NHS Grampian

Patient Group Direction For The Supply Of PoM Fluconazole 150mg Capsules Under The Minor Ailment Service By Community Pharmacists Working Within NHS Grampian

Co-ordinators:	Consultation Group:	Approver:
PGD pharmacist	See relevant page in the PGD	Medicine Guidelines and Policies Group

Signature		Signature
		

Identifier:	Review Date:	Date Approved:
NHSG/PGD/MASF/MGP G333	April 2012	April 2010

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the Employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled When Printed

Version 2

Title: Patient Group Direction For The Supply Of PoM Fluconazole 150mg Capsules Under The Minor Ailment Service By Community Pharmacists Working Within NHS Grampian

Identifier: NHSG/PGD/MASF/MGPG333
Replaces: July 2006, Version 1

Across NHS Boards	Organisation Wide	Directorate	Clinical Service	Sub Department Area
	Yes			

Author: PGD pharmacist
Subject Patient Group Direction
Key word(s): PGD patient group direction MAS pharmacist fluconazole vaginal candidiasis thrush

Policy application: NHS Grampian

Purpose: This Patient Group Direction (PGD) authorises appropriately qualified Community Pharmacists to supply fluconazole to individuals without the requirement for a patient specific prescription written by a medical practitioner.

Responsibilities for implementation:

Organisational: Scottish Government Health Department
Corporate: NHS Grampian, Interim Director of Pharmacy and Medicines Management
Departmental: Pharmacy Medicines Unit
Operational Management Unit: Community Pharmacy Contractors

Policy statement: It is the responsibility of individual pharmacists and their managers (where applicable) to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that pharmacists using this PGD act within their own level of competence.

Review: This policy will be reviewed at least every two years or sooner if current treatment recommendations change.

This policy is also available in large print and on computer disk. Other formats and languages can be supplied on request.

Please call 01224 556088 or 556610 for a copy.

Responsible for review of this document:	Pharmacist Facilitator, Pharmacy Medicines Unit
Responsible for ensuring Registration of this document on the NHS Grampian Information/ Document Silo:	Medicine Management Pharmacist, Pharmacy Medicines Unit
Physical location of the original of this document:	Pharmacy Medicines Unit, Westholme, Woodend Hospital
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Revision History:

Date of change	Approval date of PGD that is being superseded	Summary of Changes	Section heading
Jan 2010	July 2008	2 yearly update into new template	
		Removal of terfenadine and cisapride	2.3 and 3.3
		Addition of ciclosporin, theophylline, rifampicin	3.3
		Removal of anaphylaxis advice	3.4
		Removal of necessity to have received anaphylaxis training	4
		Addition of “or exceptionally, CP1”	5.1

Contents

Part A – Specific Drug Information

Part B – PGD General Information

Part C – PGD Specific Information

Patient Group Direction For The Supply Of PoM Fluconazole 150mg Capsules Under The Minor Ailment Service By Community Pharmacists Working Within NHS Grampian

Part A

1. Introduction

This patient group direction (PGD) is designed to guide pharmacists on the supply of fluconazole under the Minor Ailment Service (MAS). This will allow pharmacists to dispense a PoM pack of fluconazole under PGD to treat vaginal candidiasis.

Candidiasis (thrush) 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. The condition develops when Candida albicans, which is often present in the vagina, causes itching, irritation, redness, soreness and swelling of the vagina and vulva and a thick, white vaginal discharge.

2. Clinical Decision Making

2.1 Patients who may be considered for the supply of fluconazole

Women with previous history of medically diagnosed vaginal candidiasis who are registered for MAS, presenting in community pharmacy with a need for treatment of symptoms of vaginal candidiasis.

2.2 Patients who may receive the administration of fluconazole

All patients in 2.1 above, who do not want specifically to consult with a doctor and are willing to receive treatment from the pharmacist.

Women must be between 16 and 60 years of age.

2.3 Contraindications

Patients may not receive a supply of fluconazole if they:

(i) are experiencing the symptoms for the first time.
(ii) have a history of liver or kidney disease.
(iii) are at risk of sexually transmitted infection (STI) or other cause for vaginal discharge.
(iv) are experiencing irregular or abnormal vaginal bleeding.

(v) are experiencing genital ulceration.
(vi) have a known hypersensitivity to fluconazole, related azole compounds or any of the components of the capsule.
(vii) are pregnant.
(viii) are breast-feeding.
(ix) are a known diabetic with recurring candidiasis.
(x) are presenting for a second request within one month.
(xi) are presenting with vaginal pain, bleeding or blistering.
(xii) are known to have had more than two infections of thrush within the last six months.
(xiii) are aged under 16 years of age or over 60 years of age.

2.4 Precautions

Fluconazole should be used with caution in patients with potentially pro-arrythmic conditions:

(i) Heart conditions such as cardiomyopathy, heart failure, bradycardia, arrythmias.
(ii) Concomitant medication not metabolized by CY34A but known to prolong QT-interval.
(iii) Electrolyte disturbances such as hypokalaemia, hypomagnesaemia and hypocalcaemia.

2.5 Action to be taken when a patient is excluded from treatment under this PGD

The patient should be referred to their doctor where they are excluded from treatment in 2.4.

2.6 Action to be taken when a patient does not wish to receive treatment under this PGD

The patient should be referred to their doctor.

2.7 Patient referral to General Practitioner

Urgent referral: Not applicable.

Routine referral:

(i) if symptoms not clearing within 3 days
(ii) pregnancy
(iii) breast-feeding
(iv) renal impairment
(v) known diabetic and recurring candidiasis
(vi) second request within one month
(vii) more than two infections of thrush within the last six months
(viii) vaginal pain, bleeding or blistering.

3. Description of Treatment Available Under This Direction

3.1 Fluconazole 150mg

Fluconazole 150mg capsule (non-proprietary) single-capsule PoM pack.

Description and excipients can vary with manufacturer.

Fluconazole is available as both a Pharmacy (P) only and a Prescription Only Medicine (PoM). This PGD relates only to the PoM medicine.

3.2 Dose, route and frequency

For the treatment of vaginal candidiasis – a single dose of 150mg by mouth. One capsule completes the course. Ideally the patient should be encouraged to take the capsule whilst still on the premises.

3.3 Concurrent medication

Drug interactions relate to the use of multiple-dose fluconazole, and the relevance to single-dose fluconazole 150mg has not yet been established and in most cases, they are unlikely to be significant. (Refer to the BNF and Summary of Product Characteristics for full information on drug interactions).

Interactions are possible with the following classes of drugs: Anticoagulants, Benzodiazepines (Short Acting), Sulphonylureas, Phenytoin, Ciclosporin, Theophylline, Rifabutin, Rifampicin, Tacrolimus, Zidovudine.

3.4 Adverse effects

Occasional: nausea, abdominal discomfort, diarrhoea, flatulence, headache, rash.

Rare: dyspepsia, vomiting, taste disturbance, hepatic disorders, hypersensitivity reactions, anaphylaxis, dizziness, seizures, alopecia, pruritus, toxic epidermal necrolysis, Stevens-Johnston syndrome, hyperlipidaemia, leucopenia, thrombocytopenia, hypokalaemia.

Also see current BNF and Summary of Product Characteristics.

In the event of a Suspected Adverse Drug Reaction, please complete a Yellowcard and submit to the MHRA or on the website at www.yellowcard.gov.uk . A Yellowcard can be found at the rear of the BNF. Record findings, advice and actions and inform the patient's general practitioner in order that the person's medical record can be updated in cases of anaphylaxis.

Treatment of overdose

Not applicable when only one capsule supplied.

Effects on ability to drive or operate machinery

Experience with fluconazole indicates that therapy is unlikely to impair a patient's ability to drive or use machinery.

3.5 Advice to patient

(i) Advice should be given on what to expect and what to do for major and minor reactions.
(ii) The patient information leaflet contained in the medicine(s) should be made accessible to the patient/parent/guardian. Where this is unavailable, or unsuitable, sufficient information should be given to the patient/parent/guardian in a language that they can understand.
(iii) Advise that treatment can be taken at any time of menstrual cycle, including during periods.
(iv) Discuss any possible side-effects with the patient.
(v) Advice regarding re-infection and that partner may need treatment if asymptomatic.
(vi) Advise to wash the vaginal area with water only, avoiding the use of perfumed soaps, vaginal deodorants and douches.
(vii) Advise avoiding using latex condoms, spermicidal creams and lubricants if they cause irritation.
(viii) Advise wearing cotton underwear and loose-fitting clothes if possible.

3.6 Follow up treatment

Not applicable.

Part B

4. Designated Staff Authorised To Administer Under This PGD

The following staff are authorised to administer the drug specified in this PGD without an individual medical prescription providing the patient falls into one of the categories listed in 2.2 of this PGD.

Community Pharmacists working in NHS Grampian and registered as Practising Pharmacists as recognised by the RPSGB or General Pharmaceutical Council are authorised to use the PGD for the supply of the drug specified in the PGD under the Minor Ailment Service.

In addition the following requirements are necessary. Staff must:

(i) agree to be professionally accountable for their work (Appendix 1).

(ii) be competent to assess the patient's capacity to understand the nature and purpose of the supply in order for the patient to give or refuse consent.

(iii) be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.

(iv) have the experience and competence considered necessary and relevant to the clinical condition and the drug covered by this PGD. All staff will have access to the current PGD.

(v) maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

(vi) agree to work within the terms of the NHS Grampian PGD.

The Director of Pharmacy and Medicines Management will be responsible for:

(i) Ensuring that the current PGD is available to staff providing care under this direction.

(ii) Ensuring that the staff have access to all relevant Scottish Government Health Directorate advice, including any relevant CMO letter.

(iii) Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

(iv) Maintaining a current record of all staff authorised to administer the drug specified in this PGD.

5. Documentation

5.1 Authorisation of supply

On reading this PGD and signing the Agreement to Supply (Appendix 1), community pharmacists working within NHS Grampian will be authorised to supply the drug specified in this PGD by the Director of Pharmacy and Medicines Management.

A Certificate of Authorisation (Appendix 2) signed by the Director of Pharmacy and Medicines Management will be supplied to each authorised pharmacist. This should be held in the individuals' records or as agreed locally.

5.2 Record of supply

The following information should be noted in the computerised patient information record and on the CP2 (or exceptionally, CP1) form:

(i) Dose, frequency and the quantity supplied.
(ii) Date of supply to patient.

These records should be retained:

For patients of 16 years of age, retain until the patient's 25th birthday.

For patients of 17 years of age retain until the patient's 26th birthday

For patients from 18 to 60 years of age retain for a minimum of 7 years after conclusion of treatment or for 3 years after death, or in accordance with local policy, where this is greater than above.

5.3 Consent

Prior to the administration of the drug, consent must be obtained, preferably written, either from the patient, parent, guardian or person with parental responsibility and documented either in the patient's medical records/notes or on an administration form. (See section 5.2).

The key points include:

(i) If a patient's fitness and suitability cannot be established, supply should be deferred.

(ii) There is no legal requirement for consent to be in writing but written consent serves to record the decision and the discussions that have taken place and that the patient or person with parental responsibility giving consent on a child's behalf has been informed about the process, benefits and risks of supply.

(iii) Consent - either written or verbal - is required at the time of each supply.

(iv) Consent remains valid unless the individual who gave it withdraws it. If there is new information between the time consent was given and when the supply is offered, including new evidence of risk, new medicines becoming available or where there is a significant change in the individual's condition, it may be necessary for the patient to re-confirm their consent.

(v) Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used in order that they can make informed consent.

(vi) Individuals (patient, parent, guardian or person with parental responsibility) should also be informed about how data on the administration will be stored, who will be able to access that information and how that data may be used.

(vii) Where consent is either refused or withdrawn, this decision must be documented.

(viii) Consent obtained before the occasion upon which a patient is brought for the supply is only an agreement for the patient to be included in the supply programme and does not mean that consent is in place for each future supply.

Consent for administration to adolescents under 16 years of age.

Patients under 16 years of age are not eligible for treatment under this PGD.

6. Further Points

The manufacturers' leaflet inside boxes of drug should be read and advice from them taken into consideration.

7. Facilities And Supplies To Be Available At Sites For The Administration Of The Drug

The following should be available at sites where the drug is to be administered:

(i) Clean and tidy work areas.
(ii) Cups and fresh drinking water.
(ii) Copies of the current PGD for the administration of the drug specified in the PGD.

8. Audit

All CP1 or CP2 prescriptions for the drug specified in the PGD will be forwarded to the prescription pricing department and be subject of payment verification and review.

Part C

9. Management And Monitoring Of Patient Group Direction

9.1 Consultative Group

Christine Bond	Consultant in Pharmaceutical Public Health
Karen Braithwaite	Community Pharmacist
David Hood	General Practitioner
Elizabeth Kemp	Development Pharmacist
Sam Melrose	Community Pharmacist
Wendy Robertson	Development Pharmacist
Pauline Strachan	Deputy Medical Director

9.2 Professional Advisory Group approving PGD

Medicine Guidelines and Policies Group.

9.3 Authorising Managers

Dr Roelf Dijkhuizen
Medical Director, NHS Grampian

Dr. Caroline Hind
Interim Director of Pharmacy and Medicines Management, NHS Grampian

10. References

1. Electronic Medicines Compendium http://www.medicines.org.uk

   Diflucan® 150 capsules - Date of revision of text November 2004, accessed 21.01.10

2. British National Formulary, 58 September 2009 –The Pharmaceutical Press. www.bnf.org

3. NHS Pharmaceutical Services Regulations SSI No 183 (2009)

Document:	Drafted:	July 2006
	Completed:	July 2006
	Reviewed:	July 2008, January 2010

Review date: At least every 2 years or sooner if current treatment recommendations change.

Appendix 1

Health Care Professional Agreement To Supply Medicines Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ Pharmacy name

As – please circle

- an employee Yes / No
- a locum Yes / No

Agree to supply medicines under the direction contained within the following Patient Group Direction.

Patient Group Direction For The Supply Of PoM Fluconazole 150mg Capsules Under The Minor Ailment Service By Community Pharmacists Working Within NHS Grampian

I have completed the appropriate training to my professional standards enabling me to supply medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: _____

Print Name: _____

Date: _____

RPSGB Registration No _____

Appendix 2

Certificate Of Authorisation To Supply Medicines Under Patient Group Direction

This authorises: _____ (Insert name)

Working within: _____ Pharmacy name

To supply medicines under the following Patient Group Direction.

Patient Group Direction For The Supply Of PoM Fluconazole 150mg Capsules Under The Minor Ailment Service By Community Pharmacists Working Within NHS Grampian

The above named person has satisfied the training requirements and is authorised to supply medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: _____

Caroline Hind - Interim Director of Pharmacy and Medicines Management

Date: _____