Abbreviated Prescribing Information for **Diflucan™** (fluconazole)

**Presentation:** Capsules containing 50mg, 150mg or 200mg fluconazole; Intravenous infusion containing fluconazole 2mg/ml in 0.9% sodium chloride solution; Powder for Oral Suspension 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. Oesophageal 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. Dermal fungal infections: 50mg once daily for up to 6 weeks (usually 2-4 weeks) - see data sheet. Vaginal candidiasis and candidal balanitis: 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: 3-12mg/kg daily depending on severity of disease. Prevention of fungal infections in neutropenic patients following cytotoxic chemotherapy or radiotherapy: 3-12mg/kg daily. Maximum dose of 400mg daily. Children below 4 weeks of age: First two weeks of life: the same mg/kg dosing as above to a maximum dose of 12mg/kg, administered every 48 hours. During weeks 2-4 of life: same mg/kg dose to a maximum of 12mg/kg, given every 48 hours. Administration: 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; coadministration of terfenadine and cisapride. **Warnings:** Lactation: Not recommended. Renal impairment: Dose reduction in both adults and children may be necessary, see data sheet. **Drug interactions:** Relevance to single-dose has not yet been established. Antacids, astemizole, cyclosporin, diuretics, oral sulphamethoxas, phenytoin, rifabutin, rifampicin, terfenadine, theophylline and zidovudine. Co-administration of terfenadine and cisapride contraindicated. **Side-effects:** Nausea, abdominal discomfort, diarrhoea, flatulence, rash, headache and rarely anaphylaxis. **Legal Category:** POM. Basic NHS Cost and Package Quantities: Diflucan capsules in calendar packs containing 7 x 50mg (£16.61, PL 57/02289), 7 x 200mg (£6.62, PL 57/0317) or 1 x 150mg (£7.12, PL 57/0290); Powder for Oral Suspension, 35ml bottle of 50mg/5ml (£16.61, PL 57/0343), 35ml bottle of 200mg/5ml (£6.62, PL 57/0344); Intravenous Infusion: 25ml (150mg) bottle (£7.32, PL 57/0351), 100ml (200mg) bottle (£9.28, PL 57/0315). Hospital prices are available on request. Further information on request. *Diflucan™ is well tolerated with few adverse effects - Osterloh I (1992) In: The Antifungal Agents Vol 1 Fluconazole Johnson S & Johnson PN (Eds) Marius Press: 40-60. Further information on request. Pfizer Limited, Sandwich, Kent CT13 9XW, 51794 December 1997*