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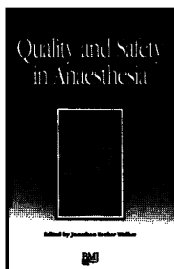
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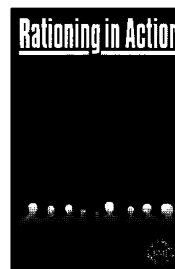
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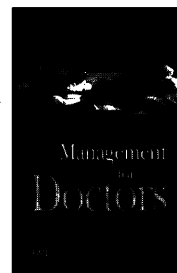
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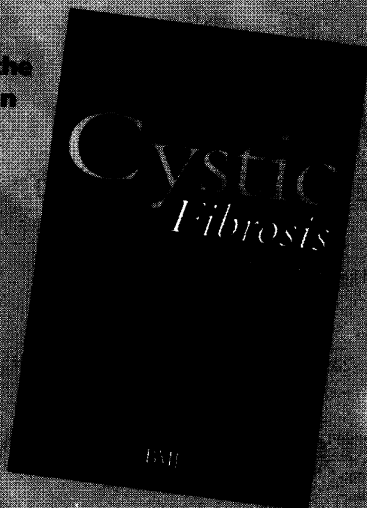
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## References:

1. Chadwick D., *J. Neurol. Neurosurg. Psychiatry* 1994; **57**: 264-277.
2. Gilham R.A., *Epilepsy Res.*, 1990; **7**: 219-225.

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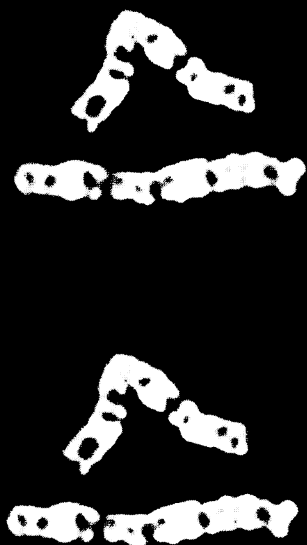
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surface area per week (approximately 1 IU/kg body weight per week) is recommended. Higher doses may be needed if growth velocity is too low. Dose correction may be required after six months treatment. The weekly dose should be divided into 6-7 subcutaneous injections. The injection site should be varied to prevent lipatrophy. **Preparation of Solution:** Somatropin (rbe) is reconstituted using the KabiMixer, KabiVial, KabiQuick or Genotropin Pen devices. Instructions on how to effect reconstitution are supplied separately at the specialist growth clinic, as are the Genotropin Pen and KabiMixer devices, and necessary needles. **Contra-indications, Warnings etc.:** Genotropin should not be used when there is any evidence of tumour activity. Intracranial lesions must be inactive and any antitumour therapy completed prior to starting therapy. Genotropin should not be used for growth promotion in patients with closed epiphyses. **Precautions:** Therapy with Genotropin should be initiated by suitably qualified physicians. In diabetes mellitus, insulin dosage may need adjustment. Thyroid function may be affected and should be monitored periodically. In patients with endocrine disorders, slipped epiphyses of the hip may occur. Some rare cases of benign intracranial hypertension have been reported. In chronic renal insufficiency, renal function should have decreased to below 50 per cent of normal and disturbed growth followed for a year preceding institution of therapy. Conservative treatment for renal insufficiency should have been established and should be maintained during treatment. Treatment should be discontinued after renal transplantation. **Pregnancy and Lactation:** Clinical experience of use in pregnancy is limited. Treatment should be interrupted if pregnancy occurs. **Overdosage:** Acute overdosage is unlikely, though may lead initially to hypoglycaemia and subsequently to hyperglycaemia. Long-term overdosage could result in symptoms consistent with the known effects of growth hormone excess. **Side Effects:** Common effects are related to transient local skin reactions. **Pharmaceutical**

**Precautions:** Store at 2 - 8°C. Protect from light. Once reconstituted Genotropin should be stored in the refrigerator and protected from light. Genotropin 36 IU, Genotropin 16 IU and Genotropin 4 IU KabiVial Multidose in use may be stored for up to 14 days under these conditions. Once reconstituted Genotropin 2, 3 and 4 IU KabiQuick should be used immediately, or within 24 hours if kept in the refrigerator. **Legal Category:** POM. **Package Quantities:** Genotropin 36 IU Pack containing one cartridge for use in the Genotropin Pen 36/KabiMixer devices. Genotropin 16 IU Pack containing one cartridge for use in the Genotropin Pen 16/KabiMixer devices. Genotropin 4 IU KabiVial Multidose Two compartment cartridge in a reconstitution device. Pack containing one Genotropin 4 IU KabiVial Multidose. Genotropin 2,3 and 4 IU KabiQuick Two compartment cartridge in a reconstitution and injection device. Pack containing ten Genotropin 2 IU KabiQuick. Pack containing ten Genotropin 3 IU KabiQuick. Pack containing ten Genotropin 4 IU KabiQuick. **Product Licence Numbers and Basic NHS Prices:** 36 IU - 0022/0098, 1 x 36 IU - £274.50. 16 IU - 0022/0085, 1 x 16 IU - £122.00. 4 IU KabiVial Multidose - 0022/0088, 1 x 4 IU - £30.50. 2 IU KabiQuick - 0022/0089, 10 x 2 IU - £160.00. 3 IU KabiQuick - 0022/0090, 10 x 3 IU - £240.00. 4 IU KabiQuick - 0022/0091, 10 x 4 IU - £320.00. **Product Licence/Product Authorisation Holder:** Pharmacia & Upjohn Ltd, Davy Avenue, Milton Keynes, MK5 8PH. Distributed in Ireland by Cahill May Roberts Ltd, for Pharmacia Ireland Ltd., Pharmapark, Chapelizod, Dublin 20. Further information is available on request from the Product Licence holder. Genotropin, KabiMixer, KabiVial and KabiQuick are registered trademarks. **Date of preparation:** April 1996. P2346/9/95



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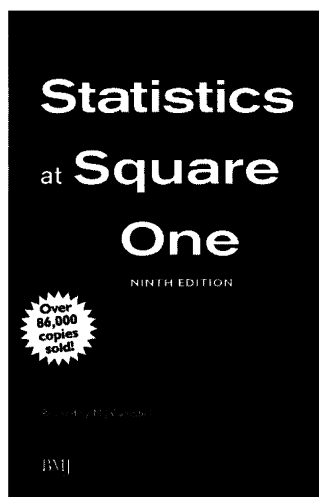
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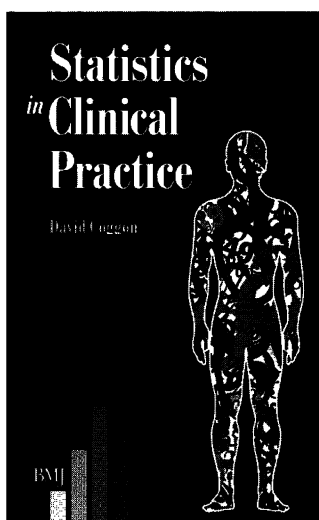
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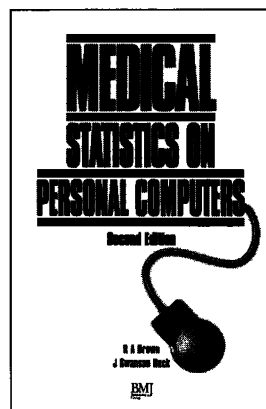
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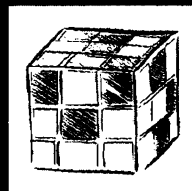
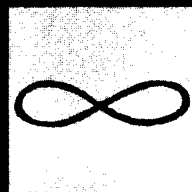
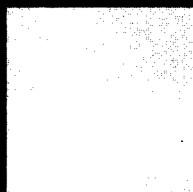
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#### **PRESCRIBING INFORMATION**

**Presentations:** Pulmicort Respules, (2ml single dose unit ampoules) containing 0.25mg/ml or 0.5mg/ml budesonide in a suspension for nebulisation. **Uses:** Bronchial asthma where use of a pressurised inhaler or dry powder formulation is unsatisfactory or inappropriate. **Dosage and administration:** Dosage schedules: Administer from suitable nebulisers. Dose delivered to the patient varies depending on the nebulising equipment used (see data sheet). Adjust dosage individually. Initially during periods of severe asthma and while reducing or discontinuing oral glucocorticosteroids the recommended dose in adults (including elderly and children 12 years and older) is usually 1-2mg twice daily. In very severe cases the dosage may be further increased. Children (3 months to 12 years): 0.5-1mg twice daily. The maintenance dose should be the lowest dose which keeps the patient symptom free. Recommended doses are: Adults (including elderly and children 12 years and older): 0.5-1mg twice daily. Children (3 months to 12 years): 0.25-0.5mg twice daily. For an increased therapeutic effect increase dose of Pulmicort rather than combine

treatment with oral corticosteroids because of the lower risk of systemic effects. **Contra-indications, warnings, etc.:** Contra-indications: Hypersensitivity to any of the constituents. Special warnings and precautions: Care is needed in patients with pulmonary tuberculosis and viral infections in the airways. A short course of oral steroids in addition to Pulmicort may be required in patients with excessive mucus in the bronchi. Transfer of patients dependent on oral steroids to Pulmicort demands special care; see data sheet for further details. The nebuliser chamber should be cleaned and dried after every administration. Pulmicort does not affect the ability to drive and use machines. Pulmicort Respules can be mixed with 0.9% saline and with solutions of terbutaline, salbutamol, sodium cromoglycate or ipratropium bromide. **Side-effects:** Mild irritation in the throat, coughing and hoarseness and oral candidiasis have been reported. In rare cases inhaled drugs may provoke bronchoconstriction in hyperreactive patients. Facial skin should be washed after use of the face mask as irritation can occur. Coughing can usually be prevented by inhaling a  $\beta_2$ -agonist (e.g. terbutaline) 5-10 minutes before inhalation of

Pulmicort Respules. Avoid in pregnancy. **Pharmaceutical precautions:** Store below 30°C. Use within 3 months of opening the ampoule envelope. Protect opened ampoule from light. Use within 12 hours of opening. **Legal status:** POM. **Basic NHS price:** Pulmicort Respules 0.25mg/ml (20 single dose units) £32.00. Pulmicort Respules 0.5mg/ml (20 single dose units) £44.64. **Product licence nos.:** Pulmicort Respules 0.25mg/ml PL 0017/C/399. Pulmicort Respules 0.5mg/ml PL 0017/0310. **Name and address of product licence holder:** Astra Pharmaceuticals Ltd., Home Park, Kings Langley, Herts WD4 8DH.

Inspired  
control  
before  
their first  
steps

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**ASTRA**  
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**Pulmicort<sup>®</sup>**  
**Respules<sup>®</sup>**  
BUDESONIDE

Nebulised Steroid Control