**Patient Group Direction for Administration of Fluconazole 150mg under Community Pharmacy Minor Ailment Service.**

This Patient Group Direction relates to the following specific preparation:

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| Name of medicine | Fluconazole 150mg Capsule |
| Legal status | POM |
| Storage | Store below 30°C |
| Dose | Vaginal candidiasis – a single dose of 150mg by mouth |
| Route/method | Oral |
| Frequency | One capsule completes the course |
| Total dose number | One |
| Advice | ▪ Provide Patient Information Leaflet<br>▪ Treat at any time of menstrual cycle, including during periods.<br>▪ Discuss any possible side effects with the patient.<br>▪ Advise regarding re-infection and that partner may need treatment if symptomatic<br>▪ Washing the vaginal area with water only, avoiding the use of perfumed soaps, vaginal deodorants or douches.<br>▪ Avoiding using latex condoms, spermicidal creams and lubricants if they cause irritation.<br>▪ Wearing cotton underwear and loose-fitting clothes if possible.<br><br>Adverse Reactions<br><br>Occasional : nausea, abdominal discomfort, diarrhoea, flatulence, headache, rash<br><br>Rare: dyspepsia, vomiting, taste disturbance, hepatic disorders, hypersensitivity reactions, anaphylaxis, dizziness, seizures, alopecia, pruritus, toxic epidermal necrolysis, Stevens-Johnston syndrome, hyperlipidaemia, leucopoenia, thrombocytopenia, hypokalaemia |

**2. Clinical condition**

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| Clinical Condition to be treated | Candidiasis is a yeast infection caused by the Candida species of fungus, usually Candida albicans. Many women are affected by vaginal thrush at some point in their lives and in some women it may recur regularly.<br><br>The condition develops when Candida albicans, which is often present in the vagina, causes itching, irritation, discharge, redness, soreness and swelling of the vagina and vulva and a thick, white vaginal discharge. |
| Criteria for inclusion | Woman with previous history of vaginal candidiasis presenting in Community Pharmacy with a need for treatment of symptoms of vaginal candidiasis, and registered for the Minor Ailment Service (MAS). |
| Criteria for exclusion | ▪ Patient not participating in MAS<br>▪ Under 16 and over 60 years of age<br>▪ Women who are experiencing the symptoms for the first time<br>▪ Liver and kidney disease<br>▪ Risk of sexually transmitted disease (STD) or other cause for vaginal discharge.<br>▪ Irregular or abnormal vaginal bleeding<br>▪ Genital ulceration<br>▪ Known hypersensitivity to fluconazole<br>▪ More than two infections of thrush within the last six months |
| Action if excluded | Refer to GP<br><br>Routine referral should also be expected if:<br><br>▪ If symptoms not clearing within 3 days<br>▪ Pregnant<br>▪ Breast feeding<br>▪ Renal impairment<br>▪ Known diabetic and recurring candiasiasis<br>▪ Second request within one month<br>▪ Vaginal pain, bleeding or blistering |
| Action if declines | |
| Interactions with other medicaments and other forms of interaction | The following drug interactions relate to the use of multiple-dose fluconazole, and the relevance to single-dose fluconazole has not yet been established:<br><br>**Anticoagulants** In an interaction study, fluconazole increased the prothrombin time (12%) after warfarin administration in healthy males. In post-marketing experience, as with other azole antifungals, bleeding events (bruising, epistaxis, gastrointestinal bleeding, hematuria and melaena) have been reported in association with increases in prothrombin time in patients receiving fluconazole concurrently with warfarin. Prothrombin time in patients receiving coumarin-type anticoagulants should be carefully monitored. |

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| | **Benzodiazepines (Short acting)** Following oral administration of midazolam, fluconazole resulted in substantial increases in midazolam concentrations and psychomotor effects. This effect on midazolam appears to be more pronounced following oral administration of fluconazole than with fluconazole administered intravenously. If concomitant benzodiazepine therapy is necessary in patients being treated with fluconazole, consideration should be given to decreasing the benzodiazepine dosage and the patients should be appropriately monitored.<br><br>**Sulphonylureas** Fluconazole has been shown to prolong the serum half-life of concomitantly administered oral sulphonylureas (chlorpropamide, glibenclamide, glipizide and tolbutamide) in healthy volunteers. Fluconazole and oral sulphonylureas may be co-administered to diabetic patients, but the possibility of a hypoglycaemic episode should be borne in mind.<br><br>**Hydrochlorothiazide** In a kinetic interaction study, co-administration of multiple-dose hydrochlorothiazide to healthy volunteers receiving fluconazole increased plasma concentrations of fluconazole by 40%. An effect of this magnitude should not necessitate a change in the fluconazole dose regimen in subjects receiving concomitant diuretics, although the prescriber should bear it in mind.<br><br>**Phenytoin** Concomitant administration of fluconazole and phenytoin may increase the levels of phenytoin to a clinically significant degree. If it is necessary to administer both drugs concomitantly, phenytoin levels should be monitored and the phenytoin dose adjusted to maintain therapeutic levels.<br><br>**Rifampicin** Concomitant administration of fluconazole and rifampicin resulted in a 25% decrease in the AUC and 20% shorter half-life of fluconazole. In patients receiving concomitant rifampicin, an increase in the fluconazole dose should be considered.<br><br>**Ciclosporin** A kinetic study in renal transplant patients found fluconazole 200 mg daily to slowly increase ciclosporin concentrations. However, in another multiple dose study with 100 mg daily, fluconazole did not affect ciclosporin levels in patients with bone marrow transplants. Ciclosporin plasma concentration monitoring in patients receiving fluconazole is recommended.<br><br>**Theophylline** In a placebo controlled interaction study, the administration of fluconazole 200 mg for 14 days resulted in an 18 % decrease in the mean plasma clearance of theophylline. Patients who are receiving high doses of theophylline or who are otherwise at increased risk for theophylline toxicity should be observed for signs of theophylline toxicity while receiving fluconazole, and the therapy modified if signs of toxicity develop.<br><br>**Cisapride** There have been reports of cardiac events including torsades de pointes in patients to whom fluconazole and cisapride |

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| | were co-administered. In most of these cases, the patients appear to have been predisposed to arrhythmias or had serious underlying illnesses, and the relationship of the reported events to a possible fluconazole-cisapride drug interaction is unclear. Because of the potential seriousness of such an interaction, co-administration of cisapride is contra-indicated in patients receiving fluconazole.<br><br>**Zidovudine** Two kinetic studies resulted in increased levels of zidovudine most likely caused by the decreased conversion of zidovudine to its major metabolite. One study determined zidovudine levels in AIDS or ARC patients before and following fluconazole 200 mg daily for 15 days. There was a significant increase in zidovudine AUC (20 %). A second randomised, two-period, two-treatment cross-over study examined zidovudine levels in HIV infected patients. On two occasions, 21 days apart, patients received zidovudine 200 mg every eight hours either with or without fluconazole 400 mg daily for seven days. The AUC of zidovudine significantly increased (74 %) during co-administration with fluconazole. Patients receiving this combination should be monitored for the development of zidovudine-related adverse reactions.<br><br>**Rifabutin** There have been reports that an interaction exists when fluconazole is administered with rifabutin, leading to increased serum levels of rifabutin. There have been reports of uveitis in patients to whom fluconazole and rifabutin were co-administered. Patients receiving the two concommitantly should be carefully monitored.<br><br>**Tacrolimus** There have been reports of an interaction when fluconazole is given concomitantly with tacrolimus, leading to increased serum levels of tacrolimus. There have been reports of nephrotoxicity in patients to whom fluconazole and tacrolimus were co-administered. Patients receiving the two concomitantly should be carefully monitored. |

**3. Records**

1. **Following to be noted in the computerised patient information record and on the CP 2 form:**
   Dose, frequency and the quantity supplied
   Date of supply to patient
2. **Storage**:
   Standards must be consistent with the Summary of Product Characteristics.

**4. Professional Responsibility - to be modified as appropriate to preparation**

- ❖ All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate. For those involved in immunization, regular anaphylaxis updates are mandatory.

- Nurses will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards of Administration for Nurses and other Health Professionals for their own professional Code of Ethics.

**Patient Group Direction For Provision and/or Administration of Fluconazole 150mg Caps**

**By Community Pharmacists operating a Minor Ailment Service on behalf of NHS Borders**

| This Patient Group Direction is Approved for use by the under-signed : | | | |
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| **Job Title** | **Name** | **Signed** | **Date** |
| **Senior Doctor/GP for relevant clinical area** | WR CAMERON | | 26/6/06 |
| **NHS Borders Chief Pharmacist** | D J D ARCHIBALD | | 27/6/06 |
| **NHS Borders Senior Nurse for relevant clinical area** | | | |

**PGD AUTHORISED ON** ..23../...6.../...6... **BY NHS BORDERS ADTC/ADTC CHAIR**

**Signed by ADTC CHAIRPERSON:** .....A.Riley.....

**Name:** .....DR A RILEY.....

**The Community Pharmacists signed below are authorised to provide and/or administer this medication under this Patient Group Direction and agree to provide and/or administer this medication in accordance with this Patient Group Direction**

| Name of Health Professional | Job Title | Signed | Date |
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