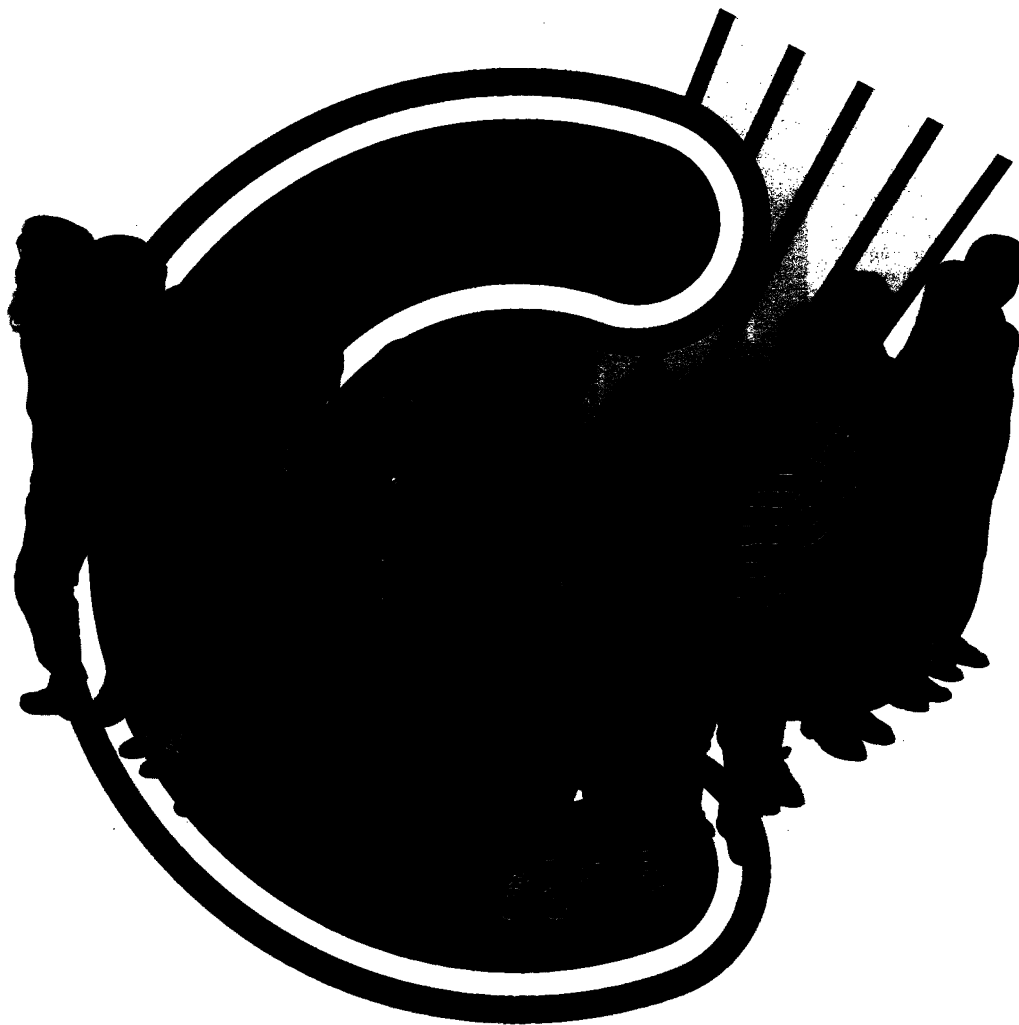


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PRESCRIBING INFORMATION

Presentation 1. Creon - brown/yellow capsules containing enteric coated granules of pancreatin, equivalent to: 8,000 PhEur units of lipase; 9,000 PhEur units of amylase and 450 PhEur units (total) of protease (210 BP units). Available in packs of 100. Basic NHS price of £13.33. PL 5727/0001. 2. Creon sachets - unit dose sachets containing enteric coated granules of pancreatin, equivalent to: 20,000 PhEur units of lipase, 22,500 PhEur units of amylase and 1,125 PhEur units (total) of protease. Available in packs of 40. Basic NHS price of £13.33. PL 5727/0007.

Indication Pancreatic exocrine insufficiency.

Dosage and Administration: Adults and children: 1. Creon - initially one or two capsules with meals, then adjust according to response. 2. Creon sachets - initially the contents of one sachet with meals, then adjust according to response. (Note that two sachets of Creon granules are equivalent to five capsules of Creon.) The contents of each sachet can be taken from a spoon or tipped directly onto the tongue, and then washed down with a drink of water or other fluid. The granules contained in Creon capsules or sachets can also be sprinkled on soft food, which should then be

swallowed without chewing. If the granules are mixed with food, it is important that they are taken immediately, otherwise dissolution of the enteric coating may result.

Contra-indications, Warnings etc. **Contra-indications:** substitution with pancreatic enzymes is contra-indicated in the early states of acute pancreatitis. Use in pregnancy: there is inadequate evidence of safety in use during pregnancy. **Warnings:** The product is of porcine origin. Rarely cases of hyper-uricosuria and hyper-uricaemia have been reported with very high doses of pancreatin. Perianal irritation, and rarely, inflammation, could occur when large doses are used.

Legal Classification: P

Name and Address of Licence Holder: Kali Chemie Pharma GmbH, Postfach 220, D-30173, Hannover 1, Germany.

Further information available from: Duphar Laboratories Limited, Gaters Hill, West End, Southampton SO18 3JD. Tel: 0703 472281.

Date of preparation August 1994

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**DUPHAR
LABORATORIES**

ABBREVIATED PRESCRIBING INFORMATION FOR DIFLUCAN*

(fluconazole) (UK) Presentation: Capsules containing 50mg, 150mg or 200mg fluconazole; intravenous infusion containing fluconazole 2mg/ml in 0.9% sodium chloride solution; Powder for Oral Suspension available as two dosage strengths containing either fluconazole 50mg/5ml or 200mg/5ml on reconstitution with 24ml water. **Indications and dosage:** **Adults:** Systemic candidiasis: 400mg on the first day followed by 200-400mg once daily. Cryptococcosis, including meningitis: 400mg on the first day followed by 200-400mg once daily. Maintenance therapy to prevent relapse of cryptococcal meningitis in patients with AIDS: 100-200mg daily. Oropharyngeal candidiasis: 50-100mg once daily for 7-14 days or longer in immunocompromised patients. Other mucosal candidal infections: 50-100mg once daily for 14-30 days. Prevention of fungal infections in neutropenic patients following cytotoxic chemotherapy or radiotherapy: 50-400mg once daily based on patient's risk for developing fungal infection. For patients at high risk of systemic infection, eg patients who are anticipated to have profound or prolonged neutropenia such as during bone marrow transplantation, the recommended dose is 400mg daily. Start dosage several days before anticipated onset of neutropenia and continue for seven days after neutrophil count rises above 1000 cells per mm³. Dermal fungal infections: 50mg once daily for up to 6 weeks (usually 2-4 weeks - see data sheet). Vaginal candidiasis: Single 150mg dose. Use in the elderly - as above except for those renally impaired - see data sheet. **Children: Over 4 weeks old:** Mucosal candidiasis: 3mg/kg daily. A loading dose of 6mg/kg may be used on the first day. Systemic candidiasis and cryptococcal infection: 6-12mg/kg daily depending on severity of disease. Prevention of fungal infections in neutropenic patients following cytotoxic chemotherapy or radiotherapy: 3-12mg/kg daily depending on the extent and duration of the neutropenia. **Children below 4 weeks of age:** First two weeks of life: The same mg/kg dosing as above but administered every 72 hours. During weeks 2-4 of life same mg/kg dose should be given every 48 hours. Doses of less than 10mg fluconazole should only be administered in hospital. A suitable measuring device should be used for administration of the suspension. **Administration:** DIFLUCAN may be administered either orally or by intravenous infusion at a rate of approximately 5-10ml/min. The dosages for the two routes are equivalent. **Contra-indications:** Hypersensitivity to fluconazole or related azoles, pregnancy and women of childbearing potential unless adequate contraception is employed. **Warnings:** Lactation: Not recommended. Renal impairment: Dosage reduction in both adults and children may be necessary, see data sheet. **Drug interactions:** Anticoagulants, cyclosporin, oral sulphonylureas, phenytoin, rifampicin and theophylline. **Side-effects:** Nausea, abdominal discomfort, diarrhoea, flatulence and rarely anaphylaxis. **Legal Category:** POM. **Basic NHS Cost and Package Quantities:** DIFLUCAN capsules in calendar packs containing 7x50mg (£16.61, PL 57/0289), 7x200mg (£66.42, PL 57/0317) or 1x150mg (£7.12, PL 57/0290); Powder for Oral Suspension, 35ml bottle of 50mg/5ml (£16.61, PL 57/0343), 35ml bottle of 200mg/5ml (£66.42, PL 57/0344); Intravenous Infusion: 25ml (50mg) bottle (£7.32, PL 57/0315); 100ml (200mg) bottle (£29.28, PL 57/0315). Hospital prices are available on request. † DIFLUCAN is well tolerated with few adverse effects: Marchisio P *et al.* (1994) *Eur J Clin Microbiol Infect Dis* 13: 338-340. Fasano C *et al.* (1994) *Eur J Clin Microbiol Infect Dis* 13: 344-347. Further information on request.

* Trade Mark. Pfizer Limited, Sandwich, Kent.
51336 March 1995.



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GENTLE STRENGTH

Targocid Abridged Prescribing Information.
Presentations Vials of 200mg or 400mg teicoplanin and ampoule of diluent [Water for Injections Ph.Eur.].

Uses Indications: Treatment of potentially serious Gram-positive infections including patients who cannot be treated with other antibiotics. Therapy of serious staphylococcal infections in patients who cannot receive or have not responded to penicillins or cephalosporins or who have infections with staphylococci resistant to other antibiotics. As antimicrobial prophylaxis in orthopaedic surgery at risk of Gram-positive infection.

Dosage and Administration Preparation: See data sheet. **Administration:** Either i.v. (bolus or 30min infusion) or i.m. **Adults or elderly patients with normal renal function:** — Prophylaxis: 400mg intravenously at the induction of anaesthesia. — Severe infections: 400mg i.v. every 12 hours for first 3 doses followed by 400mg i.v. or i.m. once daily. — Moderate infections: 400mg i.v. on day 1 followed by 200mg i.v. or i.m. once daily. **Children:** 10mg/kg i.v. every 12 hours for first 3 doses followed by 10mg/kg i.v. or i.m. daily in severe infections and neutropenic patients or 6mg/kg i.v. or i.m. daily in moderate infections. Can be used from 2 months of age. **Neonates:** A single loading dose of 16mg/kg on the first day of treatment, followed on subsequent days by maintenance doses of 8mg/kg once daily. These doses should be given as intravenous infusions over 30 minutes. See data sheet for dose in unusual situations, elderly, renally impaired and patients on CAPD.

Contra-indications, Warnings etc. Contra-indications: Hypersensitivity to teicoplanin. **Warnings:** Caution in patients sensitive to vancomycin. 'Red Man Syndrome' is not a contra-indication. Thrombocytopenia has been reported with teicoplanin. Perform periodic haematological studies, liver and renal function tests. Perform serial renal and auditory function tests in prolonged treatment in renal insufficiency or concurrent and sequential use of neurotoxic or nephrotoxic drugs. Renal impairment — see data sheet. Consider risk-benefit ratio in pregnancy and lactation. **Side-Effects:** Generally mild and transient rarely requiring cessation of therapy. The following have been reported: Erythema, local pain, thrombophlebitis, rash, pruritus, fever, bronchospasm, anaphylactic reactions, nausea, vomiting, diarrhoea, eosinophilia, leucopenia, neutropenia, thrombocytopenia, thrombocytosis, increases in serum transaminases and/or serum alkaline phosphatase, transient elevations of serum creatinine, dizziness and headache, mild hearing loss, tinnitus, vestibular disorder. **Overdosage:** Not removed by haemodialysis. Treat symptomatically.

Pharmaceutical Precautions Store below 25°C and protect from heat. Use immediately after reconstitution. See data sheet.

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Legal Category POM.

NHS price and Product Licence Numbers
Targocid 200mg PL 4425/0088 £26.05. Targocid 400mg PL 4425/0089 £52.10. Water for Injections PL 4425/0090.

Date of Last Review February 1994.

Date of Preparation: September 1994.

References: 1. Lewis P *et al.* *J Antimicrob Chemother* 1988; 21 (Suppl.A): 61-67. 2. Williams AH *et al.* *RSM International Congress and Symposium Series* No.156, 1990: 75-81. 3. Kuraishi A *et al.* *Antimicrob Agents Chemother* 1991; 35 (11): 2246-2252. Further information including full data sheet is available from the licence holder:

Marion Merrell Dow Ltd., Lakeside House, Stockley Park, Uxbridge, Middlesex UB11 1BE.



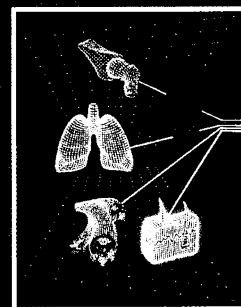
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Presentations: Pulmicort Respules. (2 ml single dose unit ampoules) containing 0.25 mg/ml or 0.5 mg/ml budesonide in a suspension for nebulisation. **Uses:** Bronchial asthma where use of a pressurised inhaler or dry powder formulation is unsatisfactory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