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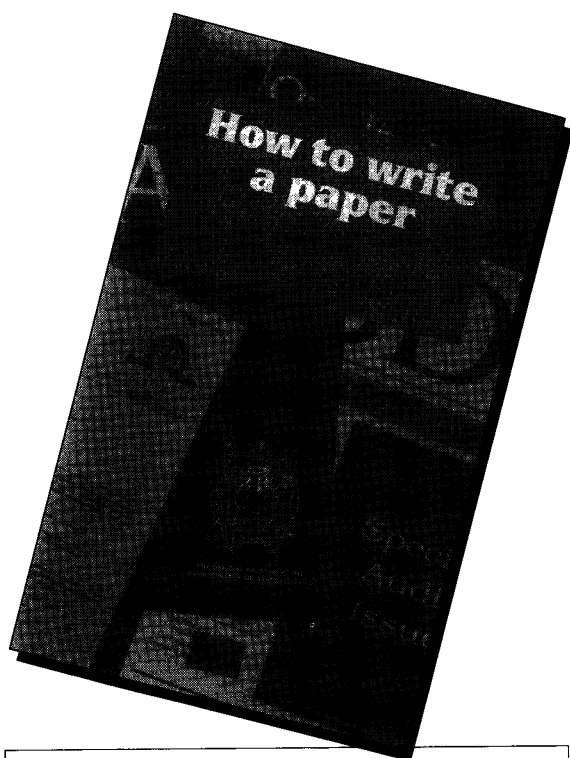
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Beclazone Easi-Breathe Inhaler

Beclomethasone Dipropionate BP

(Please refer to full data sheet before prescribing)

■ **Presentation** Metered Dose Aerosol supplied in a Breath-Operated Inhaler containing 200 doses. **Beclazone 50 Easi-Breathe, Beclazone 100 Easi-Breathe and Beclazone 250 Easi-Breathe Inhalers** deliver 50, 100 and 250 microgram Beclomethasone Dipropionate BP per actuation of the valve.

■ **Uses** Provides automatic actuation of inhaler with inspiration. For the management of bronchial asthma, especially in patients inadequately controlled by bronchodilators and sodium cromoglycate.

■ **Dosage and Administration** Use regularly. **Adults, Beclazone 50 and 100 Easi-Breathe Inhalers;** 100 microgram three or four times daily. **Beclazone 250 Easi-Breathe Inhaler;** 500 microgram twice a day or 250 microgram four times a day. **Elderly** no dose adjustment necessary, including patients with renal or hepatic impairment. **Children, Beclazone 50 and 100 Easi-Breathe Inhalers;** 50 to 100 microgram two to four times daily. **Beclazone 250 Easi-Breathe Inhaler** is not indicated for use in children.

■ **Contra-Indications** Hypersensitivity to the ingredients.

■ **Precautions** Patients should be instructed in the correct use of inhalers. May induce systemic corticosteroid effects with reduction in plasma cortisol levels and adrenal suppression (above 2000 microgram daily – monitor adrenal function and provide systemic steroids in appropriate cases of stress. Caution in patients with history of, or active pulmonary tuberculosis. Avoid sudden cessation of treatment).

■ **Pregnancy/Lactation** Use inhalers only if the potential benefit outweighs the risk.

■ **Side Effects** Paradoxical bronchospasm – discontinue use immediately and seek medical advice. Candidiasis, hoarseness or throat irritation – relieve by rinsing throat with water.

■ **Product Licence Numbers and Basic NHS Cost**
Beclazone 50 Easi-Breathe Inhaler PL 0530/0451 (4.4,34)
Beclazone 100 Easi-Breathe Inhaler PL 0530/0452 (63.24)
Beclazone 250 Easi-Breathe Inhaler PL 0530/0453 (18.92)

■ **Legal Category** POM.

■ **Further information** is available on request from: Baker Norton Gemini House, Flex Meadow, Harlow, Essex CM19 5TJ.

■ **Date of issue** July 1995

Salamol Easi-Breathe Inhaler

Salbutamol BP

(Please refer to full data sheet before prescribing)

■ **Presentation** Metered Dose Aerosol supplied in a Breath-Operated Inhaler containing 200 doses. **Salamol Easi-Breathe Inhaler** metered dose aerosol delivering 100 microgram of Salbutamol BP per actuation.

■ **Uses** Provides automatic actuation of inhaler with inspiration. For the treatment and prophylaxis of bronchial asthma.

■ **Dosage and Administration** For optimum results use as required. Each administration has a bronchodilator effect which should last about 4 hours. **Adults** (i) Acute bronchospasm and intermittent episodes of asthma, including relief of symptoms such as wheezing, breathlessness and tightness of the chest – one or two inhalations as a single dose. (ii) Chronic maintenance or prophylactic therapy – two inhalations three or four times daily. (iii) To prevent exercise induced bronchospasm – two inhalations should be taken before exertion. **Children** (i) Acute bronchospasm and episodic asthma, including relief of symptoms such as wheezing, breathlessness and tightness of the chest, or before exercise – one inhalation. (ii) Routine maintenance or prophylactic therapy – one inhalation three or four times daily. The doses in children may be increased to two inhalations if necessary. Children should be supervised.

■ **Contra-Indications** In spite of the fact that salbutamol has been used intravenously and orally in the management of uncomplicated premature labour, **Salamol Easi-Breathe Inhaler** should not be used for managing premature labour or for threatened abortion. **Salamol Easi-Breathe Inhaler** is contra-indicated in patients with a history of hypersensitivity to any of its components.

■ **Warnings** Potentially serious hypokalaemia may result from beta2-agonist therapy. It is recommended that serum potassium levels are monitored when the hypokalaemic effect may be potentiated by concomitant drugs or hypoxia. Propranolol and other non-cardioselective beta adrenoceptor blocking agents antagonise the effect of salbutamol.

■ **Precautions** Patients with hyperthyroidism, who are hypersusceptible or who are suffering from diabetes mellitus, serious cardiovascular disorders or hypertension should use salbutamol containing products with caution. Asthmatic patients whose condition deteriorates despite salbutamol therapy or where a previously effective dose fails to give relief for at least three hours should seek medical advice. Alternative or additional therapy including corticosteroids should be instituted promptly although adverse metabolic effects of high doses of salbutamol may be exacerbated by concomitant administration of high doses of corticosteroids. Patients should not increase the dosage or frequency of administration without seeking medical advice.

■ **Side Effects** Potentially serious hypokalaemia may result from beta2-agonist therapy (see Warnings). Salbutamol may cause fine tremor of skeletal muscle (particularly the hands), palpitations and muscle cramps. Slight tachycardia, liveness, headaches and peripheral vasodilatation have also been reported but these are less usually associated with the inhalation dosage form. Hypersensitivity reactions have been reported very rarely. Reports of hyperactivity in children are rare with beta2 agonists.

■ **Pregnancy/Lactation** **Salamol Easi-Breathe Inhaler** should be used during pregnancy or lactation only after careful consideration by the medical practitioner that the expected benefit outweighs the risk. **Salamol Easi-Breathe Inhaler** should not be used for managing premature labour or for threatened abortion (see Contra-Indications).

■ **Product Licence Number and Basic NHS Cost**
Salamol Easi-Breathe Inhaler PL 0530/0399 (46.30)

■ **Legal Category** POM.

■ **Further information** is available on request from: Baker Norton Gemini House, Flex Meadow, Harlow, Essex CM19 5TJ.

■ **Date of issue** July 1995

Beclazone, Beclazone Easi-Breathe and Salamol, Salamol Easi-Breathe and Baker Norton are trademarks of Norton Healthcare Limited.

References:

- 1 Lindgren S, Boke B, Larsson S, Lur J, Resque D (1987) 70-104
- 2 Chompton G, Tar J, Respir Dis 1982; 63 Suppl 139: 133-134
- 3 Goodman D, et al. Am J Respir Crit Care Med 1994; 150 1266-1271
- 4 Etzelat M, et al. The Pharmaceutical Journal, 1994; 253 677-680
5. MIMS July 1995
6. Data on file, Baker Norton
7. Based on IMS Data

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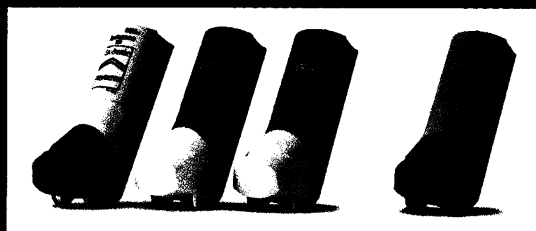
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PRESCRIBING INFORMATION

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 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 0017/03109. 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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P.Res. 0382

Pulmicort[®]
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BUDESONIDE

Nebulised Steroid Control

(Flixotide Accuhaler and Flixotide Diskhaler)
Further Describing Information:
Please refer to the full data sheet before
prescribing.

Flixotide is a topically active corticosteroid for
the symptomatic management of asthma.

Dosage and administration
For inhalation only. Use regularly. Onset
of therapeutic effect usually occurs in
1 to 7 days. **Adults:** 100 to 1,000
micrograms twice daily. **Children aged 4
and over:** 50 to 100 micrograms twice
daily. Equivalent disease control usually
obtained at half the daily dose of other
currently available inhaled steroids.

Contra-indications: Hypersensitivity.
Precautions: Special care is required in
quiescent pulmonary tuberculosis and/or
unstable asthma. Warn patients to seek
medical advice if short-acting
bronchodilator use increases or is
less effective. Consider additional
steroids and/or maximum doses of
inhaled corticosteroids. Treat severe
exacerbations in the normal way.
Symptoms: Not for relief of acute
symptoms. A short-acting inhaled
bronchodilator is required. **Systemic
effects:** Adrenal function and reserve
usually remain within the normal range.
Some systemic effects may occur in a
small proportion of adults after long-
term treatment at high doses. Some
biochemical changes reported in
children, but no stunting of growth
observed. **Transfer from oral steroids:**
Special care is needed. Monitor adrenal
function. Do not stop Flixotide abruptly.
Consider additional corticosteroid
therapy in situations likely to produce
stress. **Pregnancy and lactation:** Experience
is limited. Balance risks against benefits.
Side effects: Candidiasis of mouth and
throat. Hoarseness. Rarely, cutaneous
hypersensitivity. **Paradoxical bronchospasm:**
discontinue alternative therapy.

Representations and Basic NHS cost
Flixotide Accuhaler: 60 inhalations.
100 micrograms - £8.23. 250 micrograms - £12.80.
500 micrograms - £40.23. **Flixotide
Diskhaler:** 120 actuations. 25 micrograms -
£6.86. 50 micrograms - £11.43.
100 micrograms - £22.86.
250 micrograms - £38.86.

Flixotide Diskhaler: 14 four-place disks
with Flixotide Diskhaler. 50 micrograms -
£8.23. 100 micrograms - £12.80.
250 micrograms - £24.23.
500 micrograms - £40.23. **Flixotide
Accuhaler:** 14 four-place disks. 50 micrograms - £7.66.
100 micrograms - £12.23.
250 micrograms - £23.66.
500 micrograms - £39.66.

Flixotide Diskhaler and Inhaler: Hospital packs
also available.
Product licence numbers: 10949/0001,
10949/0227, 10949/0228, 10949/0229,
10949/0001, 10949/0002, 10949/0003,
10949/0004, 10949/0005, 10949/0006,
10949/0007, 10949/0008.

Product licence holder: Glaxo
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Park West, Uxbridge UB11 1BT.

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June 1995

FLIXOTIDE
budesonide propionate



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BRIEFED PRESCRIBING INFORMATION
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 bossed 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 bossed 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 allowed 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, imipramine, sulphapyrazole 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, oxazepam hydrochloride and oral contraceptives. Disorders such as viral infections, liver disease and heart failure also reduce theophylline clearance. **Theophylline toxicity resulting from beta₂ agonist therapy** Beta₂ agonists and theophylline may be potentiated by each other. Particular care is advised in patients suffering from severe asthma who require bronchodilation. It is recommended that beta₂ agonist therapy should be discontinued in such circumstances. Caution is advised in patients with pre-existing cardiac disease. Theophylline toxicity usually manifests as tremor, tachycardia, and nervousness. Other symptoms such as nausea, gastric irritation, headache and CNS stimulation is significantly reduced when UNIPHYLLIN CONTINUS tablet preparations are used. 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 sustained release xanthine preparations without re-titration and clinical assessment. **Legal category** P. **Pack quantities and basic NHS price** UNIPHYLLIN CONTINUS tablets 400 mg - 56's: £7.32; 250's: £23.36; 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, Camphrey Science Park, Milton Road, Cambridge CB4 4SW, UK. Tel: 01223 424444. Member of Napp Pharmaceuticals. Further information is available from Napp Laboratories Limited. © The NAPP device. UNIPHYLLIN and CONTINUS are Registered Trade Marks. © NAPP Laboratories Limited 1995. **References** 1. Kennedy J, Dominguez M. *for P.N.*, et al. In press. **Date of preparation** May 1995.



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Prescribing Information ▼@FORADIL eformoterol fumarate **Presentation** 12 micrograms dry powder inhalation capsules for use with breath activated inhaler device. **Indications** Regular maintenance treatment of bronchospasm in patients with reversible obstructive airways disease. **Dosage** Adults including the elderly: 1-2 capsules twice daily. Not recommended for children. **Contra-indications** Hypersensitivity to eformoterol fumarate or lactose. **Precautions** Steroid treatment should continue unchanged. FORADIL is not for relief of acute symptoms - a short- acting β_2 -agonist is required.

Thyrototoxicosis, severe cardiovascular disorders, dysrhythmia, hypokalaemia, diabetes mellitus. Pregnancy and lactation. Avoid use with β -adrenergic blockers. **Side-effects** Occasionally: tremor, palpitations, headache. **Rarely:** muscle cramps, myalgia, tachycardia, agitation, dizziness, insomnia, paradoxical bronchospasm, oropharyngeal irritation. **Legal category** POM. **Packs** Dry powder capsules of 12 micrograms (PL0001/0192) together with an inhaler device, in calendar packs of 56 (basic NHS price £24.00). ® denotes registered trademark.

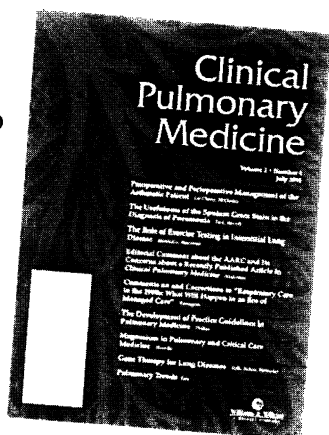
Full prescribing information is available on request from Geigy Pharmaceuticals, Horsham, West Sussex, RH12 4AB. Telephone (01403) 272827. **Date of preparation** February 1995. © Ciba-Geigy PLC 1995



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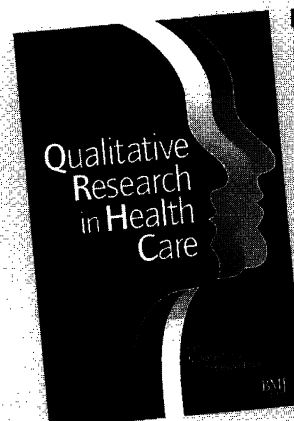
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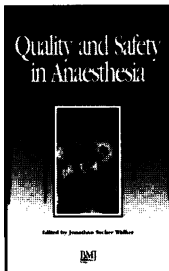
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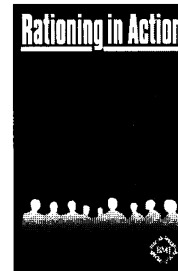
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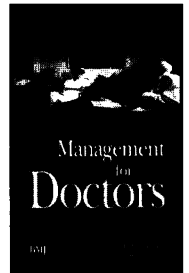
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Turbohaler Kids have a certain air about them



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:** Contra-indications: 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 β_2 -agonist therapy. Administer with caution during the first trimester of pregnancy. Do not administer concurrently with non-selective β -blockers. Use with caution with other sympathomimetics. Side effects: Tinnitus, headache, nervousness 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 no.:** PL 0017/02241.

Presentation: Pulmicort Turbohaler 100: 100µg/puff budesonide dry powder inhaler containing 200 actuations. Pulmicort Turbohaler 200: 200µg/puff budesonide dry powder inhaler containing 100 actuations. Pulmicort Turbohaler 400: 400µg/puff budesonide dry powder inhaler containing 50 actuations. **Uses:** Bronchial asthma. **Dosage and administration:** Individualise dose. Adults (including elderly): 200-1600µg daily in divided doses. Children: 200-800µg 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.:** Contra-indications: Active pulmonary tuberculosis. **Precautions:** Special care is needed in patients with quiescent lung tuberculosis, 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. Titrated 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. **Basic NHS price:** Pulmicort Turbohaler 100 (200 actuations) £18.50. Pulmicort Turbohaler 200 (100 actuations) £18.50. Pulmicort Turbohaler 400 (50 actuations) £18.50. **Legal status:** POM. **Product licence nos.:** Pulmicort Turbohaler 100 PL 0017/0319. Pulmicort Turbohaler 200 PL 0017/0272. Pulmicort Turbohaler 400 PL 0017/0271.

For further information contact the Product Licence holder: Astra Pharmaceuticals Limited, Home Park, Kings Langley, Herts WD4 8DH. ©Pulmicort, Bricanyl and Turbohaler are registered trademarks of Astra Pharmaceuticals Limited. Date of preparation: August 1995. **TRADE MARKS:**

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Turbohaler®

TERBUTALINE SULPHATE

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BUDESONIDE

DESIGNED FOR EFFICIENCY

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