Depression... disturbed sleep...

Sinequan®
brand of doxepin

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 of 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, £5.64.

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 500 enteric-coated is recommended for patients requiring high dosages.

Adults: Dosage should start at 600mg/day, divided doses, increasing by 200mg/day at three- to six-month intervals until control is achieved. (Maximum Dose: 2400mg/day.

In patients already receiving another 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 stabilization 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Once known enzyme-inducers have been withdrawn, it may be possible to maintain seizure control on a reduced dose of Epilim.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, optimum dosage must ultimately be determined by seizure control Children under 10kg: 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 of 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.
Liver 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 risk 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 therapy 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 baseline liver function tests (including serum transaminases 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 seizure 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 fibrinogen, the drug should be immediately withdrawn.

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. Reversal of prolongation of bleeding time and thrombocytopenia have been reported. 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. Pancuronium 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 of syrup with or after food, or by transferring the patient to the Epilim enteric-coated formulation. Transient hair loss has been noted in some patients. Regrowth normally begins within six months.

Oedema has been reported. Increase in alariness, appetite and weight may occur. Combined medication: Epilim is generally well tolerated in combination with other anti-epileptic agents; however, as interaction occurs between these compounds, it may sometimes be necessary to reduce the dosage of other drugs when adding Epilim to existing anti-convulsant therapy. Epilim may also potentiate the effect of monoamine oxidase inhibitors and other anti-depressants, and dosage of such compounds should be reduced.

Diabetic patients: Epilim may cause false positives in urine testing for ketones. Care should be taken when treating diabetic patients with Epilim syrup which contains 0.6g sucrose per 5ml.

Women of childbearing age: Valproic acid or 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.

Further Information
When plasma valproic acid is within the recommended range of 50-120 microgram (350-840 micromol/litre) and serum albumin levels are normal, about 90% of the drug is bound to albumin. If 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 proportion 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: 0623/0006 Epilim Tablets 0623/0007 Epilim 500 enteric-coated tablets: 0623/0005 Epilim Syrup 0623/0004

NHS Cost
Epilim 200 enteric-coated tablets: £7.04
Epilim 500 enteric-coated tablets: £17.60
Epilim Syrup: 200ml: £0.03
Epilim 200mg tablets: 100: £5.45

LABAZ Sanofi UK Ltd
Regent House, Heath Lane
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