

This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Metronidazole 0.75% vaginal gel (40g)

By registered health care professionals for

Bacterial vaginosis

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 48

1. Change history

| Version number | Change details | Date |
|----------------|-----------------------|-----------|
| 1 | Original PGD ratified | June 2021 |
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2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS & Manx Care [PGD website FAQs](#)

3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

| Job Title & organisation | Name | Signature | Date |
|---------------------------------|------|-----------|------|
| Author of the PGD | | | |
| Member of the PGD working group | | | |

4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

| Job Title | Name | Signature | Date |
|--|------|-----------|------|
| Medical Director | | | |
| Chief Pharmacist/ Pharmaceutical Adviser | | | |
| Senior Paramedic | | | |
| Director of Nursing | | | |
| GP Adviser | | | |
| Senior Microbiologist (if PGD contains antimicrobials) | | | |

5. PGD adoption by the provider

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

| Job title and organisation | Signature | Date | Applicable or not applicable to area |
|----------------------------|-----------|------|--------------------------------------|
| | | | |

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

| | Requirements of registered Healthcare professionals working under the PGD |
|---|---|
| Qualifications and professional registration | <ul style="list-style-type: none"> Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises |
| Initial training | <ul style="list-style-type: none"> Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD Local training in the use of PGDs |
| Competency assessment | Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs |
| Ongoing training and competency | The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years |

7. Clinical Conditions

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| Clinical condition or situation to which this PGD applies | Bacterial Vaginosis |
| Inclusion criteria | Any symptomatic individual diagnosed with Bacterial Vaginosis |
| Exclusion criteria | <ul style="list-style-type: none"> • Under 16 years and assessed as not competent using Fraser Guidelines • Known allergy/hypersensitivity to Metronidazole or Tindazole or to any of the constituents found in the medication • Pelvic pain/ suspected pelvic Inflammatory Disease • Known moderate to severe hepatic impairment • Porphyria • Pregnancy • Breastfeeding • Individual taking interacting medicines |
| Cautions (including any relevant action to be taken) | <ul style="list-style-type: none"> • Do not drink alcohol • Offer full STI screen if not already done. Give general advice about the possible triggers for Bacterial Vaginosis • If symptoms persist/worsen advise patient to contact clinic • Suggest the use of aqueous cream/emulsifying ointment as a soap substitute • No screening or treatment of male partners is required |
| Arrangements for referral for medical advice | Patient should be referred to a more experienced clinical practitioner for further assessment |
| Action to be taken if patient excluded | Patient should be referred to a more experienced clinical practitioner for further assessment |
| Action to be taken if patient declines treatment | <ul style="list-style-type: none"> • A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated |

8. Details of the medicine

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| Name, form and strength of medicine | Metronidazole 0.75% vaginal gel |
| Legal category | Prescription Only Medicine (POM) |
| Indicate any <u>off-label use</u> (if relevant) | None |
| Route/method of administration | Topically to the vagina |
| Dose and frequency | 5g application from a 40g tube (one applicator) Each night at bedtime for 5 nights |

| | |
|--|---|
| Quantity to be administered and/or supplied | One 40g tube to be supplied |
| Maximum or minimum treatment period | Maximum of 5 nightly treatments |
| Storage | Room temperature |
| Adverse effects | <ul style="list-style-type: none"> • GI disturbances • Headache • Menstrual cycle irregularities • Pelvic discomfort • vulvovaginal candidiasis • vulvovaginal disorders • Vaginal haemorrhage |
| Records to be kept | The administration of any medication given under a PGD must be recorded within the patient's medical records |

9. Patient information

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|---|--|
| Verbal/Written information to be given to patient or carer | <ul style="list-style-type: none"> • Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request |
| Follow-up advice to be given to patient or carer | If symptoms do not improve or worsen or you become unwell, seek medical advice immediately |

10. Appendix A

| References |
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| <ol style="list-style-type: none"> 1. British National Formulary (BNF) available online: https://bnf.nice.org.uk 2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk 3. Current Health Care Professions Council standards of practice 4. General Pharmaceutical Council standards 5. The General Optical Council 6. Electronic medicines compendium available online: https://www.medicines.org.uk 7. BASHH guidelines 8. Nobles' Hospital Antimicrobial formulary |

11. Appendix B

| Health professionals agreed to practice |
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| <ul style="list-style-type: none"> • Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves |