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Prescribing Information

Presentation A vial of sterile lyophilised powder of somatrem corresponding to 4IU of human somatotropin (also containing aminoacetic acid and sodium phosphate as stabilisers) and supplied with a 2ml ampoule of water for injections for use in the reconstitution of the injection.

Uses The treatment of short stature caused by decreased or absent secretion of pituitary growth hormone. The diagnosis should be verified by appropriate investigations of pituitary function by a specialist medical practitioner.

Dosage and Administration

Route of administration: By intramuscular injection. Recommended dosage. The dosage should be calculated according to the patient's body weight. Generally a dose of 0.5 IU/kg body weight per week is recommended. This weekly dose should be divided into 2 or 3 intramuscular injections.

Contra-indications, warnings, etc.

Only patients with unfused epiphyses should be treated. Diabetes mellitus. Precautions: Patients treated with Somatonorm should be regularly assessed by a specialist in child growth. Side-effects: Clinical experience with Somatonorm is limited and recipients may develop antibody to growth hormone and E. coli protein. However, as with pituitary derived hormone, only in very rare instances has growth retardation occurred. No other adverse reactions have been noted.

Package Quantities Combined package containing one vial of somatrem 4 IU and one ampoule of 2ml water for injections

Price NHS Price £28.

Further Information Somatrem is the British Approved Name for methionyl human somatotropin.

Product Licence Number 0022/0060

KabiVitrum Limited, KabiVitrum House, Riverside Way, Uxbridge, Middx UB8 2YF.

Product Authorisation Number 187/28/1.

Elire KabiVitrum, Cahill May Roberts Ltd, P.O. Box 1090, Chapelizod, Dublin 20.



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EDITED BY PETER C RUBIN

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Indications Epilepsy (generalised tonic-clonic and partial seizures).

Dosage in epilepsy Use a gradually increasing dosage scheme, adjusting to patient's needs. Adults: 100-200mg once or twice daily, increasing slowly up to 800-1,200mg daily; in some cases 1,600mg daily may be necessary. Children: up to 1 year old, 100-200mg daily; aged 1-5 years, 200-400mg daily; aged 5-10 years, 400-600mg daily; aged 10-15 years, 600-1,000mg daily. It may be helpful to monitor

drug levels: optimum therapeutic range is 3-10µg/ml (13-42µmol/l).

Side-effects Dizziness and diplopia (usually dose-dependent), less frequently dry mouth, diarrhoea, nausea and vomiting. Generalised erythematous rash, disappearing on cessation of therapy. Isolated reports of oedema, hyponatraemia, exfoliative dermatitis, leucopenia, thrombocytopenia, agranulocytosis, aplastic anaemia, cholestatic jaundice and acute renal

failure. Blood count should be checked in early stages of treatment.

Precautions Caution in patients taking oral anticoagulants or requiring oral contraception. In pregnancy, potential benefits of Tegretol must be weighed against potential hazards. Do not administer with, or within two weeks of cessation of, MAOI therapy. Macrolide antibiotics (eg erythromycin) and isoniazid may elevate carbamazepine levels. In rats treated with carbamazepine for two

years, incidence of liver tumours increased (no evidence of significant bearing on the therapeutic use of the drug). Serum folic acid levels should be observed during anticonvulsant therapy.

Contra-indications Previous drug sensitivity to Tegretol. Do not administer to patients with atrioventricular conduction abnormalities unless paced.

Packs Tablets of 100mg (PL0001/5027) basic NHS price £3.10 per 100. £14.93 per 500; tablets of 200mg

(PL0001/5028) £5.76 per 100. £27.75 per 500; tablets of 400mg (PL0001/0088) £11.32 per 100; liquid 100mg/5ml (PL0001/0050) £5.53 per 300ml bottle. * denotes registered trademark. Full prescribing information is available on request from Geigy Pharmaceuticals, Horsham, West Sussex.

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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.

Contra-indications, 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. Patients most at risk are children under the age of three and those with congenital metabolic disorders, organic brain disease or severe seizure disorders associated with mental retardation. The incidents mainly occurred during the first 6 months of therapy and usually involved multiple anticonvulsant therapy. Clinical symptoms are more helpful than laboratory investigations in the early stages of hepatic failure. 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 and those with a prior history of liver disease.

Hyperammonaemia without 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 antidepressants. 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 £6.59. Epilim 500 Enteric Coated 100 tablets, £16.45. Epilim 100mg crushable tablets 100 tablets, £3.99. Epilim Syrup 200ml, £4.03. Epilim Liquid 200ml, £4.03. Further information is available from:

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Legal category: P. **Package Quantities:** Containers of 100 capsules.
Basic NHS Cost: £15.98 (for 100 capsules). **Product Licence Number:** PL 76/129.



Further information available from:
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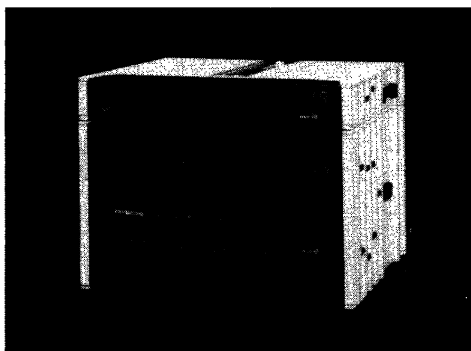
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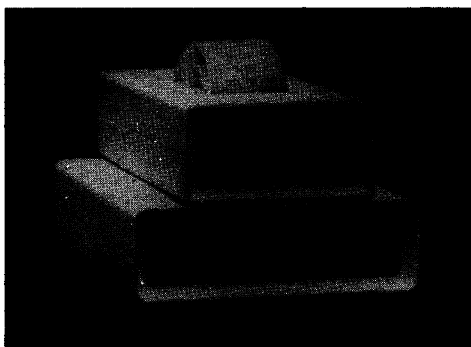
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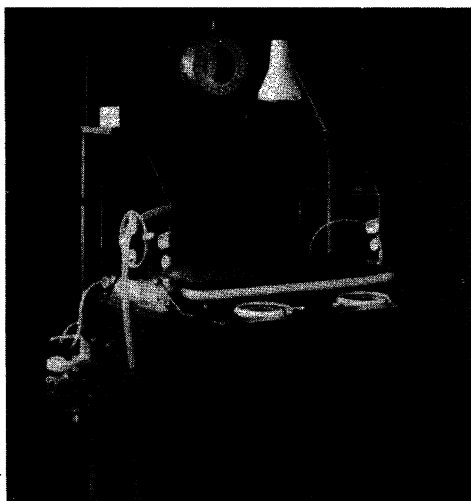
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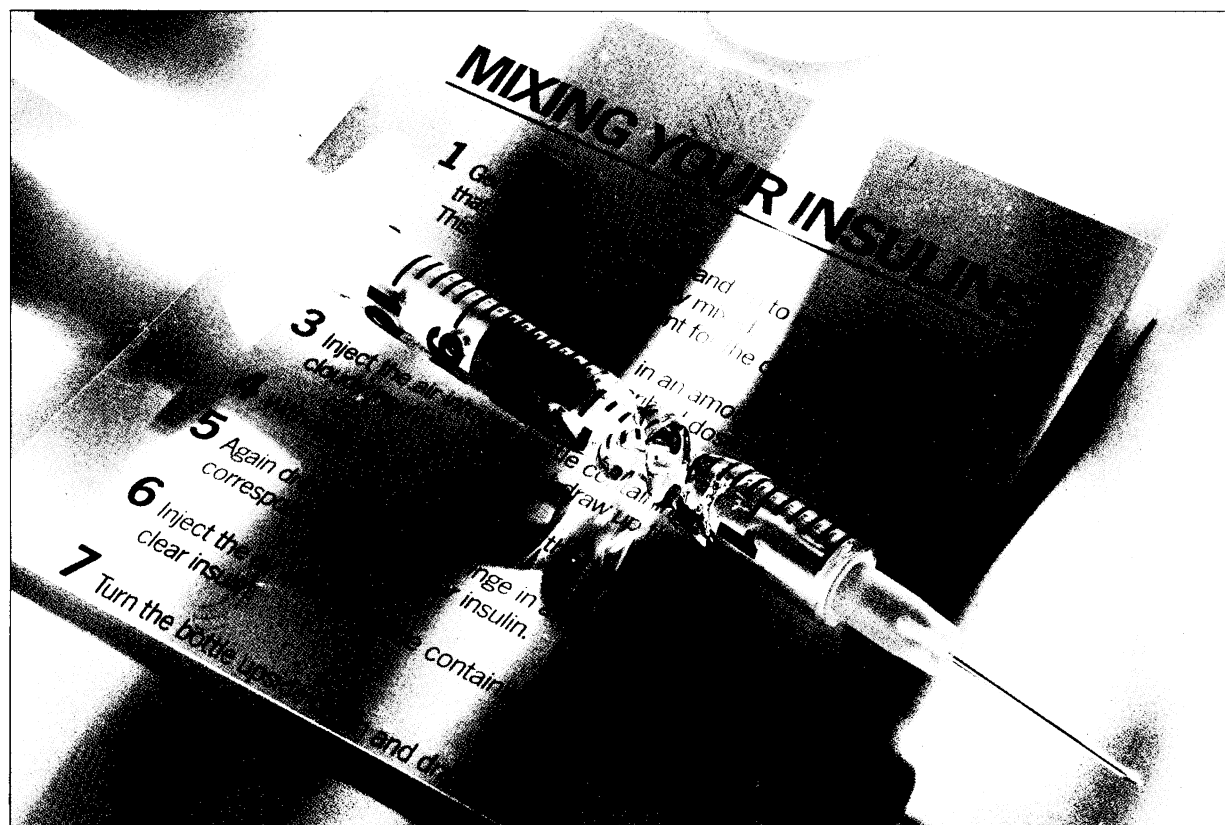
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