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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, Kabi-Vitrum House, Riverside Way, Uxbridge, Middx UB8 2YF.

Product Authorisation Number 187/28/1

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



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Thema des Monats

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Legasthenie

Was sind Teilleistungsschwächen?
Diagnostische Aspekte der Legasthenie
Behandlung der Legasthenie im Kindesalter

Pädiatrie aktuell

Was hat das Kind?

Trainingsprogramm für die Weiterbildung
zum Kinderarzt

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(Gitelman-Syndrom)

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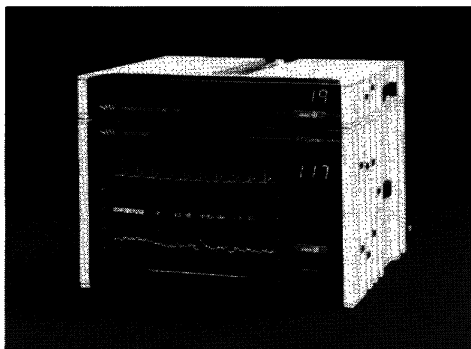
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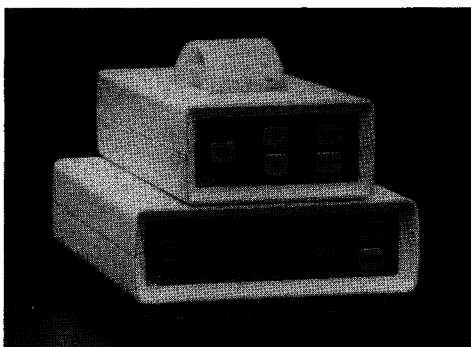
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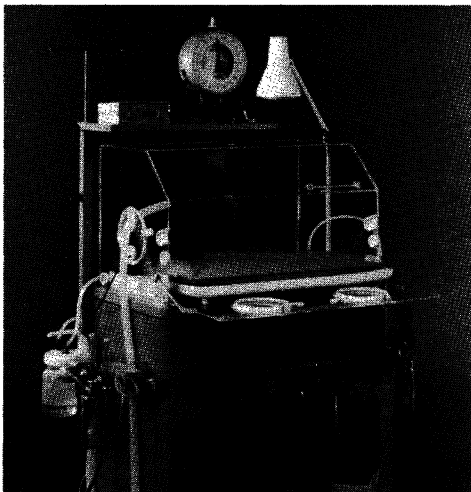
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Indications Epilepsy (generalised tonic-clonic and partial seizures).

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

Side-effects Dizziness and diplopia (usually dose-dependent), less frequently dry mouth, 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. 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.

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