured enteric coated tablet containing 200mg sodium valproate. 2. Epilim® Enteric Coated: A white 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. **Contraindications. 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 hepatic than laboratory investigations. 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 which 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 anticonvulsants, 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 36.89. Epilim 500 Enteric Coated 100 tablets 516.46. Epilim 100mg crushable tablets 100 tablets 13.99. Epilim Syrup 200mg/5ml. Epilim Liquid 200mg/5ml. Further information is available from Labaz, Sandwick Ltd, Fife Rd, Wymondshame, East Angles, Manchester M23 9NF. Tel: 0161 456 4161.

sodium valproate

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sodium valproate

helps to maintain the normality of life

Labaz



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