

PATIENT GROUP DIRECTION
FOR THE SUPPLY OF CLOTRIMAZOLE PESSARIES AND CREAM FOR THE TREATMENT OF VULVO-VAGINAL CANDIDIASIS AND CANDIDAL BALANOPOSTHITIS by registered nurses and midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:

Position of Signatory	Name	Signed	Date
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply clotrimazole and fluconazole 5mg to patients in the Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from: 1st October 2017
Review date: Aug 2019. Expires on 31st Oct 2019

Replaces PGD2916

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply clotrimazole as specified under this Patient Group direction following demonstration of the competencies below:

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Hold a recognised qualification in sexual health skills (ENB 267/BASHH competencies or equivalent post registration qualification/ in- house training/competencies in STIs)
3. An introduction to sexual health is not sufficient
4. Has been assessed as competent to provide care and treatment of genital infections
5. Has been assessed and achieved the required standard in sexual health
6. Is competent in the assessment of individuals using Fraser guidelines
7. Has undergone regular training and updating in safeguarding children and vulnerable adults
8. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
9. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
10. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
11. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines
All registered nurses details and signature must be entered onto the PGD
12. Following administration a record of the date, strength, brand and dose of the medication should be recorded in the clients records and documented in the medicine card with PGD number recorded as authorisation

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (<http://emc.medicines.org.uk>)

Supply/Administration of	<ul style="list-style-type: none"> • Clotrimazole 10% w/w vaginal cream 5g in single dose pre-filled applicator • Clotrimazole 200mg and 500mg pessaries • Clotrimazole 1% cream
Legal Classification	Prescription Only Medicine or Pharmacy Medicine
Black Triangle?	No
Type	Topical cream or vaginal pessary
Storage	Supplies will be available from central stock location, pre-labelled with the correct dose and quantity by the pharmacy department. Details of service user name and date of issue must be completed on the label prior to supplying to the patient. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	Vulvo-vaginal candidiasis Candidal balanoposthitis
Inclusion Criteria	<ul style="list-style-type: none"> • Any individual with a confirmed diagnosis of vulvo-vaginal candidiasis • An individual with symptoms of vulvo-vaginal candidiasis and candida balanoposthitis confirmed on examination: vulvo-vaginal itching, erythema, fissures, abnormal thick, lumpy, "cottage cheese" vaginal discharge
Exclusion Criteria	<p>Personal characteristics</p> <ul style="list-style-type: none"> • Individuals under 13 years of age • Under 16 years of age and not assessed as competent, using Fraser Guidelines • Adult dosages do not apply to children under 12 years of age and are therefore excluded • Individuals who are pre-pubertal • Individuals who are hypersensitive to Clotrimazole, any other imidazole antifungals, or any constituent of the preparation • Four (4) or more treated episodes of candidiasis in past 12 months • Individuals with genital sores / ulcers suggestive of other infections • Individuals with symptoms of pelvic pain • Recurrent or unresolved symptoms of candidiasis within 4 weeks of being treated • Treatment failure within the same period

	<p><u>Cautions:</u></p> <ul style="list-style-type: none"> • Choice of therapy: The treatments in this PGD are written according to national guidance; however you should also refer to your local formulary or other local supporting guidance for selection of the most appropriate preparation or regime for the individual. • Offer a full sexually transmitted infection (STI) screen • If systemic treatment is needed for candidiasis, see Fluconazole PGD • Consider referral if two or more treated episodes of candidiasis in past 6 months
Action if excluded or patient declines	<ul style="list-style-type: none"> • Refer to appropriate doctor /independent nurse prescriber • Refer to appropriate doctor/independent nurse prescriber any condition/medicine of which the nurse is unsure/uncertain • Make individual aware of the benefits of treatment • Record the refusal in the clinical record • Refer to appropriate doctor / independent nurse prescriber
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> • Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Insert into the vagina (pessaries) or apply to anogenital area (cream)
Dose	<p>Clotrimazole 10% w/w vaginal cream 5g in single dose pre-filled applicator</p> <p>or</p> <p>Clotrimazole 200mg pessary</p> <p>or</p> <p>Clotrimazole 500mg pessary</p> <p>Clotrimazole 1% cream may be supplied:</p> <ul style="list-style-type: none"> • Alone for the treatment of candidiasis of the vulva or balanoposthitis • In addition to one of the vaginal treatments (above) or with oral Fluconazole (see separate PGD), in order to provide symptomatic relief

<p>Administration Schedule</p>	<p>Clotrimazole cream 10% w/w</p> <ul style="list-style-type: none"> • Insert the cream into the vagina using the pre-filled applicator • Single dose treatment <p>Clotrimazole 200mg pessary</p> <ul style="list-style-type: none"> • Insert one pessary into the vagina once a day for three days <p>Clotrimazole pessary 500mg</p> <ul style="list-style-type: none"> • Insert the pessary into the vagina • Single dose treatment <p>Select regimen according to local protocol</p> <p>Clotrimazole Cream 1% Apply to the anogenital area two or three times a day until symptoms have resolved.</p> <p><u>Quantity to be Supplied:</u></p> <ul style="list-style-type: none"> • Clotrimazole 10% w/w Cream: Single 5g pre-filled applicator • Clotrimazole 200mg Pessary: One pack of 3 pessaries • Clotrimazole 500mg Pessary: Single pessary • Clotrimazole 1% cream: One tube of 20g
<p>Warnings/Adverse Reactions</p>	<p>Most common side effects include localised skin rash, redness, pruritus, irritation or swelling</p> <p>Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information.</p> <p>In the event of untoward or unexpected adverse reactions:</p> <ul style="list-style-type: none"> • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) <p>Use the yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of</p>

	the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk .
Advice/Management of Adverse Reactions & Follow-up Action	<p>Medicine</p> <ul style="list-style-type: none"> • Provide Manufacturer's Patient Information Leaflet (PIL) • Provide verbal and written information on candidiasis • May cause damage to latex condoms or diaphragms • Individual should be advised to use alternative contraceptive precautions for at least five days after using the cream <p>Condition</p> <ul style="list-style-type: none"> • If symptoms persist/worsen advise individual to contact clinic • Give general advice including information about possible triggers for candidiasis • Suggest use of aqueous cream/emulsifying ointment as a soap substitute • Consider suggesting use / offering supply of Clotrimazole 1% cream, according to local protocol • Give reassurance that it is not a sexually transmitted infection • No screening or treatment of male partners is required <p><u>Follow Up:</u></p> <ul style="list-style-type: none"> • No routine follow-up is required if symptoms resolve
Use in pregnancy and lactation	Appropriate
Records	<p>The nurse must ensure the following is documented in the clinical record:</p> <ul style="list-style-type: none"> • Individual's name, address and date of birth • Attendance date • Reason for attendance • Past and present medical history, including any drug history • Family history • Any known allergy • Any advice given about the medication including side effects, benefits, how to use it and when and what to do if any concerns • Details of any adverse drug reactions and what

	<p>action taken</p> <ul style="list-style-type: none">• Any referral arrangements• Any supply outside the terms of the product licence• The consent of the individual• If individual is under 16 years of age document competency using Fraser guidelines• Record the name of the medication, quantity supplied with batch numbers and expiry dates according to local policy, and PGD number recorded• Record any follow up arrangements• Include the signature and designation of the nurse who supplied the medication (follow local procedures for computer records)
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