

A NEW PRESENTATION

ATROVENT

ipratropium bromide

Autohaler[®]

Add a boost to your
bronchodilator therapy



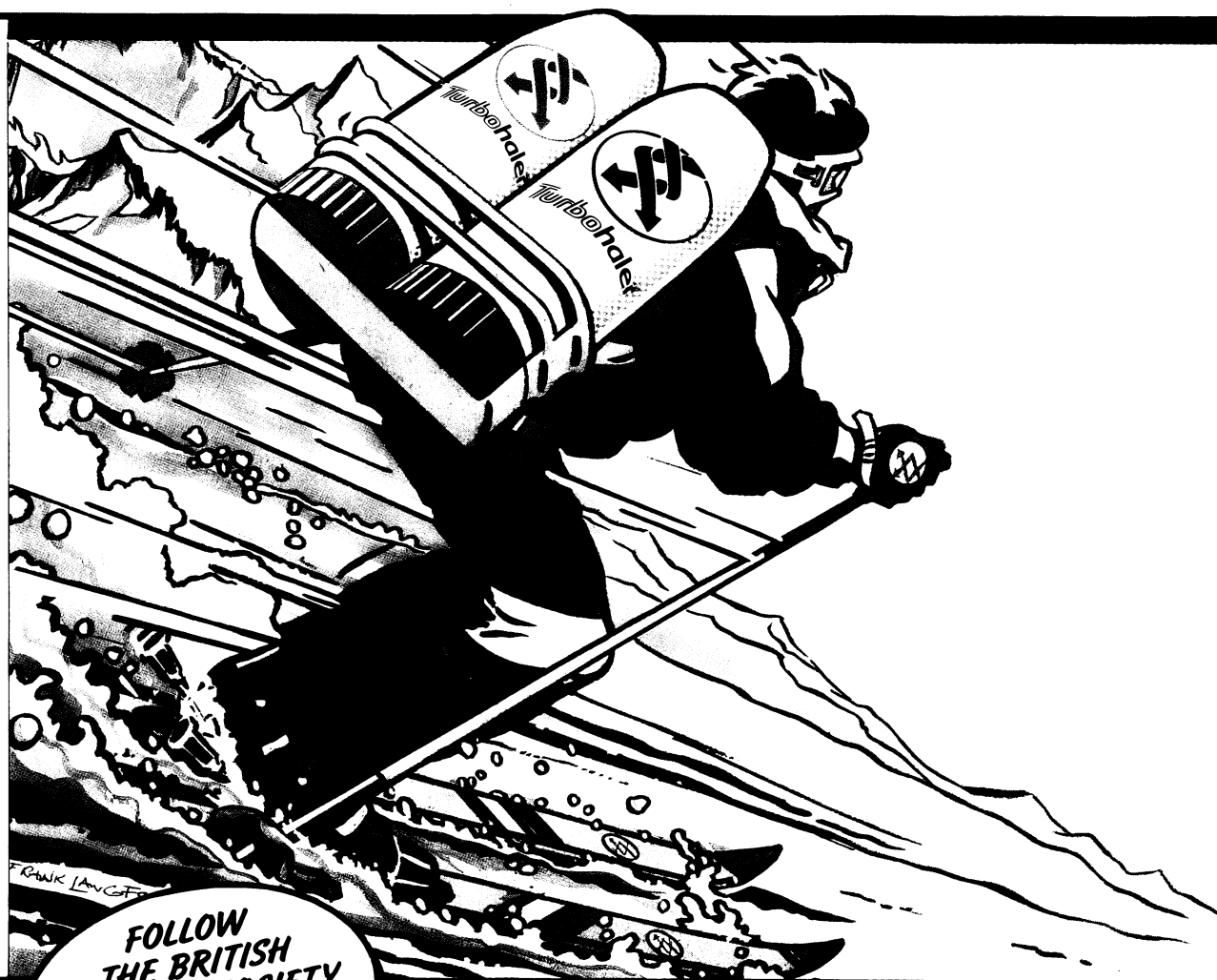
PRESCRIBING INFORMATION

ATROVENT AUTOHALER Ipratropium bromide. Indications Chronic reversible airways obstruction, particularly chronic bronchitis. Dosage *Adults:* Up to 4 puffs three or four times daily. *Children 6-12 years:* 1 or 2 puffs three times daily. *Under 6 years:* 1 puff three times daily. Contra-indication Known hypersensitivity to atropine. Precautions Glaucoma; prostatic hypertrophy; pregnancy, especially the first trimester. Advise patients to seek medical advice if response lessens. Side effects Dry mouth may occur. Presentation Breath-actuated pressurised aerosol for inhalation therapy. 10ml vial complete with mouthpiece contains 200 doses, each delivering 20 micrograms ipratropium bromide. £10.43. Legal category POM. PL 0015/0160. Product licence holder Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire RG12 8YS. For full prescribing information please see data sheet. Date of preparation September 1993.



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ASTHMATICS**

**STEP 1: INHALED BRONCHODILATOR PRN
STEP 2: ADD IN LOW-DOSE INHALED STEROID**

Bricanyl® Pulmicort®

Turbohaler®
TERBUTALINE SULPHATE

Turbohaler® 200
BUDESONIDE

Abridged Prescribing Information: Presentation: Bricanyl Turbohaler. Breath actuated metered dose powder inhaler delivering 500µg terbutaline sulphate per dose. Each inhaler contains 100 doses. **Uses:** Relief of bronchospasm. **Dosage and Administration:** Adults (including elderly) and children: One inhalation as required, up to four times daily. **Contra-indications, warnings, etc.:** Do not use in patients hypersensitive to terbutaline or with hypertrophic cardiomyopathy. Care advised in myocardial insufficiency, thyrotoxicosis and during the first trimester of pregnancy. Potentially serious hypokalaemia may result from β_2 -agonist therapy. Caution advised in severe asthma as effect may be potentiated by concomitant treatment with xanthines, steroids, diuretics and by hypoxia (see data sheet). Do not administer with β -blockers and use with caution with other sympathomimetics. Additional blood glucose measurements are recommended initially in diabetic patients. Patients should be warned to seek medical advice if the usual relief or duration of action is diminished. **Side-effects:** Infrequent: tremor, tonic cramp, tension and palpitations. **Legal Category:** POM. **Basic NHS price:** Bricanyl Turbohaler, (100 doses) £8.94. **Product Licence Number:** PL 0077/0241. For further information contact the product licence holder: Astra Pharmaceuticals Ltd., Home Park, Kings Langley, Herts WD4 8DH.

Abridged Prescribing Information: Presentations: Pulmicort Turbohaler 200 – 200µg/puff dry powder inhaler containing 100 doses of

budesonide. Pulmicort Turbohaler 400 – 400µg/puff dry powder inhaler containing 50 doses of budesonide. **Uses:** Bronchial asthma. **Dosage and Administration:** Individualise dose. **Adults:** 200µg-1600µg daily in divided doses. **Children:** 200µg-800µg daily in divided doses. **Maintenance:** Use lowest possible dose. Rinse mouth after each use. **Contra-indications:** None known. **Warnings, etc.:** Active lung tuberculosis. 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. **Licence No:** PL 0077/0271 (400µg/puff). PL 0077/0272 (200µg/puff). **Price:** Pulmicort Turbohaler 200 and Pulmicort Turbohaler 400 £18.50. For further information contact the product licence holder: Astra Pharmaceuticals Ltd., Home Park, Kings Langley, Herts WD4 8DH. **Reference:** 1. Statement by the British Thoracic Society, Research Unit of The Royal College of Physicians of London, King's Fund Centre, National Asthma Campaign. *Brit Med J* 1991; 301: 651-653.

ASTRA

Flixotide
(fluticasone propionate)
Abridged Prescribing Information
(Please refer to the full data sheet before prescribing)
Uses Topically active corticosteroid for prophylactic management of asthma.
Dosage and administration For inhalation only. Use regularly. Onset of therapeutic effect usually occurs in 4 to 7 days. *Adults:* 100 to 1,000 micrograms twice daily. *Children over 4 years:* 50 to 100 micrograms twice daily.
Contra-indication Hypersensitivity.
Precautions *Severe or unstable asthma:* Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases or becomes less effective. Consider using oral steroids and/or maximum doses of inhaled corticosteroids. Treat severe exacerbations in the normal way.
Acute symptoms: Flixotide is 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 maximum recommended dose. No systemic side effects have been seen in children.
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.
Tuberculosis: Special care is needed in active or quiescent pulmonary tuberculosis.
Pregnancy and lactation: Experience is limited. Balance risks against benefits.
Side effects Candidiasis of mouth and throat, hoarseness. *Paradoxical bronchospasm:* Substitute alternative therapy.

Presentation and Basic NHS cost
Flixotide Inhaler: 120 actuations per inhaler. 25 micrograms – £6.86. 50 micrograms – £11.43. 125 micrograms – £22.86. 250 micrograms – £38.86.
Flixotide Diskhaler: Pack of 14 four-place disks together with a Flixotide Diskhaler. 50 micrograms – £8.23. 100 micrograms – £12.80. 250 micrograms – £24.23. 500 micrograms – £40.23.
Flixotide Diskhaler refill pack: Pack of 14 four-place disks only. 50 micrograms – £7.66. 100 micrograms – £12.23. 250 micrograms – £23.66. 500 micrograms – £39.66.
Hospital packs are also available.
Product licence numbers 10949/0001, 10949/0002, 10949/0003, 10949/0004, 10949/0005, 10949/0006, 10949/0007, 10949/0008.

POM

References 1. Phillipps GH. Structure-activity relationships of topically active steroids: the selection of fluticasone propionate. *Resp Med* 1990; 84 (Suppl. A): 19-23. 2. Harding SM. Human pharmacology of fluticasone propionate *EAACI* 1989; Berlin West, Symposia Review: 15-17.



ALLEN & HANBURY'S

Further information is available on request from:
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FLIXOTIDE[▼]

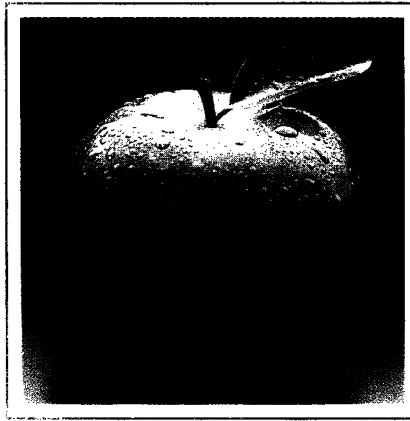
fluticasone propionate

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References

1. Emmerson, A.M. *et al.*, *Curr. Med. Res. Opin.*, 1985, **9** (5), 480-493.
2. Patel, I.H., *et al.*, *Antimicrob. Agents Chemother.*, 1981, **20** (5), 634-641.
3. Hell, K., *et al.*, *Chemotherapy*, 1989, **35** (3), 228-235.
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.



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. BOSS Study, *Thorax* 1993; 48(4).

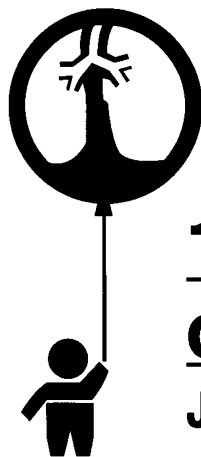
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- * Pulmonary Tuberculosis in Children.
- * Cystic Fibrosis in Children.

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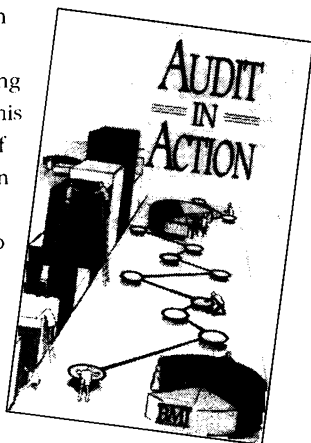
- * Lung Cell Development.
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AEROBEC 50 AUTOHALER, AEROBEC 100 AUTOHALER AND AEROBEC FORTE AUTOHALER ABBREVIATED PRESCRIBING INFORMATION

Presentation: Breath-actuated pressurized inhalation aerosols delivering 50mcg (AeroBec 50), 100mcg (AeroBec 100) or 250mcg (AeroBec Forte) of beclomethasone dipropionate (as propellant solvate) into the mouthpiece of a breath-actuated adapter. **Indications:** For the prophylactic treatment of chronic reversible obstructive airways disease. AeroBec Forte is indicated for those patients who require high doses of beclomethasone to control their symptoms. **Dosage: AeroBec 50, 100: 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 these preparations is 1000mcg. Adrenal suppression may occur in patients receiving doses of 1500mcg or more daily. **Children:** 50-100mcg two to four times daily. **AeroBec Forte: Adults:** two inhalations (500mcg) twice daily, increasing to a maximum of two inhalations four times daily if necessary. Adrenal suppression may occur in patients receiving 1500mcg or more daily. **Children:** not recommended. **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 pressurized, no attempt should be made to puncture it or dispose of it by burning. **Basic NHS prices:** AeroBec 50: £11.00 AeroBec 100: £13.50 AeroBec Forte: £25.10. **Product licence numbers:** AeroBec 50: PL 68/0143 AeroBec 100: PL 68/0145 AeroBec Forte: PL 68/0140. **Legal Category:** POM.

AEROLIN AUTOHALER ABBREVIATED PRESCRIBING INFORMATION

Presentation: A breath-actuated pressurized inhalation aerosol delivering Salbutamol Sulphate BP equivalent to salbutamol 100mcg. **Indications:** For the treatment of reversible airways obstruction associated with asthma, bronchitis and emphysema. **Dosage: Adults of all ages:** one or two inhalations as a single dose for acute symptomatic relief. For chronic maintenance/prophylactic therapy, two inhalations three or four times daily. **Children:** half of adult dose, increasing as necessary to the full

adult dose. **Precautions:** Administer cautiously to patients with thyrotoxicosis. Patients should be advised to seek medical advice if treatment ceases to be effective. **Side-effects:** Mild tremor, headache and transient muscle cramps may rarely occur. Potentially serious hypokalaemia has been reported in patients taking β_2 -agonist therapy. **Pharmaceutical precautions:** Store in a cool place protected from frost and direct sunlight. As the vial is pressurized 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 1994

Further information is available from the 3M Health Care Information Scientist: Telephone Loughborough (0509) 611611. Pharmaceutical Division, 3M Health Care, Loughborough, England

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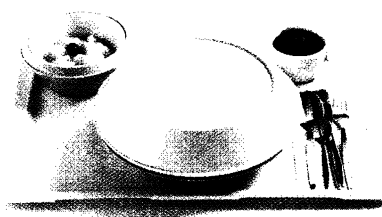
Presentation White tablets containing the equivalent of either 250mg, 500mg or 750mg ciprofloxacin. **Uses** Ciprofloxacin is indicated for the treatment of single or mixed infections caused by susceptible organisms. Also indicated for prophylaxis against infection in elective upper gastro-intestinal surgery and endoscopy where there is an increased risk of infection. **Dosage and administration** The tablets should be swallowed whole with liquid. **Adults:** 250–750mg twice daily. In surgical prophylaxis a single 750mg tablet administered 60–90 minutes before the procedure (but see interactions with oral premedicants). **Duration of treatment** For acute infections the usual treatment period is 5 to 10 days, except in cases of acute uncomplicated cystitis where treatment is 250mg twice daily for 3 days. Generally, in acute and chronic infections where sensitivity is proven, treatment should be continued for at least 3 days after the signs and symptoms of infection have disappeared. **Elderly** No dose adjustment. **Contra-indications** Hypersensitivity to ciprofloxacin or other quinolones; also in children and growing adolescents except where the benefits of treatment outweigh the risks. **Warnings and precautions** Use with caution in epileptics and patients with a history of CNS disorders. Treatment could result in impairment of ability to drive or operate machinery. Crystalluria has been reported so patients should be well hydrated and excessive urine alkalinity avoided. As haemolytic reactions with ciprofloxacin are possible in patients with latent and actual defects in glucose-6-phosphate dehydrogenase activity, use with caution. **Drug interactions** Increased plasma levels of theophylline have been observed following concurrent administration with ciprofloxacin. The dose of theophylline should be reduced and plasma levels of theophylline monitored. Where monitoring of plasma levels is not possible, avoid the use of ciprofloxacin in patients receiving theophylline. Particular caution is advised in those patients with convulsive disorders. Interactions have also been noted with anti-coagulants and cyclosporin. The tablets should not be administered within 4 hours

of medications containing magnesium, aluminium or iron salts. High doses of quinolones have shown an interaction with NSAIDs in animals leading to convulsions. Administration of quinolones and glibenclamide simultaneously can potentiate the effect of glibenclamide, resulting in hypoglycaemia. Opiate premedicants or regional anaesthetic agents must not be administered concomitantly with ciprofloxacin when used for surgical prophylaxis. **Use in pregnancy and lactation** Not recommended. **Side-effects** Gastro-intestinal, CNS, hypersensitivity/skin reactions, musculoskeletal and special sense disturbances. Renal and hepatic disturbances. Effects on haematological parameters.

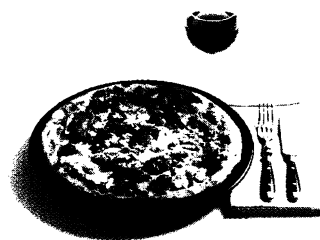
Also reported: vasculitis, pseudomembranous colitis, Stevens-Johnson Syndrome, Lyell Syndrome, haemolytic anaemia, granulocytopenia, intracranial hypertension, petechiae, haemorrhagic bullae, tenosynovitis and tachycardia. **Overdosage** Serum levels of ciprofloxacin are reduced by dialysis. **Legal category** POM. **Package quantities** Blister strips of 10 in packs of 10, 20, and 100 tablets. **Product licence numbers** PL 0010/0146-0148. **Basic NHS cost** 250mg x 10 tablets £ 7.50, 500mg x 10 tablets £ 13.75, 750 mg x 10 tablets £ 20.00. **Date of preparation** July 1993. **For further information refer to data sheet or contact:** Bayer plc, Pharmaceutical Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG13 1JA. Tel.: (0635) 39000. ® Registered trademark of Bayer AG, Germany.

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