Depression...disturbed sleep...

Sinequan
brand of doxepin
 Trade Mark

lifts depression...
promotes restful sleep

- SEDATIVE ANTIDEPRESSANT
- ONCE NIGHTLY DOSAGE

Indications: depression with or without anxiety. Contraindications: glaucoma, urinary retention, hypersensitivity to the drug. Side effects: dry mouth and drowsiness are most commonly reported. Precautions: Sinequan may potentiate other compounds – e.g. monoamine oxidase inhibitors; not recommended in pregnancy or children under 12 years age. Dosage: range 30 mg to 300 mg daily in divided doses, up to 100 mg may be given as a single dose at night. Packs and Basic N.H.S. Cost: 10 mg capsules (PL 57/5032), pack of 100, £2.98; 25 mg capsules (PL 57/5033), pack of 100, £4.24; 50 mg capsules (PL 57/5034) pack of 100, £7.01; 75 mg capsules (PL 57/0133), pack of 60, £6.64.

Full information on request to the Company.

Pfizer
PFIZER LIMITED
SANDWICH, KENT.
Epilim is a powerful anticonvulsant capable of providing control for the majority of adults with tonic-clonic seizures or other epilepsies, including those not well controlled on previous treatments. Because it controls without sedation, Epilim allows many patients to lead full, normal lives.

Presentation
2. Epilim tablets. A white scored tablet containing 200mg sodium valproate.
4. Epilim Syrup. A red cherry-flavoured syrup containing 200mg sodium valproate per 5ml.

Indications
Epilepsy. In women of childbearing 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. Enteric-coated and plain tablets should be swallowed whole. Optimum dosage should be established using the 200mg enteric-coated tablet. Epilim 300 enteric-coated is recommended for patients requiring high dosages.

Adults: Dosage should start at 600mg/day in divided doses, increasing by 200mg/day at three-day intervals until control is achieved. (Maximum Dose 2600mg/day)

In patients already receiving other therapy the same pattern should be followed. Dosage of barbiturates should be reduced as that of Epilim is increased; the respective dosages should be adjusted, during the stabilisation period, to give optimum control at the lowest possible combined-dose level, and it may be found possible to maintain control with Epilim alone.

Once known enzyme-inhibitors have been withdrawn, it may be possible to maintain seizure control on a reduced dose of Epilim. Although a method of measuring plasma levels is available, the optimum dosage must ultimately be determined by seizure-control. (Children over 20kg: Initially 400mg/day in divided doses with spaced increases until control is achieved usually in the range of 20-30mg/kg/day. Children under 20kg: 20mg/kg body weight per day, in severe cases, this may be increased up to 50mg/kg/day but should be undertaken only in patients in whom plasma valproate levels, clinical chemistry and haematological parameters can be monitored.

Contra-Indications, Warnings, etc.
Lever dysfunction, including hepatic failure resulting in fatalities has occurred in patients whose treatment included valproic acid or sodium valproate. The incidents occurred during the first six months of therapy, the period of maximum rise being 2-12 weeks. No deaths have occurred in patients receiving the drug continuously for more than six months.

Biochemical tests may not always become abnormal early in the evolution of hepatic failure. Non-specific findings such as loss of serum control, malaise, anorexia and vomiting, developing after a period of satisfactory Epilim treatment may alert the clinician to the possibility of hepatic damage.

Epilim should not be administered to patients with pre-existing hepatic dysfunction. All patients for whom treatment with Epilim is contemplated should have base line liver function assessed (including serum fibronogen and albumin levels) prior to commencement of therapy. Liver function should be carefully monitored, particularly during the first six months of therapy, and when dosage is being titrated upwards.

Patients with a prior history of liver disease or with severe or unusual jaundice disorders, e.g. those accompanied by mental retardation and or organic brain disease, should be followed particularly carefully. Transient elevations of liver enzymes are not uncommon during early treatment with Epilim, but, if elevations are accompanied by other evidence of hepatic dysfunction, especially raised serum bilirubin or lowered serum fibronogen, then the drug should be withdrawn immediately.

Hyperammonaemia without hepatic damage can occur in patients during treatment with valproic acid or sodium valproate. This may manifest clinically as vomiting, ataxia and increasing clouding of consciousness. Should these symptoms occur, Epilim should be discontinued.

Valproic acid inhibits second stage of platelet aggregation. Reversible prolongation of bleeding time and thrombocytopenia may be expected. Spontaneous bruising or bleeding is an indication for withdrawal of medication pending investigations. Patients receiving Epilim should be monitored for platelet function before major surgery. Red cell hypoplasia and leukopenia have been reported. The blood picture returned to normal when the drug was discontinued. Pancytopenia has occurred in patients receiving valproic acid or sodium valproate. Patients experiencing acute abdominal pain should have serum amylase estimated. Minor gastric irritation and, less frequently, nausea may occur at the start of treatment but these problems can usually be overcome by administering Epilim tablets or syrup with or after food, or by transferring the patient to the Epilim enteric-coated formulations. Transient hair loss has been noted in some patients. Regrowth normally begins within six months. Tremor has occasionally been observed at high dosage. Cysterna has been reported. Increase in alertness, appetite and weight may occur.

Further Information
When plasma valproic acid is within the recommended range of 50-120µg/litre (350-840µmol/litre) and serum albumin levels are normal, about 90% of the drug is bound to albumin. The total plasma valproic acid rises above the upper range of normal, or if there is hypalbuminaemia, the percentage of free valproic acid may rise markedly in disproportion to any dosage increase and may be associated with a higher incidence of adverse effects.

Product Licence Numbers, Names and Addresses
Epilim 200 enteric-coated tablets 0853:0005
Epilim tablets 0823:0001
D0500093, 0005
Epilim 300 enteric-coated tablets 0853:0004
Syrups 0853:0002
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NHS Cost
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