

Presentation

Madopar contains a combination of levodopa and the decarboxylase inhibitor benserazide in the ratio of 4:1. Madopar 62.5 capsules containing 50mg levodopa and 14.25mg benserazide hydrochloride (equivalent to 12.5mg of the base). Madopar 125 capsules containing 100mg levodopa and 28.5mg benserazide hydrochloride (equivalent to 25mg of the base). Madopar 250 capsules containing 200mg levodopa and 57mg benserazide hydrochloride (equivalent to 50mg of the base).

Indications

Parkinsonism — idiopathic, post-encephalitic

Dosage

Dosage is variable and the data sheet should be consulted for full details. The effective daily dose usually lies between four and eight capsules of Madopar 125 (two to four capsules of Madopar 250) daily in divided doses, most patients requiring no more than six capsules of Madopar 125 daily. In some elderly patients initial treatment with one capsule of Madopar 62.5 once or twice daily, increasing by one capsule every third or fourth day may suffice. Patients who experience fluctuations in response may also benefit from administration of smaller more frequent doses using Madopar 62.5.

Contra-indications

Narrow-angle glaucoma, severe psychoneuroses or psychoses. It should not be given in conjunction with monoamine oxidase inhibitors or within two weeks of their withdrawal, to patients under 25 years of age, to pregnant women, or to patients who have a history of, or who may be suffering from, a malignant melanoma.

Precautions

Drugs which interfere with central amine mechanisms should be avoided. Endocrine, renal, pulmonary or cardiovascular disease, hepatic disorder, peptic ulcer, osteoporosis, sympathomimetic drugs, antihypertensive drugs. Patients who improve on Madopar therapy should be advised to resume normal activities gradually as rapid mobilisation may increase the risk of injury.

Side-effects

Nausea and vomiting, cardiovascular disturbances, psychiatric disturbances, involuntary movements.

Packings

Madopar 62.5 capsules, Madopar 125 capsules and Madopar 250 capsules in packings of 100.

Licence Numbers

0031/0125 (Madopar 62.5 capsules), 0031/0073 (Madopar 125 capsules), 0031/0074 (Madopar 250 capsules).

Basic NHS Cost

Madopar capsules 62.5
£4.01 per 100
Madopar capsules 125
£7.23 per 100
Madopar capsules 250
£12.94 per 100



Roche Products Limited
PO Box 8
Welwyn Garden City
Hertfordshire AL7 3AY

Madopar is a trade mark
J52219i/382.

4+1 *the right balance in Parkinson's disease*



Madopar

*the original 4+1 combination
in three dosage forms, 62.5, 125 and 250*

Epilim[®]

sodium valproate

200 enteric-coated, 500 enteric-coated tablets; syrup.

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

1. Epilim 200 enteric-coated. A lilac-coloured enteric-coated tablet containing 200mg sodium valproate.
2. Epilim tablets. A white scored tablet containing 200mg sodium valproate.
3. Epilim 500 enteric-coated. A lilac-coloured enteric-coated tablet containing 500mg 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, 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-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 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 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 6 months.

Biochemical tests may not always become abnormal early in the evolution of hepatic failure; non specific findings such as loss of seizure 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 fibrinogen 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, then 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. Reversible 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 leucopenia have been reported. The blood picture returned to normal when the drug was discontinued. Pancreatitis 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. Oedema has been reported. Increase in alertness, 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 give false positives in urine testing for ketones. Care should be taken when treating diabetic patients with Epilim Syrup which contains 3.6g 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 50-120mg/litre (350-840µmol/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 0623/0001
Epilim 500 enteric-coated tablets 0623/0005
Epilim Syrup 0623/0004

NHS Cost

Epilim 200 enteric-coated tablets: 100, £7.04
Epilim 500 enteric-coated tablets: 100, £17.50
Epilim Syrup: 200ml, £4.03
Epilim 200mg tablets: 100, £5.45

LABAZ: Sanofi UK Ltd

Regent House, Heaton Lane,
Stockport SK4 1AG, Cheshire
Telephone: 061-480 0695/6/7/8

Additional Information is available from the Company

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SANOFI UK LIMITED

Additional information is available from **LABAZ: Sanofi U.K. Ltd**, Regent House Heaton Lane Stockport SK4 1AG

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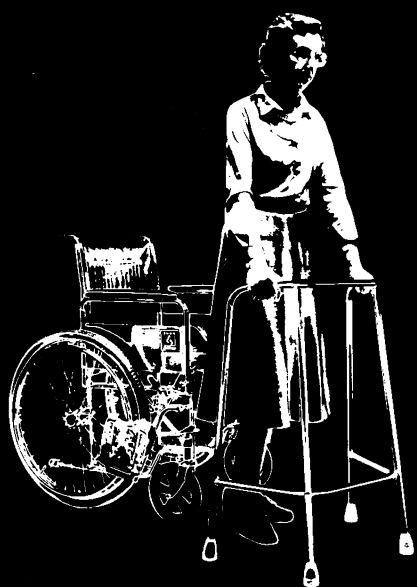


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Brings back a feeling of achievement

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Full prescribing information is available on request from CIBA Laboratories, Horsham, West Sussex.

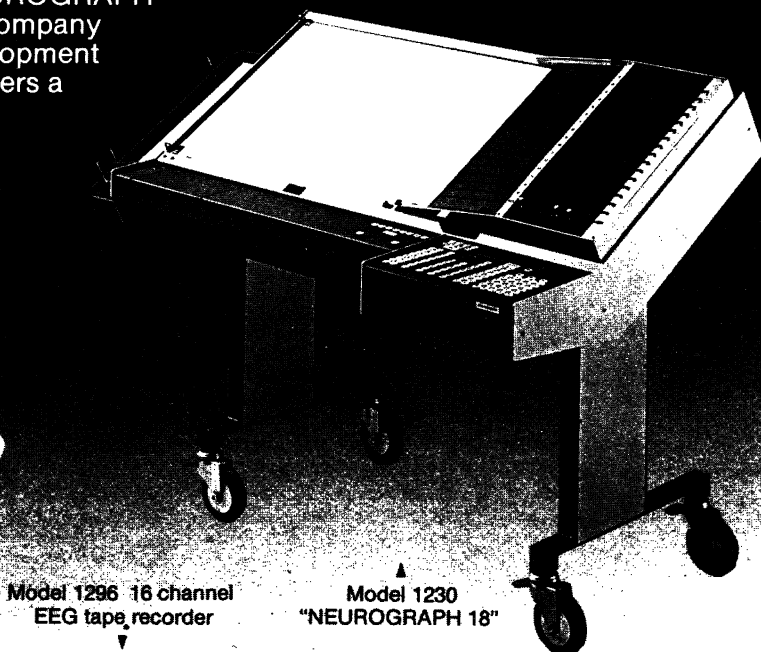
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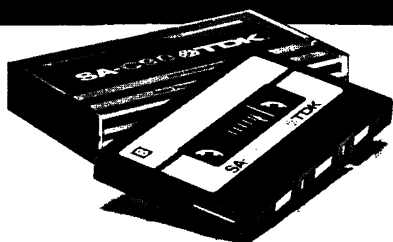
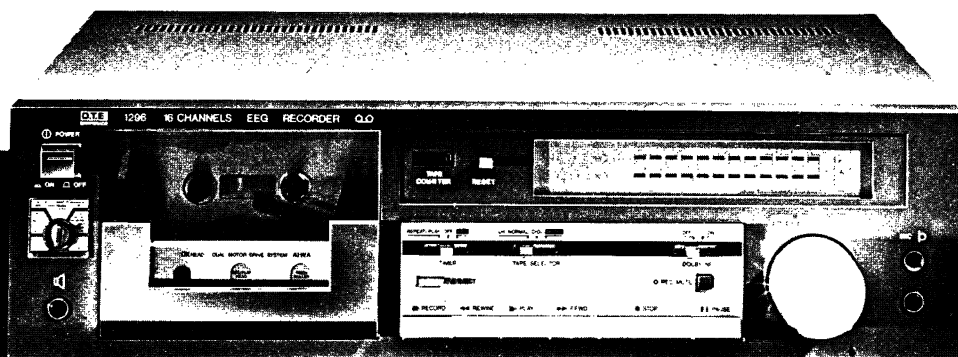


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