

ABBREVIATED PRESCRIBING INFORMATION

Preparation UNIPHYLLIN CONTINUS tablets contain Theophylline BP in a controlled release system. UNIPHYLLIN CONTINUS tablets 400 mg are white, capsule-shaped, scored tablets with the logo NAPP U400 embossed on one side and UNIPHYLLIN on the other. UNIPHYLLIN CONTINUS tablets 300 mg are white, capsule-shaped, scored tablets with U300 embossed on one side. UNIPHYLLIN CONTINUS tablets 200 mg are white, capsule-shaped, scored tablets with U200 embossed on one side. Uses Theophylline is a bronchodilator. In addition it affects the function of a number of cells involved in the inflammatory processes associated with asthma and chronic obstructive airways disease. Of most importance may be enhanced suppressor T-lymphocyte activity and reduction of eosinophil and neutrophil function. These actions may contribute to anti-inflammatory prophylactic activity in asthma and chronic obstructive airways disease. For the treatment and prophylaxis of bronchospasm associated with asthma, emphysema and chronic bronchitis. Also indicated in adults for the treatment of cardiac asthma and left ventricular or congestive cardiac failure. Dosage and administration - NB Tablets should be swallowed whole and not chewed. Adults: The usual maintenance dose for elderly patients or those less than 70 kg body weight is 300 mg, 12-hourly following an initial week of therapy on 200 mg, 12-hourly. The usual maintenance dose for patients of 70 kg body weight or over is 400 mg, 12-hourly following an initial week of therapy on 200 mg or 300 mg, 12-hourly. Children: Not recommended for children under seven years of age. The maintenance dose is 9 mg/kg twice daily. Some children with chronic asthma require and tolerate much higher doses (10-16 mg/kg twice daily). Lower dosages (based on usual adult dose) may be required by adolescents. It may be appropriate to administer a larger evening or morning dose in some patients, in order to achieve optimum therapeutic effect when symptoms are quite severe, e.g. at the time of the 'morning dip' in lung function. In patients whose night time or day time symptoms persist despite other therapy and who are not currently receiving theophylline, then the total daily requirement of UNIPHYLLIN CONTINUS tablets (as specified above) may be added to their treatment regimen as either a single evening or morning dose. Elderly: The initial dose should be 200 mg, 12-hourly increasing to 300 mg, 12-hourly. Contra-indications Should not be given concomitantly with ephedrine in children. Precautions and warnings The following increase clearance and it may therefore be necessary to increase dosage to ensure a therapeutic effect: phenytoin, carbamazepine, rifampicin, sulphapyrazone and barbiturates. Smoking and alcohol consumption can also increase clearance of theophylline. The following reduce clearance and a reduced dosage may therefore be necessary to avoid side-effects: allopurinol, cimetidine, ciprofloxacin, erythromycin, thibendazole, isoprenaline, fluvoxamine, viloxazine hydrochloride and oral contraceptives. Factors such as viral infections, liver disease and heart failure also reduce theophylline clearance. The hypolaemia resulting from beta-blockers, the anti-arrhythmics, diuretics

significantly reduced when UNIPHYLLIN CONTINUS tablet preparations are given. Furthermore, the side effects can be minimised by dose titration downwards. Transferability It is not possible to ensure bioequivalence between different sustained release theophylline products. Therefore, it should be emphasised that patients, once titrated to an effective dose, should not be changed from UNIPHYLLIN CONTINUS tablet preparations to other slow or sustained release xanthine preparations without re-titration and clinical assessment. Legal category P. Package quantities and basic NHS price UNIPHYLLIN CONTINUS tablets 400 mg - 56's: £7.32; 250's: £32.36; 1,000's: £125.29. UNIPHYLLIN CONTINUS tablets 300 mg - 56's: £6.17; 250's: £27.89. UNIPHYLLIN CONTINUS tablets 200 mg - 56's: £4.05. Product licence numbers UNIPHYLLIN CONTINUS tablets 400 mg - PL 0337/0074. UNIPHYLLIN CONTINUS tablets 300 mg - PL 0337/0129. UNIPHYLLIN CONTINUS tablets 200 mg - PL 0337/0057. Product licence holder Napp Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge CB4 4GW, UK. Tel: 01223 424444. Member of Napp Pharmaceutical Group. Further information is available from Napp Laboratories Limited. © The NAPP device, UNIPHYLLIN and CONTINUS are Registered Trade Marks. © NAPP Laboratories Limited 1995. Reference: I. Kidney J, Dominguez M, Taylor PM, et al. (In press). Date of preparation: April 1995.

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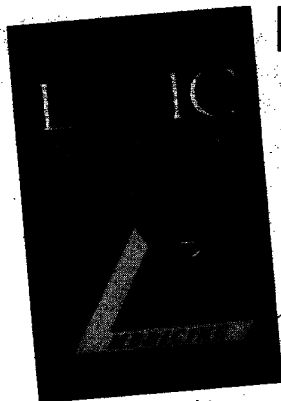
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Epilim Oral Prescribing Information

Presentation Epilim 200 Enteric Coated and Epilim 500 Enteric Coated: Enteric coated tablets containing 200mg, and 500mg Sodium Valproate Ph.Eur. respectively. Epilim Crushable Tablets containing 100mg Sodium Valproate Ph.Eur. Epilim Syrup and Epilim Liquid (sugar free) both containing 200mg Sodium Valproate Ph.Eur. per 5ml. Epilim Chrono 200, Epilim Chrono 300, and Epilim Chrono 500: Controlled release tablets containing a mixture of Sodium Valproate Ph.Eur. and Valproic Acid Fr.P. equivalent to 200mg, 300mg, and 500mg Sodium Valproate respectively.

Indications Oral formulations of Epilim are indicated for all types of epilepsy. In women of child bearing age Epilim should be used only in severe cases or in those resistant to other treatment. **Dosage and administration** *Adults*; the dose should be titrated at three day intervals until seizure control is achieved. Initially 600mg a day increasing in steps of 200mg to a maximum dose of 2500mg per day. *Children over 20kg*, initially 400mg a day increasing in steps to a maximum dose of 35mg/kg/day. *Children under 20kg*, initially 20mg/kg/day - the dose may be increased in steps to a maximum of 40mg/kg/day provided that plasma levels are monitored. Epilim Chrono may be given once or twice daily. All other formulations should be given twice daily. **Combination therapy**; levels of Epilim and co-administered anticonvulsants may be affected and optimum dosage is determined by seizure control.

Contraindications, Warnings, etc. **Contraindications** Active liver disease, family history of severe liver disease, hypersensitivity to valproate. **Side effects** Impaired hepatic function, particularly in children, occasionally leading to hepatic failure - treatment should be withdrawn in patients who suddenly develop symptoms compatible with hepatic disease such as nausea, anorexia, jaundice or malaise. **Hyperammonaemia** with or without hepatic dysfunction. Blood dyscrasia - impaired platelet function, thrombocytopenia, occasional leucopenia and red cell hypoplasia. Occasionally increased appetite, weight gain, transient hair loss, behavioural disturbances, alterations to the menstrual cycle and pancreatitis. Symptoms of intoxication include ataxia, tremor, and stupor. **Drug interactions** Epilim has significant interactions with phenytoin, lamotrigine and other anticonvulsants. Epilim may potentiate the effects of neuroleptics, MAOIs and other antidepressants, anticoagulants and salicylates. Cimetidine may inhibit the metabolism of Epilim. Epilim has no effect on the efficacy of oral contraceptives. **Pregnancy** An increased incidence of congenital abnormalities has been demonstrated in offspring born to mothers with epilepsy both untreated and treated, including those treated with sodium valproate. Neural tube defects have been reported in about 1% of offspring of women who have received valproate during the first trimester of pregnancy. Pregnancies should be screened for neural tube defects by estimation of alpha-fetoprotein and ultrasound. Folate supplementation has been shown to reduce the incidence of neural tube defects in the offspring of high risk women. **Legal category** P.O.M. **Further information** Epilim is hygroscopic - tablets should not be removed from their foil until they are used. Epilim Chrono is recommended in cases where plasma valproate levels are being measured on account of its pharmacokinetics. The effective therapeutic range for valproate is 40-100mg/l (278-694 micromol/l). **Product Licence Numbers** Epilim 200 Enteric Coated 11723/0018, Epilim 500 Enteric Coated 11723/0020, Epilim 100mg Crushable Tablets 11723/0017, Epilim Syrup 11723/0025, Epilim Liquid 11723/0024, Epilim Chrono 200 11723/0078, Epilim Chrono 300 11723/0021, Epilim Chrono 500 11723/0079. **NHS Cost** Epilim 200 Enteric Coated 100 tablets £6.42, Epilim 500 Enteric Coated 100 tablets £16.04, Epilim 100mg Crushable Tablets 100 tablets £3.89, Epilim Syrup 300ml £5.89, Epilim Liquid 300ml £5.89, Epilim Chrono 200 100 tablets £7.70, Epilim Chrono 300 100 tablets £11.55, Epilim Chrono 500 100 tablets £19.25. **Address:** Sanofi Winthrop Ltd., One Onslow Street, Guildford, Surrey GU1 4YS. **Telephone:** (01483) 505515 **Fax:** (01483) 35432. Epilim, Epilim Chrono and the Chrono device are registered trade marks. **Date of preparation** August 1995.

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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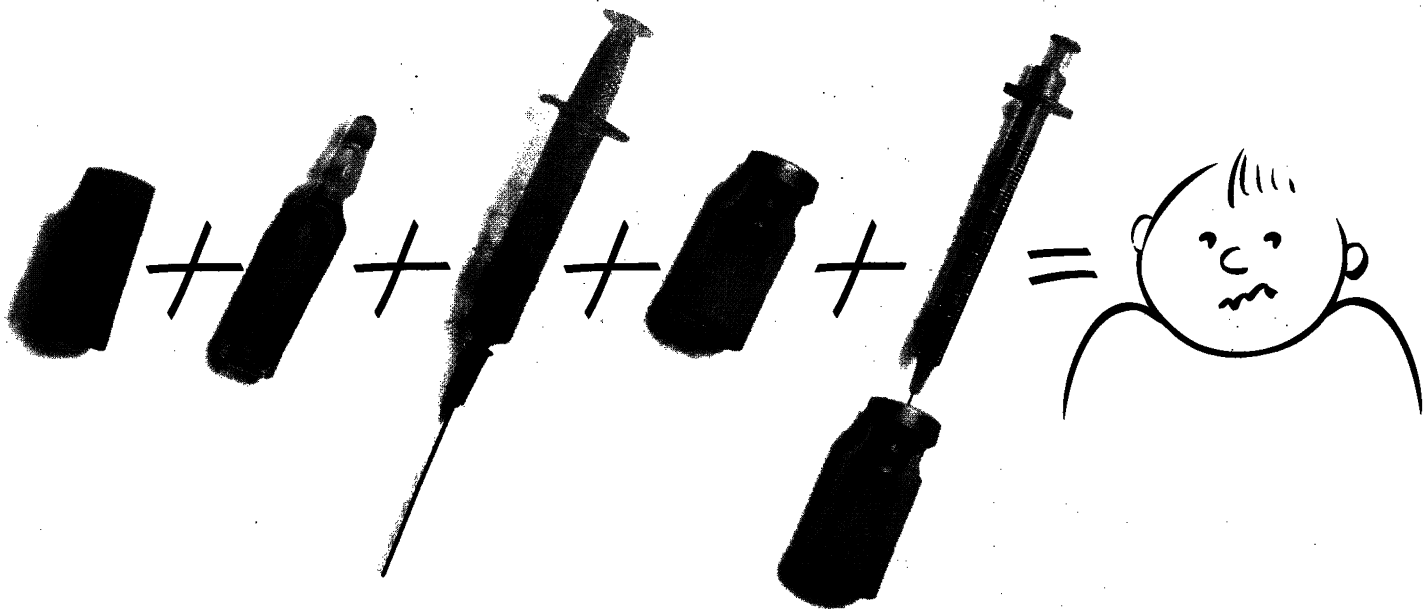
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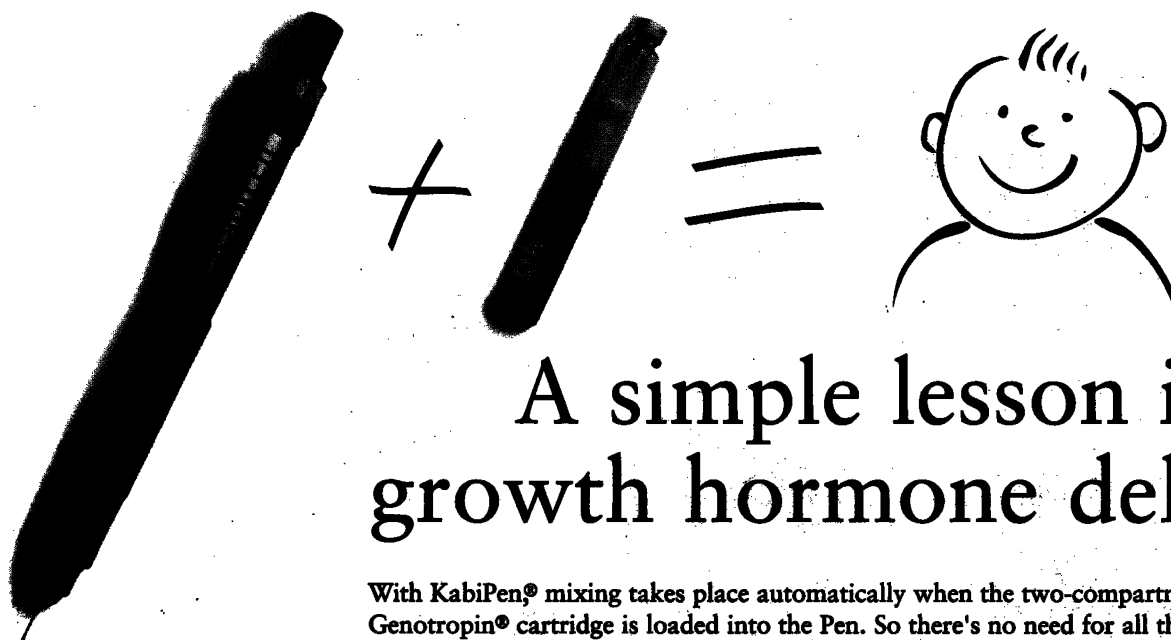
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somatropin (rbe)

Prescribing Information Genotropin 36 IU. **Presentation** Genotropin: 36 IU Two-compartment cartridge for use in the KabiPen 36 device. One compartment contains 36 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.3% m-cresol in 1ml of Water for Injections. **Uses:** The treatment of short stature due to decreased or absent secretion of pituitary growth hormone. The diagnosis should be verified by a specialist medical practitioner. The treatment of short stature in gonadal dysgenesis (Turner syndrome). **Dosage and Administration:** Route of Administration: By subcutaneous injection. Recommended dosage: The dosage is individual. Generally a dose of 0.5-0.7 IU/kg body weight per week is recommended. In Turner Syndrome a dose of 1.0 IU/kg body weight per week is recommended. Preferably the weekly dose should be divided into six or seven daily subcutaneous injections. The injection site should be varied to prevent lipoatrophy. **Preparation of solutions:** Somatropin (rbe) is reconstituted using the KabiPen device. Instructions on how to effect reconstitution are supplied separately at the specialist growth clinic, as is the KabiPen device. **Contra-indications, Warnings etc:** Only patients with unfused epiphyses should be treated. Genotropin should not be used when evidence of tumour activity exists; Intracranial lesions must be inactive and antitumour therapy completed before treatment begins. Treatment with these products should be discontinued when there is evidence of tumour growth. **Precautions:** Patients with diabetes mellitus may require adjustment of their antidiabetic therapy. Patients treated with Genotropin should be regularly assessed by a specialist in child growth. This assessment should include accurate determination of the growth response and endocrinological status, as relative deficiencies of other pituitary hormones may be exposed or exacerbated by an adequate growth response. Hypothyroidism in particular is a reported occurrence. Some cases of acute leukaemia have been reported in growth hormone deficient children untreated as well as treated with growth hormone and might possibly represent a slightly increased incidence compared with non growth hormone deficient children. A causal relationship to growth hormone therapy has not been established. **Pregnancy and lactation:** Treatment should be discontinued in the event of a pregnancy occurring during therapy with Genotropin, as there is no evidence from either human or animal studies of the safety of growth hormone treatment during pregnancy. No information is available as to whether peptide hormones pass into breast milk, but the quantities involved would not have any clinical effect on the infant. **Overdosage:** Acute overdosage is unlikely and does not represent a hazard to the patient. The consequences of long-term administration of doses above the therapeutic range are unknown. **Side-effects:** Recipients may develop antibodies to growth hormone and E.coli protein. However, as with pituitary-derived hormone, only in rare instances has growth retardation occurred. Reactions at the site of injection have been reported, such as itching, lumps, redness and lipoatrophy. Lipoatrophy can be prevented or minimised by varying the injection site. In Turner Syndrome temporary exacerbation of lymphoedema has been reported. **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, may be stored for up to 14 days under these conditions. **Legal Category:** POM **Package quantities:** Genotropin 36 IU: Pack containing one cartridge for use in the KabiPen 36 device. **Further Information:** Somatropin (rbe) is the British Approved Name for recombinant human somatotropin. **Product Licence Number:** 0022/0098, 1 x 36 IU. **Basic NHS Price:** £274.50. **Product Licence Holder:** Pharmacia Ltd, Davy Avenue, Milton Keynes, Bucks MK5 8PH. Further information is available on request from the Product Licence holder. Genotropin and KabiPen are registered trademarks. **Date of preparation:** August 1995.

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References

1. Kissling, M., Ruch, W., Hemex, M., Medipress (1988), 4(2), 1-7.
2. Estimated current cash annual sales worldwide - Data on File, Roche Products Ltd.

Brief Prescribing Information

Indications: Pneumonia, septicæmia, meningitis, bone, skin and soft tissue infections, infections in neutropenic patients, gonorrhoea, peri-operative prophylaxis of infections associated with surgery. Treatment may be started before the results of susceptibility tests are known. **Dosage and Administration:** Rocephin should be administered by deep intramuscular injection, slow intravenous injection, or as a slow intravenous infusion, after reconstitution of the solution. **Adults and children 12 years and over:** Standard dosage - 1g once daily. Severe infections - 2-4g normally once daily. Duration of therapy varies according to course of disease. Gonorrhoea - single dose of 250mg i.m. Peri-operative prophylaxis - usually single dose of 1g. Colorectal surgery 2g in conjunction with a suitable agent against anaerobic bacteria. **Children under 12 years:** Standard dosage - 20-50mg/kg once daily. Severe infections - maximum 80mg/kg once daily. Doses of 50mg/kg or over should be given by slow intravenous infusion over at least 30 minutes. **Renal and hepatic**

impairment: In the absence of hepatic impairment dose reduction is required only in severe renal failure (creatinine clearance < 10ml/min), when the daily dose should be 2g or less. No dose reduction is required in liver damage provided renal function is intact. In severe renal impairment accompanied by hepatic insufficiency the plasma concentration should be determined at regular intervals and dosage adjusted. Serum concentrations should be monitored in dialysis. **Contra-indications, Warnings etc.** Cephalosporin hypersensitivity. Premature infants. Full term infants during first six weeks of life. Safety in pregnancy has not been established. **Precautions:** Stated dose should not be exceeded. Caution in patients with a history of hypersensitivity (especially anaphylactic reaction) to penicillins or other non-cephalosporin beta-lactam antibiotics. Anaphylactic shock requires immediate countermeasures. Severe renal impairment accompanied by hepatic insufficiency (see Dosage). **Side-effects and Adverse Reactions:** Gastro-intestinal side effects including loose stools, diarrhoea, nausea, vomiting, stomatitis and glossitis. Cutaneous reactions including maculopapular rash, pruritus, urticaria, oedema and erythema multiforme. Haematological reactions including anaemia (all grades), leucopenia, neutropenia, thrombocytopenia, eosinophilia, agranulocytosis, positive Coombs' test and prolongation

of prothrombin time. Regular blood counts should be carried out during treatment. Other reactions include headache, dizziness, drug fever and transient elevations in liver function tests. Rarely glycosuria, oliguria, haematuria, anaphylaxis and bronchospasm. Very rarely, precipitation of ceftriaxone calcium salt in urine in patients on higher than recommended dose. Reversible precipitates of calcium ceftriaxone have been detected by gallbladder sonograms. In symptomatic cases (which are rare), conservative non-surgical management is recommended. Superinfections with yeasts, fungi or other resistant organisms. Rare instances of pseudomembranous colitis. Injection site pain and local phlebitis. **Legal Category:** POM. **Presentations and Basic NHS Cost:** 250mg vials (i.m. and i.v. (containing 250mg ceftriaxone)) - £2.87. 1g vials (i.m. and i.v. (containing 1g ceftriaxone)) - £11.46. 2g vials for infusion (containing 2g ceftriaxone) - £22.92. **Product Licence Numbers:** PL 0031 0189 (250mg vials), PL 0031 0171 (1g vials), PL 0031 0172 (2g vials). **Product Licence Holder:** Roche Products Limited, PO Box 8, Welwyn Garden City, Hertfordshire, AL7 3AY. Full prescribing information is available on request.

Date of preparation February 1994
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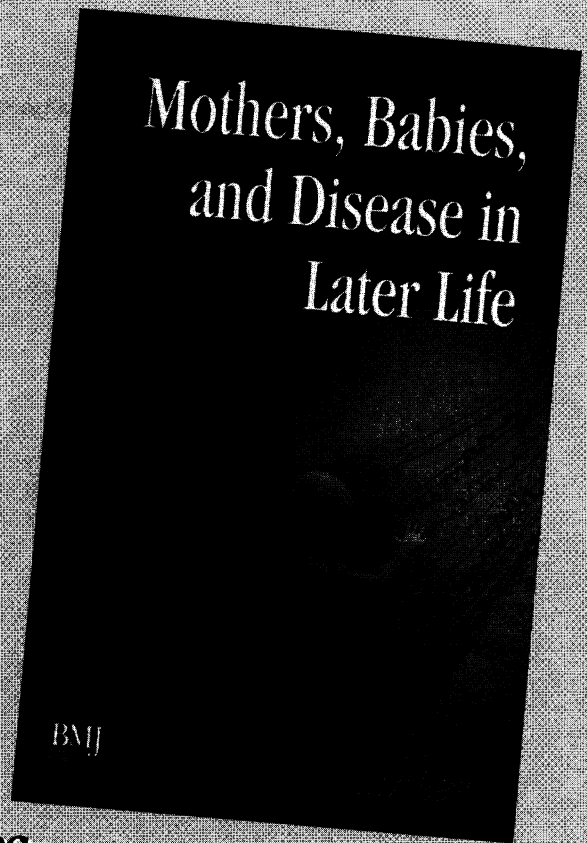


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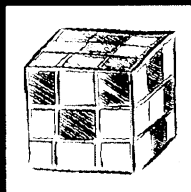
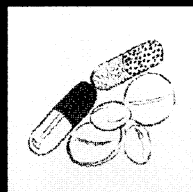
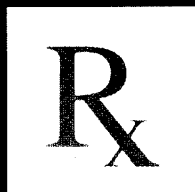
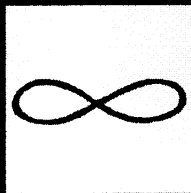
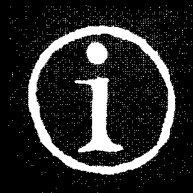
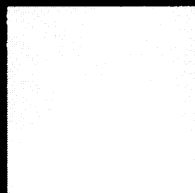
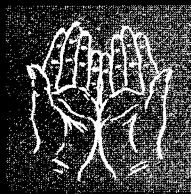
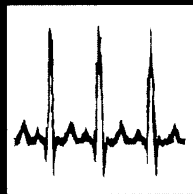
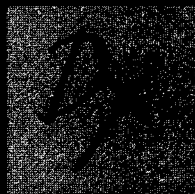
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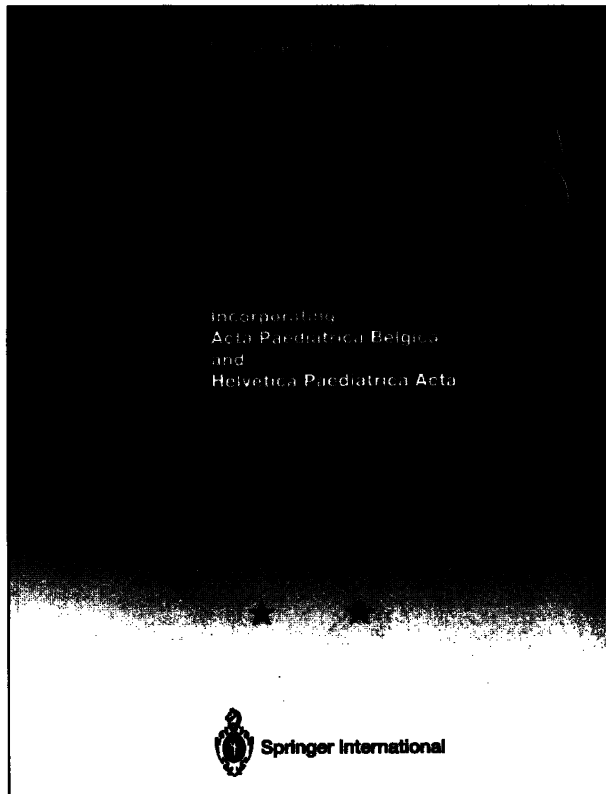
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Presentations: Pulmicort Respules, (2ml single dose unit ampoules) containing 0.25mg/ml or 0.5mg/ml budesonide in a suspension for nebulisation. **Uses:** Bronchial asthma where use of a pressurised inhaler or dry powder formulation is unsatisfactory 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 β_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 foil 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 0017/0309. 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.

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