Prescribing information Combivent Metered Aerosol containing 200 doses, each delivering ipratropium bromide (anticholinergic bronchodilator) 20 micrograms and salbutamol (β_2-adrenergic agonist) 100 micrograms. **Indication:** treatment of bronchospasm associated with chronic obstructive pulmonary disease in patients who require regular treatment with both ipratropium and salbutamol. **Dosage:** Adults only: two puffs four times a day. **Contra-indication:** known hypersensitivity to any of the components or to atropine or its derivatives. **Precautions:** cardiac disorders; hyperthyroidism; diabetes mellitus; co-prescription with β-blockers, corticosteroids, xanthine derivatives, other β-agonists or anticholinergics; pregnancy, especially the first trimester, and breast feeding. Potentially serious hypokalaemia may result from β_2-agonist therapy. Advise patient to seek medical advice in the event of acute, rapidly worsening dyspnoea or if response lessens; do not spray into the eye. **Side-effects:** tremor and nervousness may occur; tachycardia, dizziness, palpitations, headache, local reactions such as dryness of the mouth are less frequent; urinary retention has been reported rarely. As with other bronchodilators, cough and, very rarely, paradoxical bronchoconstriction have been observed. **Basic NHS price:** 10ml vial complete with mouthpiece UK £6.00. POM. PL 0015/0191. PA 752/1 **Product Licence and Authorisation Holder:** Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, RG12 8YS. **Date of Preparation:** November 1994. For full prescribing information please see data sheet.

Boehringer Ingelheim

Prepared November 1994.

Presentations: Pulmicort Respules (2 ml single dose unit ampoules) containing 0.25 mg/ml or 0.5 mg/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 1-2 mg twice daily. In very severe cases the dosage may be further increased. Children 3 months to 12 years: 0.5-1 mg 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): 0.5-1 mg twice daily. Children (3 months to 12 years): 0.25-0.5 mg 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-indication:** 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 category:** POM. **Basic NHS price:** Pulmicort Respules 0.25 mg/ml (20 single dose units) £32.00. Pulmicort Respules 0.5 mg/ml (20 single dose units) £44.64. **Product licence numbers:** Pulmicort Respules 0.25 mg/ml PL 0017/0309. Pulmicort Respules 0.5 mg/ml PL 0017/0310. **For further information contact the product licence holder:** Astra Pharmaceuticals Ltd., Home Park, Kings Langley, Herts WD4 8DH. **Reference:** 1. Higenbottam TW et al. Eur J Clin Res 1994, **5:** 1-10.

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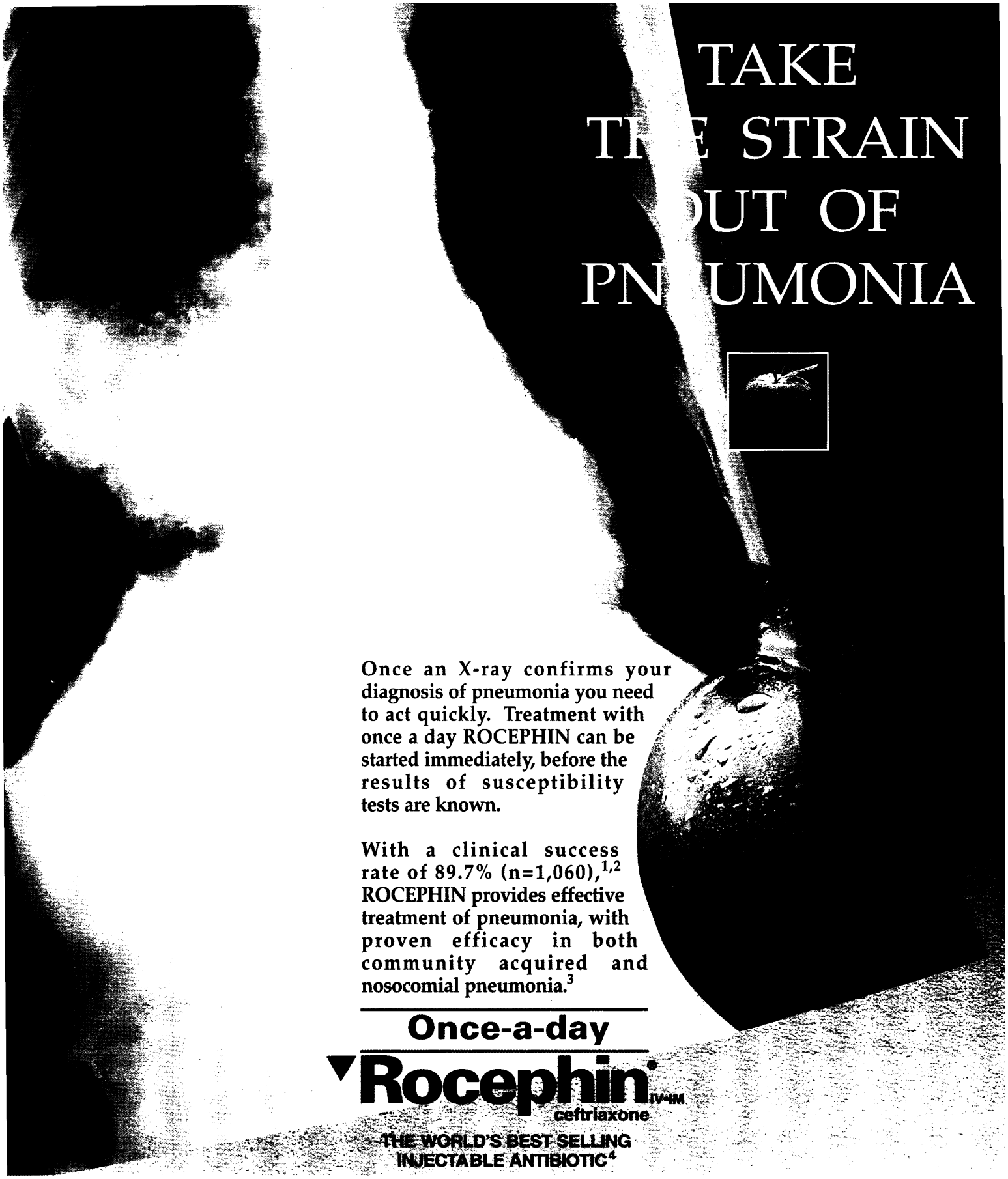
Glaxo

...further information is available on request ...rom: Glaxo Laboratories Limited, ...tockley Park West, Uxbridge, Middlesex ...B11 1BT Tel: 081-990 9444. ...ortum is a Glaxo trade mark ...December 1993

Peregrine falcon



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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.

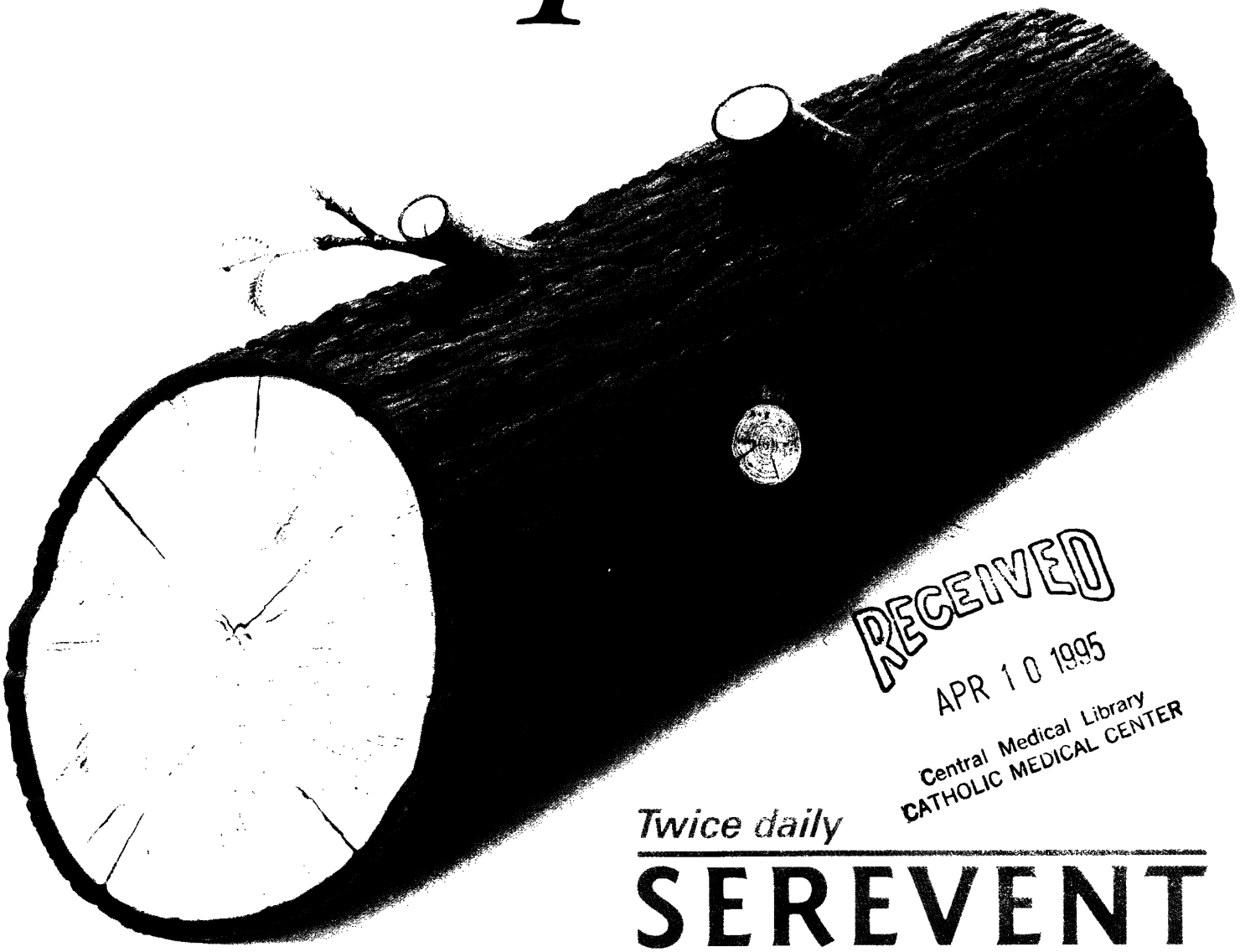
Brief Prescribing Information

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

"I sleep well"



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SEREVENT

salmeterol xinafoate

FOR ACTIVE DAYS AND RESTFUL NIGHTS

Serevent (salmeterol xinafoate)
Abridged Prescribing Information
(Please refer to the full data sheet before prescribing)
Uses Treatment of asthma (including nocturnal and exercise-induced) in patients requiring long-term regular bronchodilator therapy. Patients should normally also be receiving regular and adequate doses of inhaled anti-inflammatory agents, or oral corticosteroids. **Dosage and administration** For inhalation only. *Adults and children 4 years and over:* 50 micrograms twice daily. *Adults only:* More severe cases 100 micrograms twice daily. *Children below 4 years:* Not recommended at present. **Contra-indication** Hypersensitivity. **Precautions** *Steroid therapy:* Serevent is not a replacement for corticosteroids and/or, in children, sodium cromoglycate. Warn patients not to stop or reduce such therapy. *Severe or unstable asthma:* Bronchodilators should not be the only or main treatment. Consider using oral steroids and/or maximum doses of inhaled corticosteroids. Warn patients to seek medical advice if short-acting bronchodilator use increases or becomes less effective. Treat severe exacerbations in the normal way. *Acute symptoms:* Serevent is not for relief of acute symptoms. A short-acting inhaled bronchodilator is required. *Thyrotoxicosis:* Use with caution. *Drug interactions:* Avoid beta-blockers. *Hypokalaemia:* May occur, particularly in acute severe asthma. It may be potentiated by xanthine derivatives, steroids, diuretics and hypoxia. Monitor serum potassium levels in these situations. *Pregnancy and lactation:* Experience is limited. Balance risks against benefits. **Side effects** Tremor, subjective palpitations and headaches have been reported, but are usually mild and transient. Skin reactions, muscle cramps, non-specific chest pain, local irritation and arthralgia have been reported. Potentially serious hypokalaemia may result from β_2-agonist therapy. *Paradoxical bronchospasm:* Substitute alternative therapy. **Presentation and Basic NHS cost** *Serevent Diskhaler:* Pack of 14 four-place disk foils, together with a Serevent Diskhaler. 50 micrograms – £29·97. *Serevent Diskhaler refill pack:* Pack of 14 four-place disk foils only – £29·40. *Serevent Inhaler:* 120 actuations per inhaler. 25 micrograms – £28·60. Hospital packs are also available. **Product licence numbers** 0045/0158, 0045/0157.

POM

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Further information is available on request from:
Allen & Hanburys Limited
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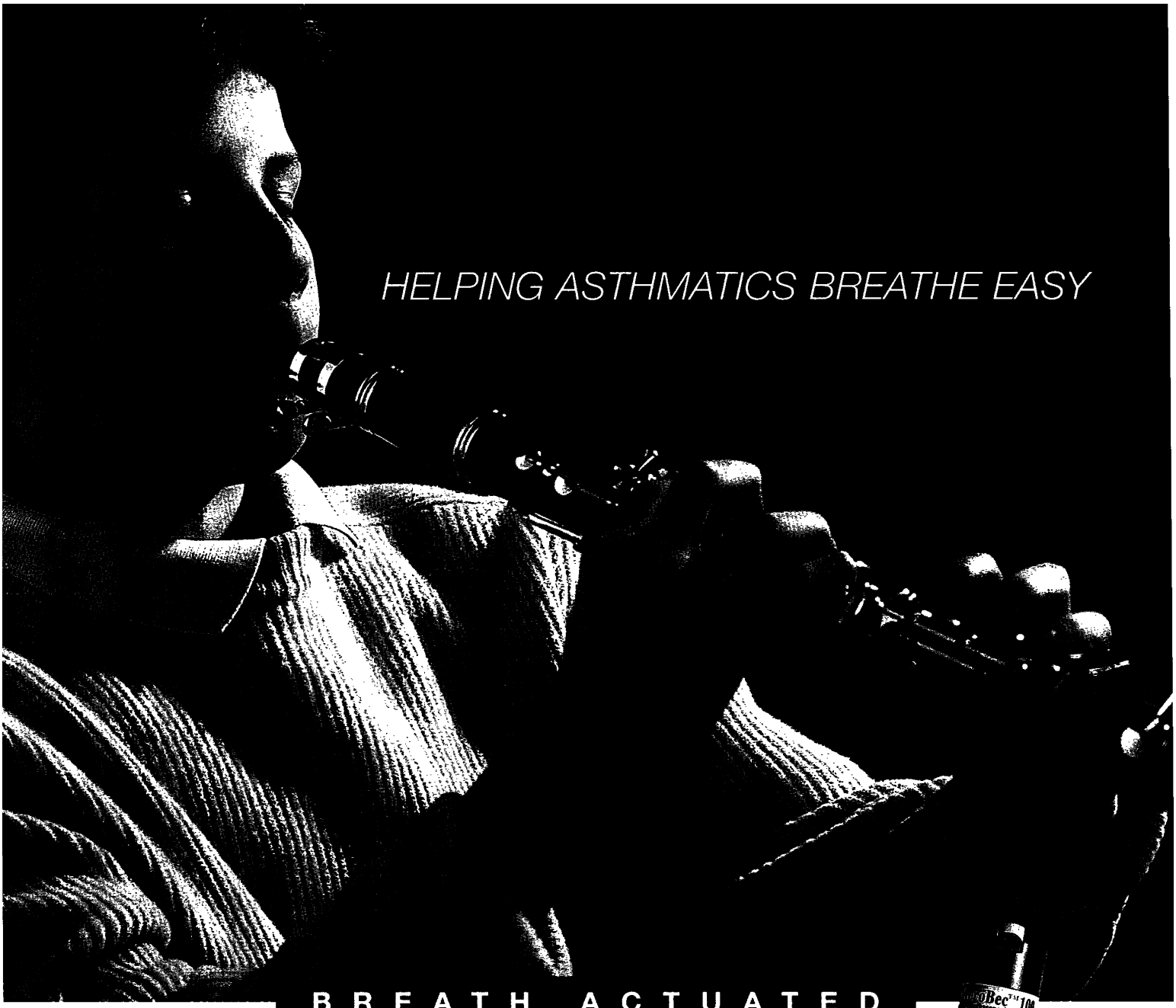
September 1993

When introducing Serevent in adults we strongly recommend that you do not stop or reduce the dose of corticosteroids. Similarly, in children, do not stop or reduce corticosteroids or sodium cromoglycate.



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beclomethasone dipropionate breath-actuated inhaler

CONSISTENT BECLOMETHASONE DELIVERY FOR RELIABLE THERAPY

AEROBEC™ 100 AUTOHALER™ ABBREVIATED PRESCRIBING INFORMATION. Presentation: Breath-actuated pressurised inhalation aerosol delivering 100mcg of beclomethasone dipropionate (as propellant solvate) into the mouthpiece of a breath-actuated adaptor. **Indications:** For the prophylactic treatment of chronic reversible obstructive airways disease. **Dosage:** *Adults:* 200mcg twice daily or 100mcg three or four times daily. In more severe cases a dose of 600-800mcg is recommended, with subsequent reductions. Maximum recommended daily dose of this preparation is 1000mcg. Adrenal suppression may occur in patients receiving doses of 1500mcg or more daily. *Children:* 50-100mcg two to four times daily. **Contra-indications:** Hypersensitivity to beclomethasone. Caution in patients with pulmonary tuberculosis. **Side-effects:** Candidiasis of throat or mouth. Hoarseness. **Precautions:** Patients with adrenocortical suppression should have systemic steroids withdrawn slowly when converting to AeroBec therapy. During periods of stress or when asthma worsens supplementary systemic steroids may be needed. Discontinuation of systemic steroids may cause exacerbation of other allergic diseases. **Pregnancy:** There is inadequate evidence of safety in human pregnancy. Use should be avoided unless benefits outweigh risks. **Lactation:** Beclomethasone is probably excreted in milk. In breast-feeding mothers the therapeutic benefits of the drug should be weighed against the potential hazards to mother and baby. **Pharmaceutical precautions:** Store in a cool place 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:** AeroBec 100: £13.50. **Product licence number:** AeroBec 100: PL 68/0145. **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. AeroBec, Autohaler and 3M are registered trademarks of the 3M company.

3M Health Care

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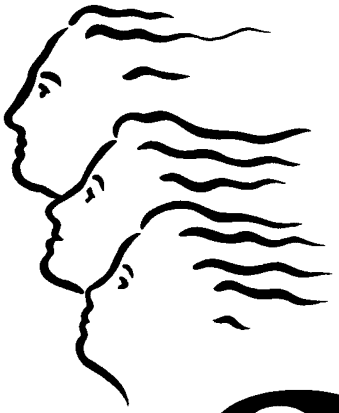

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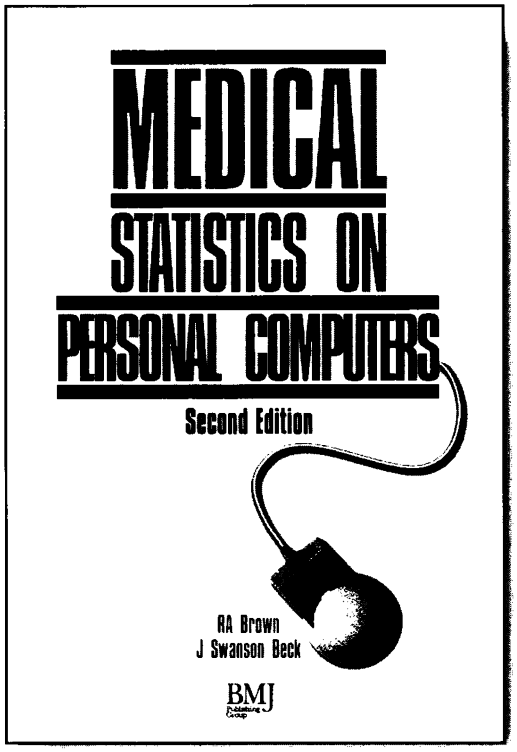

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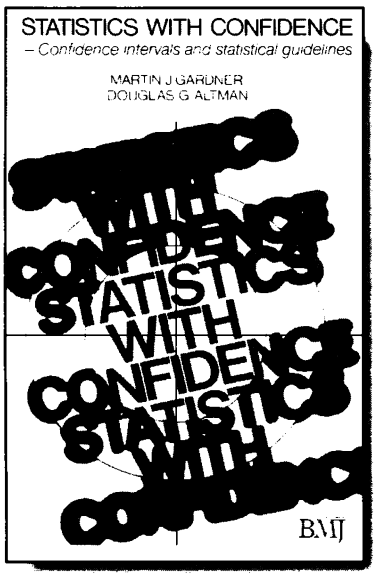

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For everyone using statistical methods to present their findings, this book gives the reasons for using confidence intervals, followed by detailed methods of calculation, including numerous worked examples and specially compiled tables.

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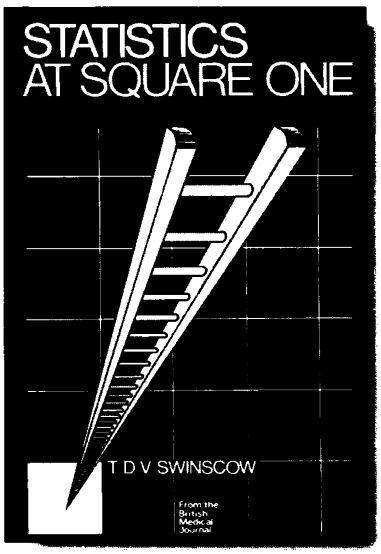

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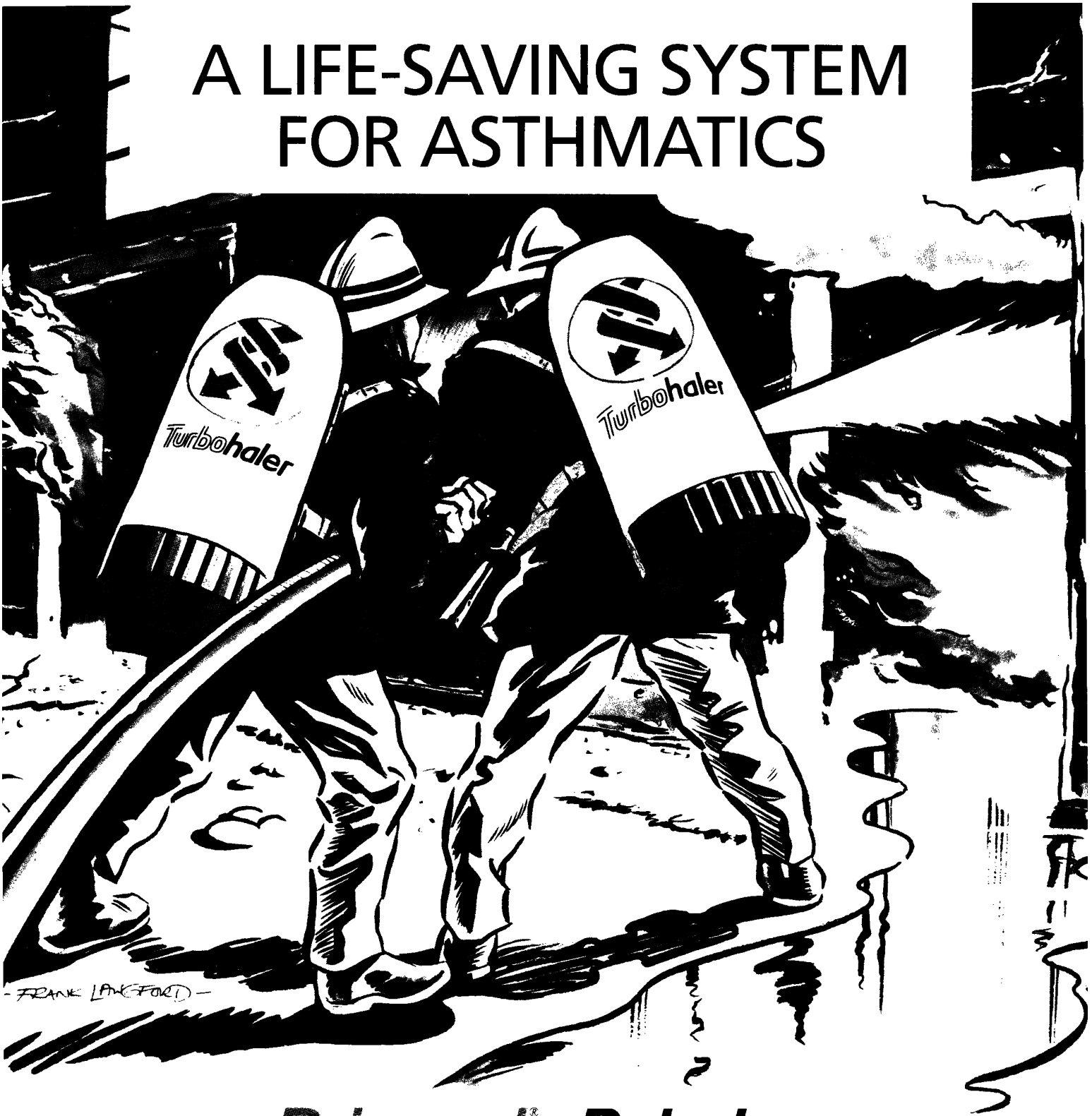

Bricanyl® Turbohaler®
TERBUTALINE SULPHATE

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 availab[1] from the product licence holder:** Astra Pharmaceuticals Limited, Home Pa Kings Langley, Herts WD4 8DH. ®Registered trade mark

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TURB95232

Date of preparation: January 1995