

PATIENT GROUP DIRECTION
FOR THE SUPPLY OF FLUCONAZOLE 150MG CAPSULES TO WOMEN
BETWEEN 16 TO 60 YEARS OF AGE BY COMMUNITY PHARMACISTS UNDER
THE MINOR AILMENTS SERVICE IN NHS HIGHLAND

THE COMMUNITY PHARMACIST SEEKING TO SUPPLY FLUCONAZOLE 150MG CAPSULES MUST ENSURE THAT ALL PATIENTS HAVE BEEN SCREENED AND MEET THE CRITERIA BEFORE SUPPLY TAKES PLACE

NHS Highland has authorised this patient group direction to help patients by providing them with more convenient access to an efficient and clearly defined service within NHS Highland.
It cannot be used until Appendix 1 & 2 is completed.

Warning- Document uncontrolled when printed
--

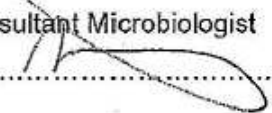

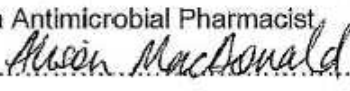
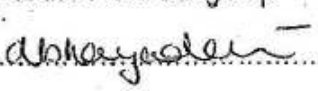
Further information on the use of Patient Group Directions in NHS Highland and the PGD procedure can be obtained from

<http://intranet.nhsh.scot.nhs.uk/Organisation/ADTC/PGDSG>

Warning- document uncontrolled when printed	
Lead reviewer: Andrew Green	Ratified by: PGD Subgroup of the ADTC
PGD number: 05_10_v6	Date direction comes into effect on: 11/12/2015
Page 1 of 9	Date direction is not valid after: 10/12/2018

PATIENT GROUP DIRECTION FOR THE SUPPLY
OF FLUCONAZOLE 150MG CAPSULES

Management and monitoring of patient group direction

Prepared by:	
Medical Practitioner	Name: Dr Adam Brown Title: Consultant Microbiologist Signature: 
Senior representative of the professional group who will provide care under the direction.	Name: Andrew Green Title: Area Regulations, Contracts & Controlled Drugs Governance Pharmacist Contact details: Pharmacy Services, NHS Highland, John Dewar Building, Inverness, IV2 7GE. Telephone: (01463) 706886 Fax: (01463) 713844 Signature: 
Pharmacist	Name: Alison MacDonald Title: Area Antimicrobial Pharmacist Signature: 
Authorised by:	
Patient Group Direction Sub-group Chair or Secretary	Name: Abhayadevi Tissington Title: Chair of the PGD Subgroup Signature: 
Date of ratification of the direction on behalf of the Area Drug & Therapeutics Committee	Date 11 th December 2015
Review Date	Three years from final ratification and every two years thereafter. Or when there is a change in clinical practice, evidence or the Summary of Product Characteristics for any of the medicines included is updated, whichever is first.

Warning- document uncontrolled when printed	
Lead reviewer: Andrew Green	Ratified by: PGD Subgroup of the ADTC
PGD number: 05_10_v6	Date direction comes into effect on: 11/12/2015
Page 2 of 9	Date direction is not valid after: 10/12/2018

Clinical indication to which this patient group direction applies

Definition of situation/condition	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).
Clinical criteria for inclusion	<p>Candidiasis is a yeast infection caused by the <i>Candida</i> species of fungus, usually <i>Candida albicans</i>. Many women are affected by vaginal thrush at some point in their lives and in some women it may recur regularly.</p> <p>The condition develops when <i>Candida albicans</i>, which is often present in the vagina, causes itching, irritation, discharge, redness, soreness and swelling of the vagina and vulva and a thick, white curd-like, non-offensive vaginal discharge.</p> <p>Use of fluconazole is an alternative to the first line treatment of clotrimazole 500mg pessary or clotrimazole 10% vaginal cream.</p>
Clinical criteria for exclusion	<ul style="list-style-type: none"> • Under 16 and over 60 years of age • Women who are experiencing the symptoms for the first time • Liver and kidney disease • Risk of sexually transmitted infection (STI) or other cause for vaginal discharge. • Irregular or abnormal vaginal bleeding • Genital ulceration • Known hypersensitivity to fluconazole • More than two infections of thrush within the last six months • Individuals with acute porphyria • Past or current history of cardiac rhythm disturbance • Interacting medicines: see Appendix 1 of current BNF
Criteria for seeking further clarification from doctor	<p>Urgent referral : Not applicable</p> <p>Routine referral :</p> <ul style="list-style-type: none"> • If symptoms not clearing within 3 days • Pregnant • Breast feeding • Renal impairment • Known diabetic and recurring Candidiasis • Second request within one month • Vaginal pain, bleeding or blistering <p>Patients who fall into the categories detailed in the exclusion criteria. Healthcare professionals should not supply/administer if they feel that it is inappropriate for the patient.</p>
Action if patient excluded from treatment	<p>Refer patient to general practitioner.</p> <p>The reason why the patient was excluded under the PGD will be documented in the patient's medication record (PMR).</p>
Action if patient declines treatment	<p>Refer patient to general practitioner.</p> <p>The reason why the patient refused treatment under the PGD will be documented in the patient's medication record (PMR).</p>

Warning- document uncontrolled when printed

Lead reviewer: Andrew Green	Ratified by: PGD Subgroup of the ADTC
PGD number: 05_10_v6	Date direction comes into effect on: 11/12/2015
Page 3 of 9	Date direction is not valid after: 10/12/2018

Characteristics of staff authorised to take responsibility for the supply or administration of medicines under the patient group direction

Qualifications required	Pharmacist registered with the General Pharmaceutical Council
Initial training	<p>Received and understood training to undertake the supply of medicines under a PGD and must be familiar with the content of the PGD Powerpoint presentation.</p> <p>Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD.</p> <p>Familiar with the Female Vaginal Discharge Pathway NHS Highland Shared Clinical Guidelines in the References</p>
Competency assessment	Not applicable
Ongoing training and competency	<ul style="list-style-type: none"> • Maintenance of own level of updating with evidence of continued professional development • Individual requirements identified through Personal Development Plan & Review • Familiar with the Female Vaginal Discharge Pathway NHS Highland Shared Clinical Guidelines in the References

Warning- document uncontrolled when printed	
Lead reviewer: Andrew Green	Ratified by: PGD Subgroup of the ADTC
PGD number: 05_10_v6	Date direction comes into effect on: 11/12/2015
Page 4 of 9	Date direction is not valid after: 10/12/2018

Description of treatment available under the patient group direction

Name, form & strength of medicine	Fluconazole Capsule 150mg - One capsule
Legal status	POM
Indicate any off-label use (if relevant)	None
Route/Method of Administration	Oral
Frequency of dose/ duration of treatment	Vaginal candidiasis – a single dose of 150mg by mouth
Quantity to be administered and/or supplied	One capsule
Maximum or minimum treatment period	Single dose
Advice to be given to the patient before treatment	<ul style="list-style-type: none"> • Offer clotrimazole pessary and cream as a first line treatment alternative. • Provide Patient Information Leaflet. • Treat at any time of menstrual cycle, including during periods. • Discuss any possible side effects with the patient. • Advise regarding re-infection and that partner may need treatment if symptomatic. • Good hygiene. • Avoid the use of perfumed soaps, vaginal deodorants or douches. • Recommend use of vulval moisturisers, such as Diprobase or feminine hygiene products which are non-perfumed & non-soap in place of soap or shower gel. • Avoiding using latex condoms, spermicidal creams and lubricants if they cause irritation. • Wearing cotton underwear and loose-fitting clothes if possible.
Written information to be given to the patient or carer	Patient information leaflet
Follow-up advice to be given to patient or carer	None
Identifying and managing possible adverse reactions	<p>Occasional : nausea, abdominal discomfort, diarrhoea, flatulence, headache, rash</p> <p>Rare: dyspepsia, vomiting, taste disturbance, hepatic disorders, hypersensitivity reactions, anaphylaxis, dizziness, seizures, alopecia, pruritus, toxic epidermal necrolysis, Stevens-Johnson syndrome, hyperlipidaemia, leucopenia, thrombocytopenia, hypokalaemia</p> <p>Also see BNF</p> <p>If an adverse reaction does occur give immediate treatment. The pharmacist should contact the GP to notify of any adverse drug reactions as soon as possible.</p> <p>Report the reaction to the MHRA using the Yellow Card System.</p> <p>https://yellowcard.mhra.gov.uk/</p>
Referral for medical advice	Appearance or suspicion of an adverse reaction, as above.

Warning- document uncontrolled when printed

Lead reviewer: Andrew Green	Ratified by: PGD Subgroup of the ADTC
PGD number: 05_10_v6	Date direction comes into effect on: 11/12/2015
Page 5 of 9	Date direction is not valid after: 10/12/2018

Facilities and supplies required	None
Special considerations/additional information	Access to current BNF
Details of records required	<p>Following to be noted in the computerised patient information records and on the CP 2 form :</p> <ul style="list-style-type: none"> • Dose, frequency and the quantity supplied • Date of supply to patient •
References	<p>BNF No. 70 Available at: https://www.medicinescomplete.com/mc/bnf/current/ Accessed on : 10th November 2015</p> <p>SPC Available at: http://www.medicines.org.uk/emc Accessed on: 10th November 2015</p> <p>Management and laboratory diagnosis of Abnormal Vaginal Discharge Quick Reference Guide for Primary Care PHE/BIA Primary Care Guidance September 2014, next Review July 2015 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/345793/Vaginal_Discharge_treatment_guidance.pdf</p> <p>http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/PrimaryCareGuidance/#VagDischarge</p> <p>Female Vaginal Discharge Pathway NHS Highland Shared Clinical Guidelines June 2013, next Review June 2014 http://guidelines.nhshighland.scot.nhs.uk/SexHlth/FVD/vagdis.htm</p>

Warning- document uncontrolled when printed	
Lead reviewer: Andrew Green	Ratified by: PGD Subgroup of the ADTC
PGD number: 05_10_v6	Date direction comes into effect on: 11/12/2015
Page 6 of 9	Date direction is not valid after: 10/12/2018

Appendix 1

Health professionals approved to provide care under the direction.

To be retained in the community pharmacy as a record of those pharmacists who have signed the PGD.

An Individual Authorisation form (Appendix 2) should be completed and returned to the Pharmacy Services Office

The lead nurse/professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.					
The manager who approves a healthcare professional to supply and/or administer medicines under the patient group direction, is responsible for ensuring that he or she is competent, qualified and trained to do so and for maintaining an up-to-date record of such approved persons in conjunction with the Head of Profession.					
The healthcare professional who is approved to supply and/or administer medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration or supply is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.					
PATIENT GROUP DIRECTION FOR THE SUPPLY OF FLUCONAZOLE 150MG CAPSULES TO WOMEN BETWEEN 16-60 YEARS OF AGE BY COMMUNITY PHARMACISTS UNDER THE MINOR AILMENTS SERVICE IN NHS HIGHLAND					
Local clinical area(s) where these healthcare professionals will operate this PGD:					
Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Warning- document uncontrolled when printed	
Lead reviewer: Andrew Green	Ratified by: PGD Subgroup of the ADTC
PGD number: 05_10_v6	Date direction comes into effect on: 11/12/2015
Page 7 of 9	Date direction is not valid after: 10/12/2018

Appendix 2

PATIENT GROUP DIRECTION

FOR THE SUPPLY OF FLUCONAZOLE 150MG CAPSULES TO WOMEN BETWEEN 16 TO 60 YEARS OF AGE BY COMMUNITY PHARMACISTS UNDER THE MINOR AILMENTS SERVICE IN NHS HIGHLAND

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

The **healthcare professional** who is approved to supply medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that the supply is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.

Note to Authorising Authority: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to provide the fluconazole 150mg capsules in accordance with this PGD.

Name of Pharmacist _____

GPhC Registration Number _____

Normal Pharmacy Location
(if pharmacy locum please
provide contact details) _____

Signature _____ Date _____

Admin Assistant
Pharmacy Services Office
John Dewar Building,
Inverness Retail & Business Park
INVERNESS. IV2 7GE

Signed copy to be returned to _____

FAX:
01463 713844

Warning- document uncontrolled when printed	
Lead reviewer: Andrew Green	Ratified by: PGD Subgroup of the ADTC
PGD number: 05_10_v6	Date direction comes into effect on: 11/12/2015
Page 9 of 9	Date direction is not valid after: 10/12/2018