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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 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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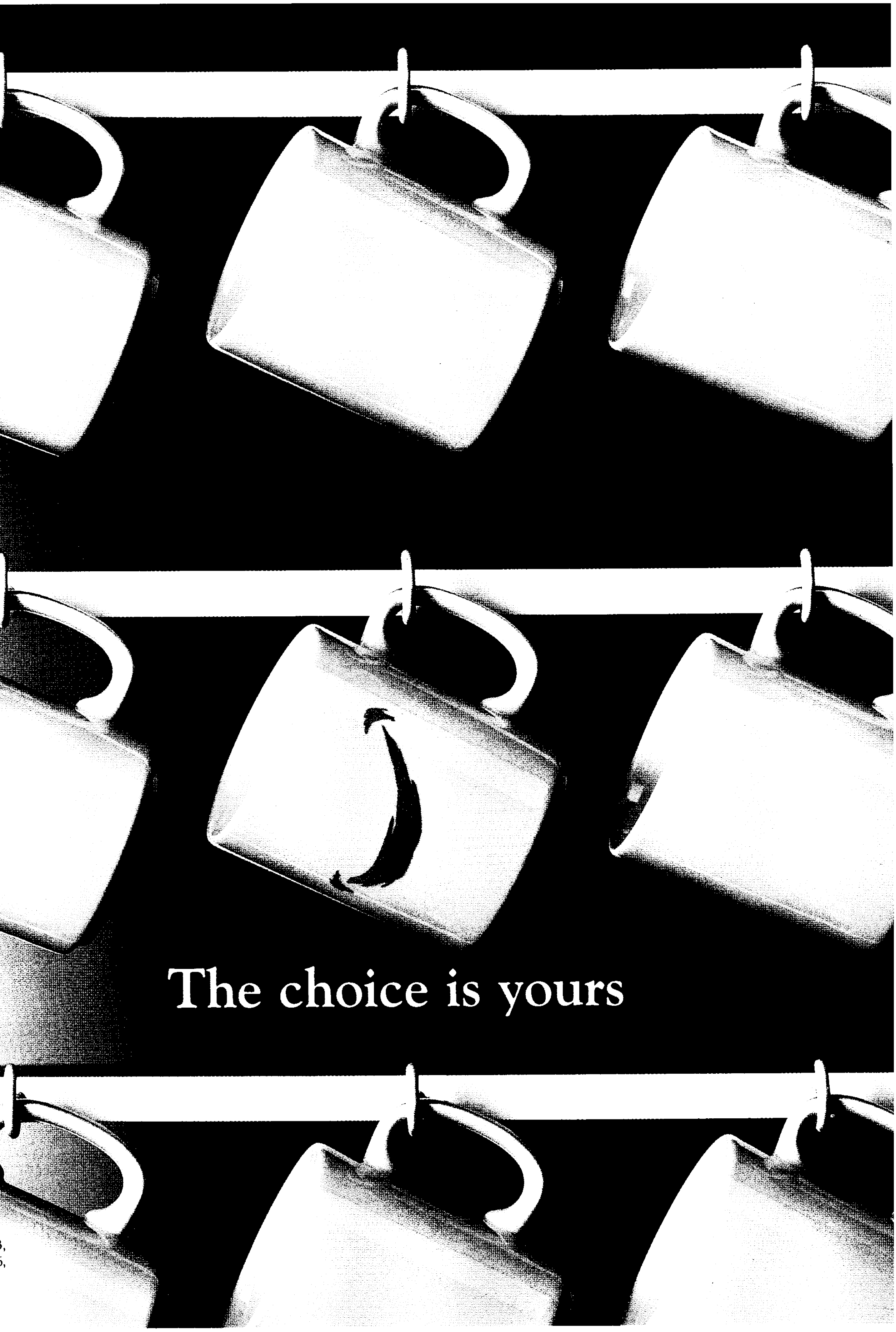

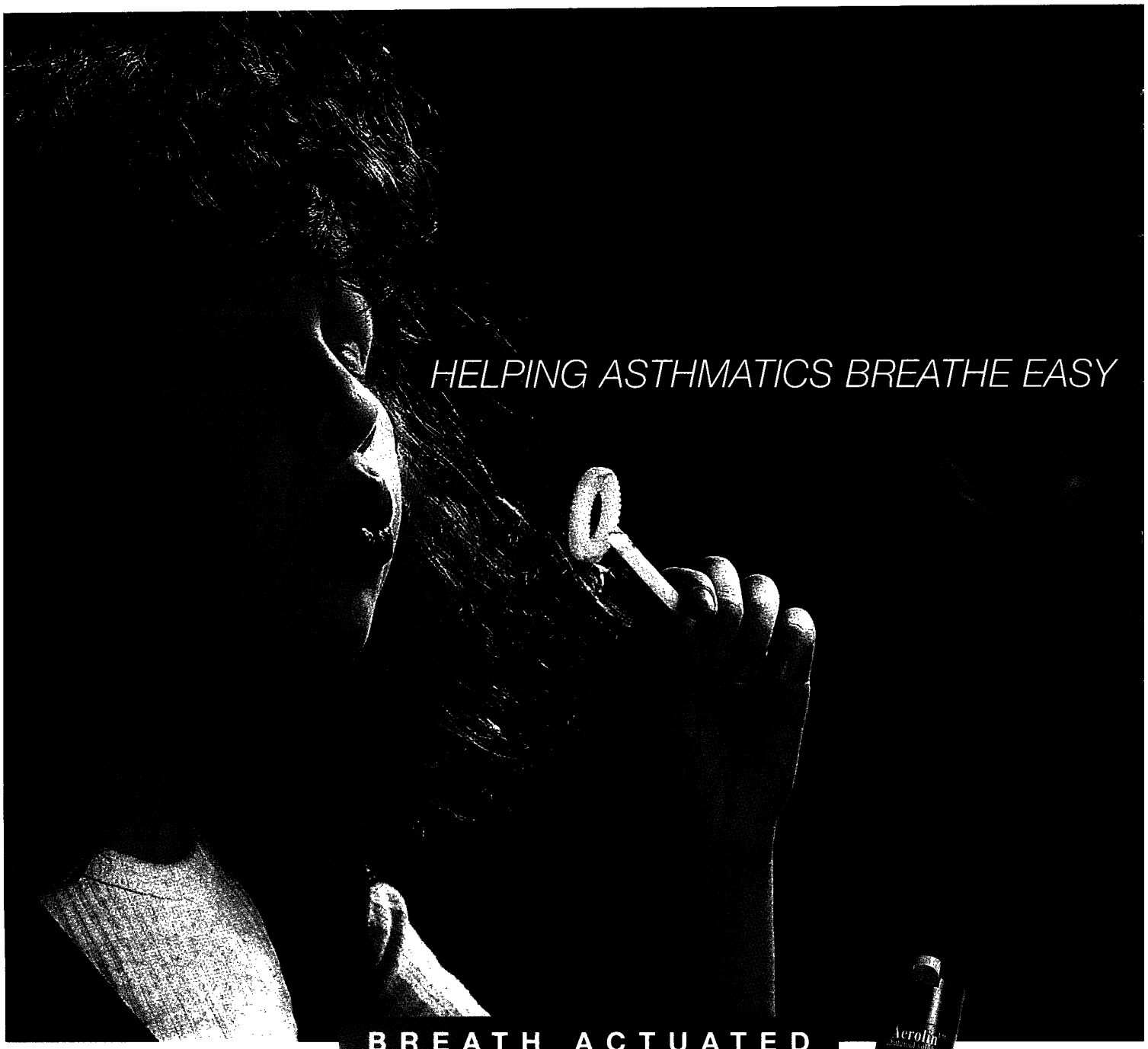

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AEROLIN™ AUTOHALER™ INHALER ABBREVIATED PRESCRIBING INFORMATION. Presentation: A breath actuated pressurised inhalation aerosol delivering Salbutamol Sulphate BP equivalent to salbutamol 100mcg into the mouthpiece of a breath-actuated adaptor. **Indications:** For the treatment of reversible airways obstruction associated with asthma. **Dosage:** *Adults and children:* one inhalation as a single dose for the relief of acute bronchospasm, increasing to two inhalations if necessary. Maximum of eight puffs in 24 hours. **Contra-indications:** Hypersensitivity to salbutamol or any of the inactive ingredients in the Aerolin Autohaler inhaler. **Precautions:** Administer cautiously to patients with thyrotoxicosis. Patients should be advised to seek medical advice if treatment ceases to be effective and/or their asthma seems to be worsening. Patients should not increase the dose without seeking medical advice. Salbutamol and non-selective beta-blockers should not usually be prescribed together. **Side-effects:** Mild tremor, headache, tachycardia, palpitations and transient muscle cramps may rarely occur. Paradoxical bronchospasm and potentially serious hypokalaemia have been reported in patients taking B$_2$ agonist therapy. **Pregnancy:** The safe use of salbutamol during pregnancy has not been established. **Lactation:** It is not known whether salbutamol is distributed into breast milk. **Pharmaceutical precautions:** Store below 30°C protected from frost and direct sunlight. As the vial is pressurised no attempt should be made to puncture it or dispose of it by burning. **Basic NHS price:** £10.51. **Product licence number:** PL 68/0117. **Legal Category:** POM. Date of preparation of advertisement: February 1995. Further information is available from the 3M Health Care Information Scientist: Telephone Loughborough (01509) 611611. Pharmaceutical Division, 3M Health Care, Loughborough, England. Aerolin, Autohaler and 3M are trade marks of the 3M Company.

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References

1. Brown, R.B. and Sands, M., Curr. Ther. Res.(1989),**46** (2), 285-91.
2. Data On File, (GCR B-116 232). **3.** Niebuhr, H. *et al.* Chemotherapie Journal (1993), **2**, 28-35. **4.** Estimated current cash annual sales worldwide - Data on File. Roche Products Ltd.

Brief Prescribing Information

Indications: Pneumonia, septicaemia; 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 0031/0169 (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.

J 738084 Date of preparation February 1994

Roche

ABBREVIATED PRESCRIBING INFORMATION
Presentation 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, sulphinpyrazone 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, thiabendazole, isoprenaline, fluvoxamine, viloxazine hydrochloride and oral contraceptives. Factors such as viral infections, liver disease and heart failure also reduce theophylline clearance. The [illegible] headache and CNS stimulation is 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: 1. Kidney J, Dominguez M, Taylor PM, *et al.* (In press).

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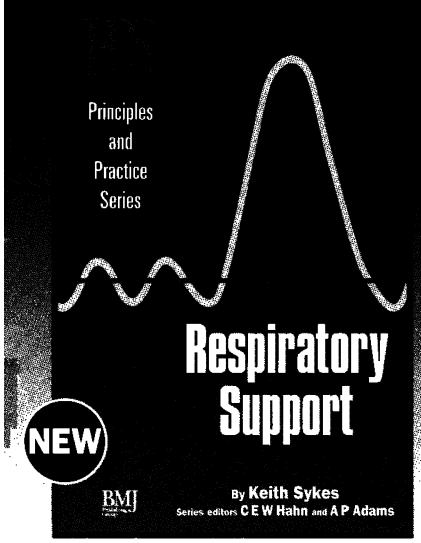

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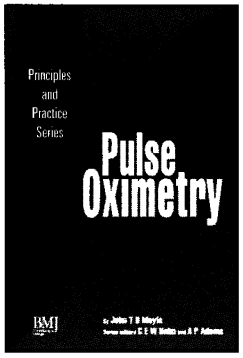

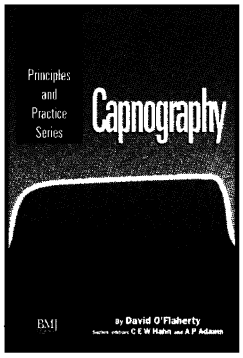

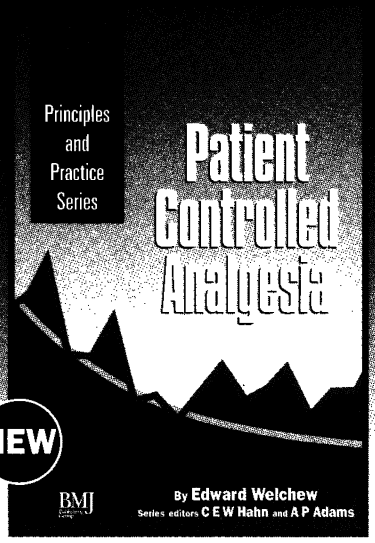

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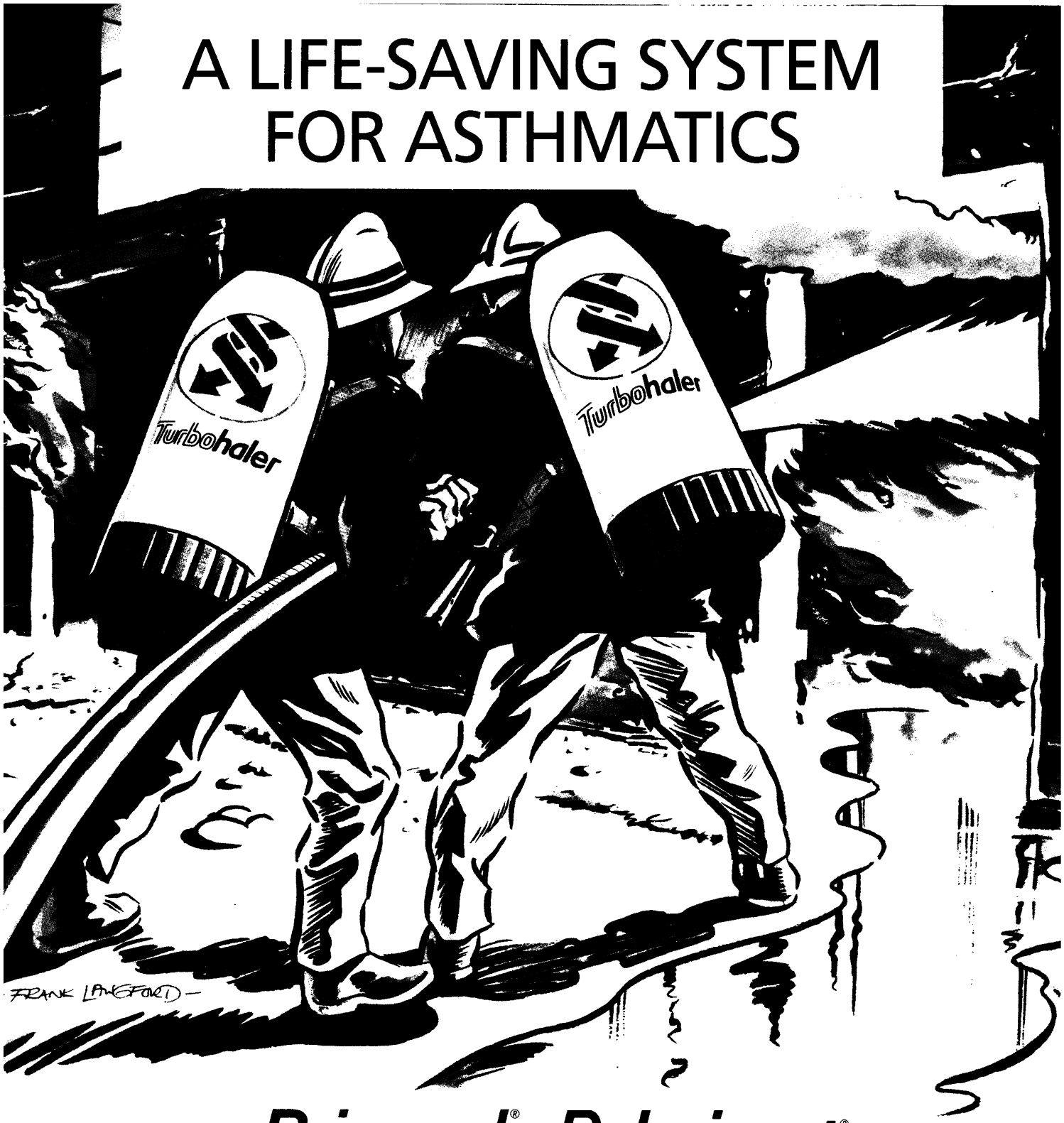

Bricanyl® Turbohaler®
TERBUTALINE SULPHATE

Pulmicort® Turbohaler®200
BUDESONIDE

Abridged prescribing information: Presentation: Bricanyl Turbohaler. Dry powder inhaler delivering 0.5 mg terbutaline sulphate per actuation. **Uses** Relief and prevention of bronchospasm in bronchial asthma and bronchopulmonary disorders in which bronchospasm or reversible airways obstruction is a complicating factor. **Dosage and administration:** Adults and children (including elderly): One inhalation (0.5 mg) as required. Not more than 4 inhalations/day. **Contra-indications, warnings, etc:** Sensitivity to terbutaline sulphate. Precautions: Care should be taken in patients with myocardial insufficiency or thyrotoxicosis. Additional blood glucose measurements are initially recommended in diabetic patients. If treatment becomes less effective or shorter acting, the patient's general condition should be reviewed. Do not use in patients with hypertrophic cardiomyopathy. Potentially serious hypokalaemia may result from ß2-agonist therapy. Administer with caution during the first trimester of pregnancy. Do not administer concurrently with non-selective ß-blockers. Use with caution with other sympathomimetics. **Side effects:** Tremor, tonic cramp and palpitations are all characteristic of sympathomimetic amines. A few patients feel tense. **Basic NHS price:** Bricanyl Turbohaler (100 doses) £7.96. **Legal category:** POM. **Product licence number:** PL 0017/0241.

Presentations: Pulmicort Turbohaler 100. 100 µg/puff budesonide dry powder inhaler containing 200 doses. Pulmicort Turbohaler 200. 200 µg/puff budesonide dry powder inhaler containing 100 doses. Pulmicort Turbohaler 400. 400 µg/puff budesonide dry powder inhaler containing 50 doses. **Uses:** Bronchial asthma. **Dosage and administration:** Individualise dose. Adults: 200-1600 µg daily in divided doses. Children: 200-800 µg daily in divided doses. Maintenance: Use lowest possible dose. Brush the teeth and rinse the mouth out with water after each use. **Contra-indications, warnings, etc:** Active pulmonary tuberculosis. Special care is needed in patients with fungal and viral infections in the airways. Avoid administration during pregnancy. 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 treatment with Pulmicort demands special care. See data sheet for further details. **Side effects:** Mild irritation in the throat, hoarseness and oral candidiasis occur in some patients. Rare cases of cataract have been reported after prolonged use of corticosteroids. **Legal category:** POM. **Basic NHS price:** Pulmicort Turbohaler 100 (200 doses) £18.50. Pulmicort Turbohaler 200 (100 doses) £18.50. Pulmicort Turbohaler 400 (50 doses) £18.50. **Product licence numbers:** Pulmicort Turbohaler 100 PL 0017/0319 (100 µg/puff). Pulmicort Turbohaler 200 PL 0017/0272 (200 µg/puff). Pulmicort Turbohaler 400 PL 0017/0271 (400 µg/puff). **Further information is available from the product licence holder:** Astra Pharmaceuticals Limited, Home Park, Kings Langley, Herts WD4 8DH. ®Registered trade mark

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