

| Patient Group Direction for the supply of : oral metronidazole 400mg twice daily for 7 days or oral metronidazole 2 gram stat for the treatment of bacterial vaginosis or trichomonas vaginalis | |
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| Title of patient group direction | Patient Group Direction for the supply of oral metronidazole 400mg twice daily for 7 days or oral metronidazole 2 gram stat for the treatment of bacterial vaginosis or trichomonas vaginalis |
| Approved at | NMP/PGD Group |
| PGD approved / valid from | September 2018 |
| Review date | June 2021 |
| Expiry date | September 2021 |
| Clinical area(s) where PGD applies | York and North Yorkshire Sexual Health services |
| Identified Lead for monitoring / review and contact details | Alison Chorlton Ext: 5465 |
| CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD) | |
| New Document | No |
| Reviewed Document | Yes |
| If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation | Current PGD due for renewal June 2018 |
| List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed). | Dr Ian Fairley Consultant Yorsexualhealth Alison Chorlton Lead Nurse Elizabeth Clarke Advanced Nurse Specialist |

| CLINICAL CONDITION | |
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| Condition | <p>First line treatment for bacterial vaginosis (BV) in adult females presenting with symptoms</p> <p>First line treatment for uncomplicated trichomonas vaginalis (TV) in adult females or their sexual contacts</p> |
| Inclusion criteria | <p>BV diagnosed by:</p> <p>The Hay/Ison criteria- Gram stained vaginal smear where gardnerella and/or mobiluncus morphotypes predominate with few or absent lactobacilli or High vaginal swab for BV positive</p> <p>TV diagnosed by:</p> <ul style="list-style-type: none"> • Direct microscopic visualization on the wet smear of the protozoan trichomonas vaginalis • Trichomonas vaginalis recorded on cervical cytology reports • Epidemiological treatment of known/suspected contacts • High vaginal swab for TV positive <p>The above criteria reflect the national recommendations made by the British Association for Sexual Health and HIV www.bashh.org.uk</p> |
| Exclusion criteria | <ul style="list-style-type: none"> • Patients/client who themselves directly present with the complicated signs and symptoms suggestive of pelvic inflammatory disease (PID) • Allergy or hypersensitivity to metronidazole or tinidazole or any constituents found within the medication • Interacting medicines (see appendix 1 BNF) • Patients/Client has already taken metronidazole but it was not effective/tolerated • Known history of alcoholism or inability to avoid alcohol |

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| | <ul style="list-style-type: none"> • Known hepatic disease (formal diagnosis or abnormal blood results) • Patients who are currently at risk of pregnancy or pregnant should not be treated with high dose metronidazole (2 Gram orally stat-see BNF) • Patients aged 12 and under • Patients aged 13-15 who are not Gillick/Fraser competent |
| Action if excluded | <ul style="list-style-type: none"> • Refer to medical practitioner/non-medical prescriber that clinical session or when next available in clinic, • As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner. • Alternatively arrange immediate assessment in Emergency Department if patient presents with an acute presentation and no doctor is available that clinical session. |
| Action for patients not wishing to receive care under the PGD | <ul style="list-style-type: none"> • Refer to medical practitioner/non-medical prescriber that clinical session or when next available in clinic. • As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner first, and defer treatment until after this discussion. |

| DESCRIPTION OF TREATMENT | | | |
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| Name of Medicine | Metronidazole | | |
| Legal Classification | Prescription only medicine (POM) | | |
| Licensing information | Is the medicine licensed for the intended use? | YES | |
| | Does it have a black triangle status? | | NO |
| | Does it have a Risk Minimisation Measures (RMM) recommendation | | NO |
| Form | Tablet | | |
| Strength | 400mg | | |
| Dose and Frequency | 400mg twice daily 12 hours apart for 7 days Or 2 Gram stat (5 tablets). | | |
| Route | Oral | | |
| Total Treatment Quantity | Total of 21 (twenty one) 400mg tablets with product/patient information leaflet supplied but only 14(fourteen)tablets required to be taken or 2 Gram stat | | |
| Interactions with other medicines (This must include all potentially serious interactions listed in the BNF) | <p>Use appendix 1 of the BNF and manufacturers SPC to identify drugs with clinically significant interactions with metronidazole</p> <ul style="list-style-type: none"> • Coumarins e.g warfarin • Psychotic reactions have been reported in patients who were using metronidazole and disulfiram concurrently. • Busulfan, capecitabine, fluorouracil- metronidazole increases the risk of toxicity • Avoid taking antacids within 2 hours of taking metronidazole <p>If in doubt, contact Medicines Information for advice</p> | | |

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| <p>Adverse Reactions (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)</p> | <ul style="list-style-type: none"> • Advise AVOID ALCOHOL consumption at same time as metronidazole, or adverse reaction (severe vomiting) may occur • Sudden breathlessness, wheezing, swelling, rash or itching • Nausea, dyspepsia, • abdominal discomfort, diarrhoea | <p>Treatment of adverse reactions</p> <p>SEEK URGENT MEDICAL ADVICE</p> <p>SEEK URGENT MEDICAL ADVICE</p> <ul style="list-style-type: none"> • Advise take tablets after food, with plenty of fluid, while sitting or standing • Discontinue drug if gastrointestinal side effects are severe and return for assessment in Sexual Health Clinic, NHS walk-in, GP or Emergency Department depending upon severity |
| <p>Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)</p> | <ul style="list-style-type: none"> • Information regarding aetiology of bacterial vaginosis/ trichomonas vaginalis • Information regarding treatment concordance and side effects; supported by patient information leaflet (PIL) • Swallow tablets whole with plenty of fluids after a meal emphasizing risk of possible GI disturbance • Avoid alcohol whilst taking metronidazole and for 48 hours after treatment is completed | |

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| | <ul style="list-style-type: none"> • Avoid using antacids within 2 hours of taking metronidazole • Take at regular intervals and complete the full prescribed course • For trichomonas vaginalis only, advice regarding avoiding any form of sexual contact until self and partner/s is also fully treated, to avoid risk of reinfection. Abstinence needs to extend until 7 days after both self and sexual partner/s are fully treated • 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 |
| Follow up action | <ul style="list-style-type: none"> • Return if Trichomonas Vaginalis symptoms persist. For a test of cure, for retreatment if non-concordance with treatment ,or a risk of re-infection • See GP if bacterial vaginosis symptoms persist |
| Storage | <ul style="list-style-type: none"> • Locked medicines cupboard – store below 25 °C • Locked briefcase for outreach use |
| Records to be Kept | <p>The following minimum details need to be documented in full in patient's records in relation to initiating treatment under PGD</p> <ul style="list-style-type: none"> • Date/time of record entry • Drug name and strength • Dose and form • Route of administration • Time of administration if appropriate • Advice given to patients, including written information. • name/job title of staff administering/supplying medicine(and signature if written records) • Details of any adverse drug reactions or side effects • Details of any problems reported with compliance and action advised/taken |

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| | <ul style="list-style-type: none"> • Consent to treatment under PGD • That treatment was supplied under a PGD • Any communication with other health care providers • If the patient is pregnant her treatment must be documented in her maternity (green) notes or her GP written to. |
| Audit Arrangements | As per current Trust PGD Policy |
| References | <p>UK National guideline for the management of bacterial vaginosis in adults, 2012, British Association for Sexual Health and HIV, www.bashh.org</p> <p>United Kingdom National guideline on the management of Trichomonas vaginalis 2014, British Association for Sexual Health and HIV, www.bashh.org</p> <p>Nursing and Midwifery Council, The Code for nurses and midwives. March 2015 www.nmc.org.uk (refers to record keeping)</p> <p>✱ Nursing and Midwifery Council, Standards for Medicines Management, 2007, minor updates 2015 www.nmc.org.uk <i>Remove no longer relevant.</i></p> <p>The British National Formulary, www.bnf.org.uk</p> |
| Competency Requirements (attach any competency frameworks / documents) | <p>Completion of a local sexual health training programme for the administration of Metronidazole under PGD within sexual health services. This will require/include:</p> <ul style="list-style-type: none"> • Clinical competence in sexual history taking • Clinical competence in sexual history taking, the clinical examination/assessment and genital screening required to enable the accurate diagnosis and treatment of bacterial vaginosis/trichomoniasis vaginalis. • Knowledge base of the interactions of metronidazole with other drugs, and other exclusions and contra-indications for issuing metronidazole. • Competence in the above will be demonstrated by |

the undertaking of a local clinical competency based training and assessment programme.

- Assessment will be undertaken by the Lead Sexual Health nurse or designated PGD assessor, who will both be fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD.
- Receiving clinical supervision and/or audit of case notes on an ongoing basis
- Evidence of continuing professional development in Sexual Health and/or the Sexual Health nurse role.
- Minimum of 6 months experience of working in Sexual Health in the preceding 3 years.
- Competence in the use of PGDS.
- Trust PGD awareness session or Trust HUB e-learning.
- Regular attendance and participation in the Tri annual educational clinical governance/audit half day at York Sexual Health Services

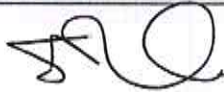

Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development.

**AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION
OF: Oral Metronidazole 400mg**

PGD Development / Review Team – responsible for PGD content

| Title | Name | Signature | Date |
|------------------------------------|----------------|--|----------|
| Lead Author | Nisha Chorlton |  | 10.7.18. |
| Clinical Director Lead Approval | Ian Fairley |  | 1/8/18. |
| Directorate Pharmacy Lead Approval | Paul Jackson |  | 21/8/18 |

PGD Approved by the NMP/PGD Group

| Title | Name | Signature | Date |
|--|---------------|--|-----------|
| NMP Lead / Lead Nurse Medicines Management | Jennie Booth |  | 24.8.2018 |
| Chief Pharmacist / Deputy Chief Pharmacist | Stuart Parkes |  | 28/8/18 |

Authorisation to work within the PGD

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

Notes to the NMP/PGD Authorising staff

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

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When the review date is exceeded, this PGD ceases to be a legal document

TEMPLATE DOCUMENTATION CONTROL

The template documentation control refers to the PGD template not the completed PGD.
Do not alter this section.

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| Author: | Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist |
| Owner: | NMP/PGD Group |
| Date of issue: | December 2017 |
| Version: | 2 |
| Approved by | NMP/PGD Group |
| Review date: | December 2020 |

