South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THESUPPLY OF METRONIDAZOLE 400mg TABLETSFOR THE TREATMENT OF BACTERIAL VAGINOSIS (BV) OR *TRICHOMONAS VAGINALIS* (TV)

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 metronidazole 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 PGD 3016

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply metronidazole 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. Qualifications in sexual health (university modules/BASHH/in house equivalent). Note: an introduction to sexual health is not sufficient
3. Is competent in the assessment of individuals using Fraser guidelines
4. Has undergone regular training and updating in safeguarding children and vulnerable adults
5. The nurse should be familiar with current BASHH guidelines on BV and TV
6. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
7. 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
8. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
9. 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
10. 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	Metronidazole 400 mg tablets
Legal Classification	Prescription Only Medicine
Black Triangle?	No
Type	Tablets
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	• Bacterial vaginosis (BV) • *Trichomonas vaginalis* (TV)
Inclusion Criteria	• Any symptomatic individual diagnosed under microscopy or a confirmed result with BV or TV TV • Sexual contacts of individuals diagnosed with TV
Exclusion Criteria	**Personal Characteristics** • Individuals under 13 years of age • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines • Individuals 16 years of age and over and assessed as not competent to consent using local safeguarding guidelines • Known allergy/hypersensitivity to metronidazole or tinidazole or any of the constituents found within the medication • Pelvic pain/suspected pelvic inflammatory disease (PID) • Known moderate to severe hepatic impairment • Porphyria • Alcohol dependence **Medical history** • Recurrent or unresolved symptoms of BV within 4 weeks of being treated • Four or more treated episodes of BV in past 12 months • Two or more documented episodes of grade 3 flora on microscopy within the preceding 3

	months • Treatment and failure within the same episode • Itching and soreness indicating inflammation suggest the possibility of other conditions **Medication history** Individual is taking interacting medicines. Check appendix 1 of current edition of British National Formulary (BNF) for full list.
Action if excluded or patient declines	• Offer full sexually transmitted infection (STI) screen if not already done • For contacts of TV, do not wait for test results to treat. • Refer to appropriate doctor/independent nurse prescriber <u>If patient declines:</u> Document refusal in clinical record **Bacterial vaginosis** • Make individual aware of the benefits of treatment • Refer to appropriate doctor/independent prescriber • Asymptomatic women who decline treatment do not require further input from nurse prescriber/doctor ***Trichomonas vaginalis*** • Make individual aware of the need for treatment as TV is a sexually transmitted infection • Refer to appropriate doctor/independent nurse prescriber
Reasons for seeking further advice from doctor	• 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	Oral
Dose	400mg
Administration Schedule	Metronidazole 400mg twice a day, orally for seven days

	<u>Quantity to Supply:</u> Seven day course 400mg x 14 tablets
Warnings/Adverse Reactions	This list may not represent all reported side effects of this medicine. Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. Common side effects include: • Nausea, vomiting and gastrointestinal disturbance • An unpleasant taste in the mouth may occur which will continue throughout the duration of treatment but will resolve once treatment finishes In the event of untoward or unexpected adverse reactions: • 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) • Use 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 the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Advice/Management of Adverse Reactions & Follow-up Action	**Medicine** • Provide Manufacturer's Patient Information Leaflet (PIL) and discuss • Explain mode of action, side effects, and benefits of the medicine • Provide verbal and written information on BV or

	TV • Advise that no alcohol should be taken for the duration of the treatment and for 48 hours afterwards • Advise to swallow the tablets whole with plenty of water • Take with food • If adverse reaction to treatment occurs advise individual to contact clinic for further advice • Women who are breast feeding should be advised that metronidazole can cause breast milk to have a bitter taste which may cause some difficulties with feeding **Condition** **Bacterial vaginosis** • If symptoms persist/worsen advise individual to contact clinic • Use of aqueous cream/emulsifying ointment as a soap substitute • BV is not an STI • No screening or treatment of male partners is required • Give general advice including information about possible triggers for BV • Avoid local excessive washing, bubble baths, soaps, douching • Use condoms because the alkalinity of semen causes bacteria in the vagina to release amines ***Trichomonas vaginalis*** • TV is an STI • Screening and treatment of male partners is required • Abstain completely from sexual intercourse (even with condom) including oral sex, for 7 days after treatment and for 7 days after partner's treated, and follow up is complete • Warn of risk of re-infection and further transmission of infection, if sexual intercourse takes place within 7 days of treatment or with an untreated partner Discuss implications of incomplete treatment <u>Follow Up:</u> **Bacterial vaginosis**

	• No follow-up is required if symptoms resolve ***Trichomonas vaginalis*** • Compliance review is recommended • Test of cure according to local policy
Use in pregnancy and lactation	Appropriate as per BASHH guidelines: http://www.bashh.org/documents/4413.pdf
Records	The authorised registered nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history • Any known allergy • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply or administration is by using a PGD and record the PGD number • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the terms of the product licence • The consent of the individual • If individual is under 13 years of age record action taken. • If individual is under 16 years of age document competency using Fraser guidelines • If individual is 16 years of age and over and assessed as not competent, record action taken • Record the name/brand, dose of the medication and quantity supplied • Record batch number and expiry date according to local policy or national guidelines • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the nurse supplying the

	medicine